IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AMGEN INC., AMGEN MANUFACTURING, LTD, and AMGEN USA INC.,

Plaintiffs;

V.

Civil Action No. 14-1317-RGA

SANOFI, SANOFI-AVENTIS U.S. LLC, AVENTISUB LLC, f/d/b/a AVENTIS PHARMACEUTICALS INC., and REGENERON PHARMACEUTICALS, INC.,

Defendants.

MEMORANDUM OPINION

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February 1, 2019



Currently pending before the Court is Defendants' Motion for Judgment on the Pleadings under Rule 12(c). (D.I. 448). The Parties have fully briefed the issues. (D.I. 449, 452, 453). The Court heard oral argument on January 3, 2019. (D.I. 703). For the following reasons, Plaintiffs' Motion is granted-in-part and denied-in-part.

I. BACKGROUND

Plaintiffs Amgen, Inc., Amgen Manufacturing Limited, and Amgen USA Inc. (collectively "Plaintiffs") filed suit against Defendants Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, and Regeneron Pharmaceuticals, Inc. (collectively "Defendants") on October 17, 2014. (D.I. 1). Plaintiffs assert that Defendants' manufacture and sale of Praluent, a drug that treats patients with high levels of low density lipoprotein cholesterol, infringes claims of U.S. Patent Nos. 8,829,165 ("the '165 patent") and 8,859,741 ("the '741 patent") (collectively, "the asserted patents"). (D.I. 1). The parties stipulated to infringement of certain claims on February 22, 2016. (D.I. 235). During trial, the Court issued two Rule 50(a) orders. The Court determined that as a matter of law, the patent claims were non-obvious and Plaintiffs had failed to meet the burden of showing that Defendants' infringement was willful. (D.I. 345 at 5:2-3; D.I. 302). The case was submitted to the jury on the remaining invalidity issues: lack of written description and enablement. The trial resulted in a judgment for Plaintiffs that the patents are not invalid. (D.I. 304). After trial, Defendants moved for renewed judgment as a matter of law on patent validity and for a new trial. (D.I. 331, 332). Plaintiffs moved for a permanent injunction. (D.I. 336). The Court denied Defendants' post-trial motions and entered final judgment in favor of Plaintiffs under Rule 54(b) on January 3, 2017. (D.I. 390, 391). The Court granted Plaintiffs' motion for a permanent injunction on January 5, 2017. (D.I. 392).

Defendants appealed from the Rule 54(b) judgment. (D.I. 402). The Federal Circuit determined that the Court had erred in precluding post-priority date evidence relevant to written description and enablement, and by giving faulty jury instructions on written description. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1371 (Fed. Cir. 2017). The Federal Circuit remanded for a new trial on written description and enablement. *Id.* Defendants now move for judgment on the pleadings regarding Plaintiffs' willful infringement claim. (D.I. 448).

II. LEGAL STANDARD

A Rule 12(c) motion for judgment on the pleadings is reviewed under the same standard as a Rule 12(b)(6) motion to dismiss when the Rule 12(c) motion alleges that the plaintiff failed to state a claim upon which relief can be granted. *See Turbe v. Gov't of the Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). The court must accept the factual allegations in the complaint and take them in the light most favorable to the non-moving party. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). "When there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The court must "draw on its judicial experience and common sense" to make the determination. *See id.* In ruling on a motion for judgment on the pleadings, the court is generally limited to the pleadings. *Mele v. Fed. Reserve Bank of N.Y.*, 359 F.3d 251, 257 (3d Cir. 2004). The court may, however, consider documents incorporated into the pleadings and those that are in the public record. *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

III. DISCUSSION

Defendants argue Plaintiffs have waived their willful infringement claim by failing to cross-appeal the Court's adverse ruling of no willfulness as a matter of law ("the willfulness ruling"), and that Plaintiffs' preservation arguments are unavailing. (D.I. 449 at 4, 7). Plaintiffs argue that no waiver has occurred because 1) the willfulness ruling was not a final judgment that could be appealed, 2) even if final, an appeal of the willfulness ruling would have been dismissed, and 3) the amended 54(b) judgment recognized that the willfulness ruling was superseded by *Halo*. (D.I. 452 at 9-10, 14).

Courts routinely hold that a party that fails to cross-appeal an adverse ruling has waived that claim on remand. See ART Midwest Inc. v. Atlantic Limited P'ship XII, 742 F.3d 206, 211 (5th Cir. 2014); Lazare Kaplan Int'l Inc. v. Photoscribe Techs., Inc., 714 F.3d 1289, 1294 (Fed. Cir. 2013). Waiver is only proper where the party who failed to cross-appeal was required to do so. "[A] party must file a cross-appeal if, although successful in the overall outcome in the district court, the party seeks, on appeal, to lessen the rights of its adversary or to enlarge its own rights." Lazare, 714 F. 3d at 1293; see also Aventis Pharma S.A. v. Hospira, Inc., 637 F.3d 1341, 1343 (Fed. Cir. 2011) ("A cross-appeal may only be filed when a party seeks to enlarge its own rights under the judgment or to lessen the rights of its adversary under the judgment.") (cleaned up).

A. The Willfulness Ruling was an Appealable Judgment under 28 U.S.C. § 1292

The parties dispute whether the Court's Rule 50(a) JMOL ruling of no willful infringement was subject to appeal. (D.I. 449 at 7-8; *see* D.I. 453 at 9). Specifically, Plaintiffs assert that the willfulness ruling was not "certified" as a final judgment because it was not included in the Rule 54(b) judgment from which Defendants appealed. (D.I. 452 at 9). I

disagree with Plaintiffs and determine that the Court's willfulness ruling was an appealable judgment under 28 U.S.C. § 1292.

Plaintiffs rely on *Bosch v. Pylon Manufacturing Corp.*, 719 F.3d 1305 (Fed. Cir. 2013) (en banc), to argue that the willfulness ruling was not an appealable final judgment. In *Bosch*, the Federal Circuit determined that under 28 U.S.C. § 1292(c)(2), which gives the Federal Circuit exclusive jurisdiction over appeals from judgments that are "final except for an accounting," the Federal Circuit may "entertain appeals from patent infringement liability determinations when willfulness issues are outstanding and remain undecided" because "an accounting . . . include[s] the determination of willfulness" in addition to a trial on damages. 719 F.3d at 1313, 1319.

There, the district court had purported to certify the judgment on liability issues as final under Rule 54(b), which the majority did not address. *Id.* at 1307-20. As Judge O'Malley noted, Rule 54(b) certification was improper because Rule 54(b) requires resolution of all issues regarding a claim including liability *and* relief. *Id.* at 1332 n.2 (O'Malley, J., dissenting) (citing *Cadleway Props. v. Ossian State Bank*, 478 F.3d 767, 769 (7th Cir. 2007); *Reyher v. Champion Int'l Corp.*, 975 F.2d 483, 487 (8th Cir. 1992)); *see also Alfred E. Mann Foundation for Scientific Research v. Cochlear Corp.*, 841 F.3d 1334 (Fed. Cir. 2016) ("judgments where assessment of damages . . . remains to be resolved have never been considered 'final' for purposes of Rule 54(b)") (cleaned up). Therefore, the relevant inquiry is not whether the willfulness ruling was included in the Rule 54(b) final judgment, but whether the willfulness ruling could have been appealed under § 1292(c)(2).

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¹ Plaintiff's reliance on *Trilogy Comm'ns, Inc. v. Times Fiber Comm'ns, Inc.*, 109 F.3d 739 (Fed. Cir. 1997) where the district court had not rendered any judgment on the cross-appellant's counter-claims, is therefore inapposite. *Id.* at 745 (cross-appellant appealed from *denial* of summary judgment).

As Bosch makes clear, had willfulness not been decided, the Federal Circuit in this case would still have had jurisdiction over the appeal under § 1292(c)(2).² Here, however, the Court had granted judgment as a matter of law of no willful infringement at the time Defendants appealed. (D.I. 302). Therefore, the question is whether the Federal Circuit had jurisdiction over a final judgment that included a final decision on willfulness. I determine that the Federal Circuit had jurisdiction to hear a cross-appeal of the willfulness ruling under § 1292(c)(2). In Alfred E. Mann Foundation for Scientific Research v. Cochlear Corp., 841 F.3d 1334 (Fed. Cir. 2016), the Federal Circuit entertained a cross-appeal of the district court's JMOL on willful infringement where judgment on infringement and invalidity had been entered and damages had yet to be determined. *Id.* at 1346. Here, as in *Mann*, the Court made a final determination on willfulness, but damages were still outstanding, as the parties had agreed to determine the damages from infringement themselves, rather than require a damages trial. (D.I. 346 at 1285:12-20). As demonstrated by *Mann*, the Federal Circuit has jurisdiction under § 1292(c)(2) over the issue of willfulness where damages have not been decided.³ See also Bosch, 719 F.3d at 1313 (separately holding that damages calculation is included in an "accounting" and therefore appeals may be taken where damages determination has yet to occur). Therefore, I determine that the Court's willfulness ruling was an appealable judgment under § 1292(c)(2).

B. Cross-Appeal was Required

Plaintiffs argue that, even if the willfulness ruling could have been appealed, cross-appeal of the willfulness ruling was not required because an appellate decision would not have enlarged

² This of course ignores that the Federal Circuit had independent jurisdiction over the injunction aspects of the appeal. 28 U.S.C. § 1292(a)(1). *See Amgen v. Sanofi*, 872 F.3d at 1371 ("[Appellants] appeal from a final judgment . . . holding [the asserted patents] not invalid and granting a permanent injunction. . . .").

³ The district court had granted a motion for new trial on damages. *Mann*, 841 F.3d at 1339.

the scope of the judgment. (D.I. 452 at 10-11). Defendants argue that a cross-appeal of the willfulness ruling would have enlarged Plaintiffs' rights because it would have permitted Plaintiffs to seek greater damages on remand. (D.I. 449 at 8). Plaintiffs respond that because damages were not included in the judgment, an appeal on willful infringement would not have enlarged its rights. (D.I. 452 at 11). However, that assertion is contrary to the Federal Circuit's decision in *Mann* where the court of appeals entertained a cross-appeal of the district court's JMOL on willful infringement where it also determined that there "ha[d] not been a final decision on the damages issue." 841 F.3d at 1346 (holding it lacked jurisdiction to consider district court's order vacating the jury's damages award and ordering a new damages trial). Thus, here, that damages had not yet been determined would not have barred a cross-appeal of the Court's willfulness ruling. Had Plaintiffs cross-appealed and succeeded, they would have enlarged their rights to seek a willfulness finding and up to a trebling of damages for infringement on remand.

C. The Amended Rule 54(b) Judgment did not Implicitly Vacate the Willfulness Ruling

Plaintiffs argue that the Court's amendment of the Rule 54(b) judgment reserved the determination of willfulness for post-appeal proceedings. (D.I. 452 at 8-9). Defendants argue that the language of the order altering the judgment does not function to reserve the determination of willfulness. (D.I. 449 at 9).

The Court's order altering the judgment does not clearly address the finality of the willfulness ruling. (D.I. 427 at 3). It references only the potential "enhancement" of those supplemental damages. (*Id.*). Plaintiffs sought preservation of supplemental damages due to Defendants' ongoing infringement and its "stipulation of infringement, a jury verdict of validity,

the judgment, and . . . a permanent injunction." (D.I. 406 at 6). However, Plaintiffs also explicitly noted that "[e]nhancement of supplemental damages is appropriate, even when there has been no prior finding of willfulness." (*Id.* at 7). Plaintiffs now suggest that the order amending the judgment was an "implicit vacatur" of the Court's willfulness ruling. Defendants argue that the willfulness ruling is dispositive as the Court's order amending the judgment did not address the willfulness ruling. (D.I. 449 at 3, 9-10).

I agree with Defendants. Willfulness is not a component of damages. As Plaintiffs recognize (D.I. 406 at 7), willfulness has independent significance as a predicate for an award of enhanced damages. As explained above, the willfulness ruling was a final decision subject to appeal. The order amending the judgment dealt only with the preservation of supplemental damages issues that had not been determined. (D.I. 427 at 3). I will not read an intent to vacate a legal ruling on an independent legal issue, willfulness, into such an order. Therefore, Plaintiffs' claim for willful infringement is barred.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Judgment on the Pleadings is GRANTED. An accompanying order will be entered.