IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.; BAUSCH HEALTH IRELAND LTD.; ALFASIGMA S.P.A.,, Plaintiffs, v. NORWICH PHARMACEUTICALS, INC., Defendant.	Civil Action No. 20-430-RGA

MEMORANDUM ORDER

I filed a final judgment in this case. (D.I. 193). Shortly thereafter, Defendant filed a motion to modify that judgment pursuant to Federal Rule of Civil Procedure 60(b). (D.I. 205). Subsequent briefing made clear that Defendant was primarily relying upon Rule 60(b)(5), which provides: "On motion and just terms, the court may relieve a party . . . from a final judgment, order, or proceeding for the following reasons: . . . (5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable." Plaintiffs oppose the motion. (D.I. 213).

The background to the pending motion is that Defendant filed an ANDA seeking to make and market a drug for two different methods of treatment—the IBS-D indication and the HE indication. I had a bench trial. After trial, I ruled in Defendant's favor on the IBS-D indication (as well as the composition claims), finding all patent claims asserted in relation to those two issues

to be invalid. I ruled in Plaintiffs' favor only on the HE indication, finding all claims asserted in relation to that issue to be infringed and not invalid. In the final judgment, I ordered the FDA not to approve the ANDA before the latest expiration (in about 2029) of the patents on which Plaintiffs won. About a month after entry of the final judgment, Defendant filed an amended ANDA that purports to carve out everything relating to the HE indication. Defendant says, if the FDA approves the amended ANDA, Defendant would not be inducing infringement by marketing the pharmaceutical with the amended label. Other than providing the proposed label, Defendant has refused to provide any other information about the amended ANDA, including its status with the FDA or anything else.

I do not think Defendant's request fits in comfortably with the requirements of Rule 60(b)(5), and I do not think, even if it did, that it could be resolved in the summary fashion that Defendant seems to think it should be.

First, the Rule. Defendant says the judgment has been "satisfied," but I think it is pretty clear that the "satisfied, released, or discharged" language is talking about money, and is therefore inapplicable. Defendant says the injunction prohibiting FDA approval before 2029 is "no longer equitable" because Defendant no longer seeks to do the act that was the basis for the injunction. The case law says that Rule 60(b)(5) is for a significant change in circumstances. *See Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 383 (1992). While such a change in circumstances does not have to be entirely unforeseeable, a "modification should not be granted where a party relies upon events that actually were anticipated at the time" the final judgment was entered. *Id.* at 385. I do not think "changed circumstances" applies here. The case was tried as essentially three independent up-or-down decisions. In my experience with ANDAs, it is common, and certainly not rare, to have split decisions. ANDA practitioners and pharmaceutical companies

surely know this. Thus, there were a limited number of possible outcomes at trial. But, of course, the trial results are not the changed circumstances, as the actual outcomes were previewed two weeks before the final judgment (D.I. 189) and disclosed at the same time as the final judgment. The only changed circumstance is that Defendant decided to amend its ANDA, which it filed on September 6, 2022 (D.I. 206 at 2), nearly one month after the final judgment. The changed circumstance is simply a voluntary decision of the trial loser to change course, which is neither unanticipated nor unforeseeable.

I also wonder about "equitableness" generally. Defendant made various strategic choices along the way, but now does not want to live with the consequences of those choices.[1] Defendant says that it is now worse off than other generics that settled with Plaintiffs and apparently can launch in 2028. While true, Defendant does not argue that it could not have settled and gotten the same deal as the other generics. Defendant says that it has gone to the effort of proving the asserted composition and IBS-D patent claims invalid, so other generics will be able to enter the market a lot sooner than 2028 by taking advantage of Defendant's accomplishments.[2] Defendant suggests this is inequitable (and perhaps it is), but the inequity does not exist between Plaintiffs and Defendant. To the extent there is inequity, it is between Defendant and other generics. Defendant says that the public will be harmed because Plaintiffs will not have any generic competition (with attendant lower costs) on the IBS-D treatment method for some period of time, even though

[1] I was assigned one related ANDA, where Defendant was only seeking approval to market the IBS-D indication, and not the HE indication. *Salix Pharms., Ltd. v. Sun Pharms. Inds., LTD*, No. 19-734-RGA (D.Del. filed April 24, 2019). That Defendant quickly resolved its case with Plaintiffs.

[2] This may be a bit speculative too, because Plaintiffs have lots of relevant patents and patent claims, and, while presumably they advanced their best claims at the trial in this case, I would expect they have more listed in the Orange Book to assert against the next generic to file an ANDA.

Plaintiffs have no right to a monopoly on that treatment method. This is a bit speculative, since there is no information about if or when the FDA might approve the amended ANDA.

Second, the record. It is not a simple matter to determine whether an ANDA applicant has successfully carved out language from a label to turn infringement into non-infringement.[3] Defendant, other than saying it has successfully carved out the HE indication, and providing me the label, has presented no evidence in support of its assertion. Further, Rule 60(b) "does not allow relitigation of issues that have been resolved by the judgment." 11 WRIGHT, MILLER, & KANE, FEDERAL PRACTICE AND PROCEDURE § 2863, at 459 (3d ed. 2012). Defendant presents no facts indicating that it could not have litigated the carve-out or that it was denied a full and fair opportunity to do so. *Allergan, Inc. v. Sandoz Inc.*, 2013 WL 6253669, at *3 (E.D. Tex. Dec. 3, 2013), *aff'd*, 587 F. App'x 657 (Fed. Cir. 2014). As in *Allergan*, Defendant fully litigated the merits of its non-infringement and invalidity case, lost, and now seeks a way around the final judgment through Rule 60(b) that "is tantamount to seeking summary judgment premised on new allegations that only came to exist after the final judgment was rendered . . . ." *Id.*

Defendant states that Plaintiffs have not tried to state a claim against the carve out, and therefore, they cannot. I am unpersuaded that Plaintiffs have some duty now to state a claim on something that Defendant never raised as an issue before entry of final judgment. It is not surprising that Defendant has cited no case that requires a plaintiff to be able to state a claim on a new issue after judgment. What Defendant wants would essentially be a second litigation.

[3] I had an ANDA trial in January 2023 where one of the issues is whether the carve out has been successful. The issue is hotly disputed. *See Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 20-804-RGA, D.I. 355 at 2 (D.Del. Feb. 17, 2023) (arguing non-infringement because Sandoz removed certain information from its proposed label).

Third, the law. Plaintiffs say, and Defendant does not present any argument to the contrary, that what Defendant seeks is unprecedented in an ANDA case. I am hesitant to be the first, because it just seems wrong to me that Defendant can litigate a case through trial and final judgment based on a particular ANDA, and then, after final judgment, change the ANDA to what it wishes it had started with, and win in a summary proceeding.

Thus, I DENY Defendant's Rule 60(b) motion. (D.I. 205).

IT IS SO ORDERED this 17th day of May, 2023.

United States District Judge