IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC, AND QUALICAPS CO., LTD.	§	
	§	
	§	Case No. 2:15-cv-01471-JRG-RSP (Lead)
v.	§	Case No. 2:17-cv-00343-JRG-RSP (Member)
	§	
TEVA PHARMACEUTICALS USA, INC.	§	

MYLAN PHARMACEUTICALS, INC., MYLAN LABORATORIES LIMITED, MYLAN, INC.	§	
	§	Case No. 2:15-cv-01740-JRG-RSP (Member)
	§	

MEMORANDUM OPINION AND ORDER

The above-captioned Hatch-Waxman cases were referred to Magistrate Judge Payne for pretrial proceedings. On September 28, 2017, Magistrate Judge Payne recommended that the motions for summary judgment of noninfringement filed by Defendants Teva Pharmaceuticals USA, Inc. ("Teva") and the Mylan defendants ("Mylan") be granted, and that judgment of noninfringement be entered on the claims asserted by Allergan Sales, LLC and Qualicaps Co., Ltd. (collectively, "Allergan"). Dkt. 258. Before the Court are the parties' objections to the Magistrate Judge's Report and Recommendation. Dkts. 260-62. For the reasons explained below, the objections are overruled and the Report and Recommendation is adopted, with the limited exception that Defendants' counterclaims as to validity and delisting are carried and stayed, pending a final and non-appealable judgment as to non-infringement, as more fully described herein.

DISCUSSION

For nondispositive matters referred to a magistrate judge, the district court "must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a); 28 U.S.C. § 636(b)(1)(A). For dispositive matters, the

district court must "determine de novo any part of the magistrate judge's disposition that has been properly objected to." Fed. R. Civ. P. 72(b)(3); 28 U.S.C. § 636(b)(1)(C). "The district judge may accept, reject, or modify the recommend disposition." Fed. R. Civ. P. 72(b)(3); 28 U.S.C. § 636(b)(1)(C). Because the Magistrate Judge's Report and Recommendation involves nondispositive claim constructions matters and a dispositive recommendation regarding Allergan's infringement claims, the Court has evaluated the parties' objections with both applicable standards in mind and has conducted a thorough, de novo review of the Report and Recommendation.

I. Allergan's Objections

Allergan objects to the Report and Recommendation on a number of grounds. Allergan argues that the Magistrate Judge re-construed the term "gelling agent" to "specifically exclude the accused product." Dkt. 260 at 1-6. The Report and Recommendation explains, however, that what initially seemed to be a factual dispute during claim construction became essentially a claim construction dispute at the summary judgment stage. Dkt. 258 at 11-15. Accordingly, the Magistrate Judge clarified that "'gelling agent' has its plain and ordinary meaning, which is a 'substance that gels the film composition,' but which cannot be water or heated water." *Id.* at 15. Importantly, this conclusion was not based on the accused product but rather on the specification of the '180 patent. *See id.* at 11-12.

The Court finds no error with the Magistrate Judge's construction. Moreover, there was no error in the Magistrate Judge's reliance on extrinsic evidence in construing the claim. Contrary to Allergan's argument, the extrinsic evidence supporting the Magistrate Judge's construction was not extrinsic evidence related to the accused product. This is because Allergan offered no direct evidence of infringement, i.e., there was no direct evidence that water gels the film composition in

the accused product. *See id.* at 9–10. Rather, as the Report and Recommendation explains, Allergan's infringement theory, its expert's opinion, and the literature upon which he relies all recognize that water merely plays a passive role in the gelling process. *See* Dkt. No. 258 at 9–10. This evidence, as the Magistrate Judge correctly concluded, establishes that a person of ordinary skill in the art would not recognize water as a "gelling agent" in the context of the '180 patent because water at most permits the hydroxypropyl methyl cellulose (HPMC) to gel on its own when an aqueous solution of HPMC is heated. *See id.* at 12.

Similarly, in citing the inventor's admission that water is not a "gelling agent," the Magistrate Judge did not improperly rely on the inventor's subjective intent regarding the meaning of a claim term. *See id.* Rather, the inventor's testimony supports the conclusion that a person of ordinary skill in the art would not generally consider water to be an agent capable of gelling an HPMC film composition. *See id.* The inventor's admission is also consistent with the evidence reviewed by the Magistrate Judge. For example, the scientific literature and Dr. Bodmeier's opinion at most establish that water may disassociate from certain HPMC groups when an aqueous solution of HPMC is heated, which allows the intrinsic gelling properties of HPMC to manifest on their own. *See id.* at 12-13. The Court finds no error in the Magistrate Judge's conclusion.

More importantly, the Magistrate Judge's clarified claim construction was but one of two alternative grounds for recommending summary judgment. *See id.* at 14-15. The second basis relied on the original claim construction to conclude that, even when all disputed facts are construed in Allergan's favor, no evidence could support a finding that water gels the film composition in the accused products. *See id.* Contrary to Allergan's arguments, the Magistrate Judge did not discredit Dr. Bodmeier's opinion. Rather, much of Dr. Bodmeier's opinion was taken as true, particularly the explanation of the role water plays during HPMC gelation. *See id.*

The Magistrate Judge only discredited Dr. Bodmeier's assumption that because water plays some role in the gelling process, by breaking away from certain HPMC groups, it is necessarily a "gelling agent." *See id.* This conclusion was properly discounted as an unsupported leap in logic that was foreclosed by the claim requirements. *See id.*; *see also Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1050-55 (Fed. Cir. 2001) (conclusory expert testimony is not entitled to weight in claim construction or at summary judgment). There is no record evidence establishing that water "gels the film composition," as the original claim construction required. *See* Dkt. No. 258 at 14–15. Indeed, Dr. Bodmeier's ultimate conclusion is contradicted by all the evidence of record, which at most establishes that water performs a passive role during HPMC gelation. *See id.* In sum, the Court finds no reason to reject or modify the Magistrate Judge's recommended disposition of Allergan's infringement claims.

II. Teva and Mylan's Objections

Teva and Mylan object to the Magistrate Judge's decision not to construe the terms "gelling agent" and "gelling aid" under 35 U.S.C. § 112, ¶ 6. *See* Dkt. Dkt. 261 at 1; Dkt. 262 at 2. The Court previously overruled Teva and Mylan's objections to the Court's construction of these terms. *See* Dkt. 207. Teva and Mylan do not identify any new ground of objection. Instead, they seek to preserve their original objections "solely for the purposes of appeal." *See* Dkt. 261 at 1; Dkt. 262 at 1-2. The decision not to construe the "gelling agent" and "gelling aid" terms under § 112, ¶ 6 is adequately explained in the Magistrate Judge's Claim Construction Order and the Report and Recommendation on Teva and Mylan's motions for summary judgment. *See* Dkt. 191 at 11-15; Dkt. 258 at 6-8. Accordingly, Teva and Mylan's objections on this basis stand overruled. *See* Dkt. 207.

The second objection raised by Teva and Mylan relates to the proper procedural disposition of these cases. *See* Dkt. 261 at 1; Dkt. 262 at 2. In response to Allergan's complaint, Teva asserted counterclaims seeking a judgment that the '180 patent is invalid, that the '180 patent should be delisted from the Orange Book, and that the '180 patent is unenforceable due to Allergan's alleged patent misuse. Teva Ans. ¶¶ 65-70, 76-99, Dkt. 97. Mylan asserted a counterclaim seeking a judgment that the '180 patent is invalid. Mylan Ans. ¶¶ 25-28, Dkt. 128. Accordingly, Teva and Mylan object to the portion of the Report and Recommendation indicating that final judgment on all claims be entered because, in Teva and Mylan's view, the outstanding counterclaims are not moot. *See* Dkt. 261 at 1; Dkt. 262 at 2; Dkt. 258 at 16.

Teva and Mylan's counterclaims must, of course, satisfy jurisdictional requirements even after dismissal of Allergan's affirmative infringement claims. To the extent the counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. § 2201, the statute demands "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant issuance of a declaratory judgment." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014) (citation omitted). Because any judgment of noninfringement would dispose of Allergan's affirmative claim, the Magistrate Judge logically assumed, at least in the absence of any evidence of impending product reformulation, that a sufficient controversy would not exist for Teva and Mylan's declaratory judgment counterclaims. Upon further review, however, certain claims of the '180 patent appear not to have been asserted by Allergan, and at least the invalidity counterclaims may not be moot in any event. *See Cardinal Chem. Co. v. Morton Intern., Inc.*, 113 S. Ct. 1967, 1975 (1993); *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296, 1302 n.1 (Fed. Cir. 2017).

Accordingly, without deciding any jurisdictional question regarding the pending counterclaims at this stage, the Court proceeds at Teva and Mylan's request to determine whether

there is an adequate basis to enter final judgment of noninfringement and certify that judgment for immediate appeal. *See* Fed. R. Civ. P 54(b); *see also* Dkt. 262 at 2. Under Rule 54(b), a district court dealing with multiple claims or multiple parties may direct the entry of final judgment as to fewer than all of the claims or parties if the court finds that there is no just reason for delay. Fed. R. Civ. P. 54(b); *Curtiss–Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 3 (1980). In deciding whether to enter a final judgment under Rule 54(b), a court must first determine whether the judgment to be certified for appeal is "final," i.e. whether it is the ultimate disposition of an individual claim. *Curtiss–Wright*, 446 U.S. at 7. This first requirement is easily satisfied by a judgment of noninfringement in Teva and Mylan's favor because such a judgment disposes of Allergan's infringement claim in all respects.

Second, the court must determine whether there is no just reason for delay, taking into account the policy against piecemeal litigation, the need for judicial efficiency, and whether an immediate appeal would be equitable. *Id.* at 8. District courts have "substantial discretion" in determining whether there is no just reason for delay. *Intergraph Corp. v. Intel Corp.*, 253 F.3d 695, 699 (Fed. Cir. 2001). "Rule 54(b) allows a district court to act as a dispatcher and determine, in the first instance, the appropriate time when each final decision upon one or more but less than all of the claims in a multiple claims action is ready for appeal." *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 445 F.3d 1348, 1350-51 (Fed. Cir. 2006) (citation omitted).

With the applicable standard in mind, the Court finds no just reason for delay. Disposition of the remaining declaratory judgment counterclaims will involve facts and legal theories sufficiently distinct from those raised by Allergan's infringement claims, which involve only a comparison of the asserted claims to the accused products. The Court will render judgment on all infringement claims, leaving no unanswered questions of infringement, and thus there is no

significant risk of piecemeal litigation. Indeed, proceeding with a determination of validity, in the face of a noninfringement judgment, would likely be unnecessary and counterproductive given that the Patent Office has instituted inter partes review (IPR) of the asserted claims of the '180 patent. *See* IPR2017-00203.

More importantly, a judgment of noninfringement may allow the Food and Drug Administration (FDA) to lift the regulatory 30-month stay, which is the only impediment to Teva and Mylan's generic market entry. *See* 21 U.S.C. §§ 355(c)(3)(C)(i)(I), 355(j)(5)(B)(iii)(I)(aa). The public interest, and indeed the purpose of the Hatch-Waxman Act, will be served by a Rule 54(b) judgment on Allergan's infringement claims to the extent such a judgment opens the market to lower-cost alternatives. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (The Hatch-Waxman process "is designed to speed the introduction of low-cost generic drugs to market.") (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)). To delay the appeal of the judgment of non-infringement based on Teva and Mylan's declaratory judgment counterclaims is contrary to reason, especially where such counterclaims were likely raised primarily to defeat Allergan's infringement allegations allowing Teva and Mylan to go forward with their generic alternatives. *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, No. 04-CV-00346, 2010 WL 4115427, at *8 (N.D. Ill. Oct. 18, 2010). Accordingly, certification under Rule 54(b) is warranted.

CONCLUSION

For these reasons,

It is **ORDERED**:

(1) Allergan's objections, Dkt. 260, are **OVERRULED**.

(2) Teva and Mylan's objections, Dkts. 261 & 262, are **OVERRULED-IN-PART** and **SUSTAINED-IN-PART**. All objections stand overruled with the exception of Teva and Mylan's objection to the recommendation that final judgment be entered on all claims by and between the parties.

(3) The Magistrate Judge's Report and Recommendation, Dkt. 258, is **ADOPTED** in all respects, except that final judgment on the counterclaims of Defendants will be taken up at a later date and after finality is achieved as to the infringement issue.

(4) Teva and Mylan's motions for summary judgment, Dkts. 213 & 214, are **GRANTED**. A separate final judgment dismissing Allergan's infringement claims will be entered and certified for immediate appeal pursuant to Rule 54(b).

(5) Teva and Mylan's counterclaims will be held in abatement until the deadline for filing an appeal has expired or until the Federal Circuit's mandate on any appeal is entered.

So ORDERED and SIGNED this 24th day of October, 2017.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE