IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMCEUTICA NV,	§	
Plaintiffs,	§	
v.	§	Civil Action No. 21-1784-WCB
TOLMAR, INC.,	§	
Defendant.	§	

OPINION AND ORDER ON RECONSIDERATION

Plaintiffs Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively "Janssen") sued Tolmar, Inc., for patent infringement under the Hatch-Waxman act. After a four-day bench trial, the court issued findings of facts and conclusions of law, in which it found all the asserted claims of U.S. Patent No. 9,439,906 ("the '906 patent") nonobvious over the asserted prior art. Dkt. No. 163. The court entered final judgment in favor of Janssen on March 13, 2024. Dkt. No. 169.

Three weeks later, on April 1, 2024, the Federal Circuit decided an appeal in a related case involving the same patent, *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.* ("*Teva*"), 97 F.4th 915 (Fed. Cir. 2024). In that case, the district court had held the asserted claims of the patent nonobvious. The court of appeals, however, vacated the district court's nonobviousness determination.

Tolmar argues that the Federal Circuit's holding in the *Teva* appeal reveals errors in this court's reasoning that require this court to amend its judgment under Federal Rule of Civil

Procedure 59(e). Tolmar separately contends that the court erred by enjoining all five dosage amounts of Tolmar's ANDA product in its final judgment, and that the court should amend its judgment to affect only the highest of the five dosage amounts. Neither of Tolmar's positions is persuasive, so Tolmar's motion for reconsideration is denied.

I. Nonobviousness

Tolmar raises three arguments regarding this court's holding of obviousness with respect to the '906 patent. First, Tolmar argues that the court improperly determined that a person of ordinary skill in the art would have had little reason to modify the NCT 548 prior art reference, because NCT 548 lacked safety and efficacy data; Tolmar argues that this court's ruling on that issue is contrary to the Federal Circuit's holding in *Teva*. Second, Tolmar argues that this court erred in finding that a person of ordinary skill in the art would not have arrived at the claimed dosing regimen based on NCT 548 and the overall prior art on dosing.[1] Third, Tolmar argues that the court erred in its analysis of the secondary considerations in this case by misapprehending the law relating to unexpected results and by failing to consider the impact of Janssen's blocking patents on commercial success.

A. Modification of NCT 548

In the findings of fact and conclusions of law, this court held that Tolmar did not prove that a person of ordinary skill in the art would have thought to modify the dosing parameters used in the NCT 548 study. Tolmar argues that this line of reasoning is erroneous in light of the Federal Circuit's decision in *Teva*. Tolmar misconstrues this court's ruling and misapplies the appellate court's decision in *Teva*. For those reasons, Tolmar's argument is unpersuasive.

[1] Tolmar briefs this issue across two sections of its motion, one addressing why this court's reasoning was wrong and the other addressing why Tolmar's position is correct. The court treats those two arguments as raising a single issue.

The Federal Circuit held that the absence of safety and efficacy data in a reference "cannot justify simply discarding that prior art." *Teva*, 97 F.4th at 928. Instead, the Federal Circuit instructed that the district court in that case should have looked to "what the '548 protocol would fairly suggest to a POSA." *Id.* at 929. That is precisely what this court did. At page 39 of the findings of fact and conclusions of law, this court analyzed what a person of ordinary skill would learn from NCT 548 and concluded that all an ordinary artisan would learn from it would have been to credit Janssen's hypothesis that the NCT 548 dosing regimens would be safe and effective based on the regimen's status as a phase III clinical trial. *See* Dkt. No. 163 at 38–39. I agree with Tolmar's characterization of the law, that "there could be several reasons to modify NCT 548 other than the failure of the protocol." Dkt. No. 176 at 13. But it was Tolmar's burden to show that there was a reason to modify NCT 548 in a manner that would result in the claimed invention, and Tolmar did not carry its burden. Rather than "discarding" NCT 548, this court's core holding, stated in the concluding paragraph of the relevant section of the findings of fact and conclusions of law, was that Tolmar "provided no persuasive reason to believe that the fixed-dose regimens of NCT 548 alone would have led a skilled artisan to" the claimed dosing regimens.

Tolmar's theory at trial was that the ordinary artisan would have started with NCT 548 and would have modified the NCT 548 dosing regimen based on the safety and efficacy data reported in the Kramer reference. Because I excluded Kramer on authentication grounds, however, that theory has no force. I referred to the "absence of safety and efficacy" data throughout the findings of fact and conclusions of law because the Kramer safety and efficacy data was central to Tolmar's theory, not because I deemed it necessary to a finding of obviousness. The Federal Circuit's discussion of safety and efficacy data in *Teva*, which explained that the lack of such data does not

preclude a person of ordinary skill from considering NCT 548, therefore relates to an issue different from the one I addressed in my discussion of that data.

B. Arrival at the Claimed Dosing Regimen

Tolmar next argues that this court erred in finding that a person of ordinary skill in the art would not have used NCT 548 as a primary reference in determining whether the claimed dosing regimen would have been obvious.[2] In particular, Tolmar argues that the court's opinion conflated Janssen's difficulties in gaining FDA approval with the difficulties a person of ordinary skill would have faced in developing the dosing regimen recited in the claims. Again, Tolmar misconstrues this court's holding that Tolmar did not meet its burden of proving that a person of ordinary skill in the art would have arrived at the claimed dosing regimen. The court noted that Janssen arrived at the claimed dosing regimen using proprietary knowledge and data, knowledge and data that a person of ordinary skill in the art would not have had. But the court did not suggest that Tolmar was foreclosed from attempting to show that such a person could have arrived at the claimed dosing regimen without such knowledge; Tolmar had the opportunity to make such a showing, but it failed to do so. *See* Dkt. No. 163 at 38, 42.

The remainder of Tolmar's arguments on this issue merely revisit the arguments raised and rejected in the court's findings of fact and conclusions of law. The court has considered those issues and is not persuaded to change its views on those issues.

C. Secondary Considerations

Tolmar also argues that this court erred in its analysis of the secondary considerations of nonobviousness relied on by Tolmar, because the court did not properly assess the evidence of

[2] To the extent that Tolmar argues the court did not use NCT 548 as a primary reference, Tolmar is wrong. The court devoted 11 pages of its opinion to discussing what a person of ordinary skill would do with NCT 548 as a primary reference. Dkt. No. 163 at 35–46.

unexpected results and did not consider the effect of Janssen's blocking patents on its analysis of the issue of commercial success. Neither argument is persuasive. Moreover, the analysis of the secondary considerations was not critical to the court's ultimate conclusion regarding obviousness.

The court compared an ordinary artisan's expectations for the NCT 548 dosing regimen with the results of the claimed dosing regimen to determine whether the claimed dosing regimen yielded results that "would have been surprising to a person of ordinary skill." Dkt. No. 163 at 44 (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)). From that examination, the court concluded that "there was no basis in the prior art to expect the dramatic difference in results between NCT 548's fixed-dose, gluteal regimen and the claimed dosing regimens" in terms of achieving "rapid onset of the therapeutic effects of the drug" without creating "proportionally higher increases in peak concentration in the patient's body." Dkt. No. 163 at 45. Specifically, the prior art taught that the deltoid and gluteal muscles are interchangeable as injection sites and that large initiation doses of paliperidone palmitate were likely to produce adverse side effects. For that reason, the court concluded that a person of ordinary skill in the art would not have expected greater success from an injection in the deltoid than from an injection in the gluteal, and would not have expected success from a large initiation dose.

Normally, the "unexpected results" inquiry compares the difference between the results obtained and those of the closest prior art. *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). The closest prior art in this case, NCT 548, produced no results at all. For that reason, the Federal Circuit in *Teva* held that the correct inquiry regarding unexpected results was to compare the "expectations based on information available to a POSA" with "the claimed regimens' results"). 97 F.4th at 935. That is what this court did in its unexpected

results analysis. *See* Dkt. No. 163 at 44–45 (considering the "conventional thinking at the time of the invention" and what was "known in the art before Dr. Samtani's work").

Tolmar argues that this court's findings are at odds with the Federal Circuit's decision in *Teva* because this court's findings rely on Janssen's internal expectations and purported discoveries. The Federal Circuit held that comparisons involving "Janssen's expectations" and "the unknown results of the PSY-3003 clinical trial"[3] were not relevant to determining whether results would have been unexpected to a person of ordinary skill in the art. *Teva*, 97 F.4th at 934. To the extent this court's opinion discussed Janssen's internal expectations regarding NCT 548 at all, it did so only insofar as those expectations indicated what a person of ordinary skill would have expected. As to Janssen's internal discoveries, I discussed the results of the PSY-3003 study in a single sentence and did so only to reject an argument that Tolmar itself raised. The core analysis did not evaluate the actual results reported in PSY-3003; it evaluated the expected results of NCT 548 based on what was known in the art at the time.

Tolmar also argues that the court wrongly relied on the Hatch-Waxman act's "safe harbor" provision to dismiss Tolmar's arguments regarding the effect of blocking patents on the commercial success analysis. In fact, the court did not dismiss Tolmar's arguments based solely on that provision. Instead, it considered the safe harbor provision as one of many factors that bore on the issue of commercial success. The Federal Circuit's decision in *Teva* is not at odds with this court's ruling on that issue; in fact, the Federal Circuit expressly agreed that the safe harbor provision is a relevant factor to be considered in determining the role of blocking patents in ANDA cases. *Id.* at 936.

[3] PSY-3003 is the clinical trial evaluating the dosing regimen proposed in NCT 548.

For the foregoing reasons, the court will not amend its holding regarding the obviousness of the '906 patent. Beyond addressing the same subject matter, this court's analysis and the analysis that the Federal Circuit found to be problematic in *Teva* are entirely different. Accordingly, the Federal Circuit's decision in *Teva* does not impact this court's decision.

II. Modification of the Final Judgment

Tolmar also moves for relief under Fed R. Civ. P. 59(e) and 60(b) to amend or otherwise obtain relief from the court's final judgment enjoining Tolmar from using, selling, offering to sell, or importing the subject of ANDA No. 211995 until the expiration of the '906 patent. Tolmar argues that the court has misread the parties' stipulation regarding infringement and that the court should amend the Final Judgment to permit Tolmar to perform those activities with respect to four of the five dosages listed in its ANDA. Alternatively, Tolmar argues that the court should reopen the record and require Janssen to prove infringement of those other four dosages. Both requests for relief are denied.

The parties in this case stipulated that "if any of claims 1–7, claim 15, and claims 17–21 (as dependent from claims 1 and 4) of the '906 patent are not found to be invalid in this Action, Tolmar will agree to entry of a judgment of infringement and order pursuant to 35 U.S.C. § 271(e)(4)(A) with respect to such claim." Dkt. No. 86 at ¶ 1. Although it does not say so expressly, the stipulation unambiguously encompasses all five dosage sizes in Tolmar's ANDA within the scope of what the judgment of infringement would cover.

Tolmar's argument that only one of the dosage sizes described in its ANDA infringes is contrary to the stipulation. The stipulated scope of the judgment of infringement applies to "the filing of Tolmar's ANDA" and "the commercial use, sale, or offer for sale of the drug product set forth in Tolmar's ANDA." *Id.* The stipulation does not distinguish between dosage sizes.

Tolmar's argument for distinguishing dosage sizes is based on language in a different paragraph of the stipulation, which states that, if certain conditions are met, "Janssen will agree to entry of a judgment of non-infringement with respect to claims 8–14, claim 16, and claims 17–21 (as dependent from claims 8 and 11)." Tolmar argues that four of the five dosages in its ANDA are noninfringing under the latter stipulation, and that only one is infringing under the former.

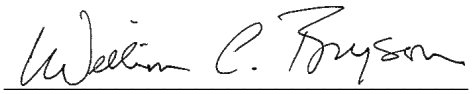
Tolmar's position is plainly incorrect. The language in the stipulation governing Janssen's concession of noninfringement applies to the exact same subject matter as Tolmar's concession of infringement: "the filing of Tolmar's ANDA" and "the commercial use, sale, or offer for sale of the drug product set forth in Tolmar's ANDA." Dkt. No. 86 at ¶ 5. Identical language in the same document indicates identical meaning. Tolmar's position, that one paragraph of the stipulation addresses a single dosage and the other addresses the remaining four, cannot be correct, because both paragraphs say that they govern the exact same subject matter: Tolmar's ANDA itself and Tolmar's ANDA product. The only plausible interpretation of the stipulation is that all dosage amounts described in Tolmar's ANDA infringe claims 1–7, 15, and 17–21 as dependent from claims 1 and 4, and that none of the dosage amounts infringe claims 8–14, 16, or 17–21 as dependent from claims 8 and 11.

The court will not amend or otherwise grant relief to Tolmar from the final judgment. Even if this court were to exercise its discretion in considering the effect of Tolmar's amendment eliminating the 150 mg-eq dosage size from its ANDA, *see Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1069 (Fed. Cir. 2024), it would not affect the outcome of this case, because the parties' stipulation applies to infringement of all dosage amounts. As for Tolmar's motion for relief, an injunction preventing Tolmar from marketing its ANDA products is not inequitable within the meaning of Rule 60(b)(5). It is also not the sort of unexpected hardship to Tolmar that

would justify relief under Rule 60(b)(6). An injunction governing the entire ANDA product is the expected result of a Hatch-Waxman trial in which the plaintiff prevails. Tolmar's various motions for relief from the final judgment or amendment of the final judgment are therefore denied.

IT IS SO ORDERED.

SIGNED this 13th day of June, 2024.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE