IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 1:22-cv-00061-TSK

DEFENDANT'S RULE 56(d) MOTION TO DEFER AND CONDUCT FURTHER DISCOVERY TO ADEQUATELY OPPOSE SUMMARY JUDGMENT

Regeneron Pharmaceuticals, Inc.'s ("Regeneron") Motion for Summary Judgment (Dkt. 428) ("Regeneron's Motion") presents assumptions Regeneron wrongly characterized as "undisputed facts" regarding the effective dates of U.S. Patent Nos. 8,110,546 ("Dix '546" or "the '546 patent"), 10,406,226 ("Dix '226" or "the '226 patent") (collectively the "Dix Prior Art") or International Patent Application No. WO2006/088650 ("Wiegand"), on the one hand; and the effective date for the asserted U.S. Patent No. 11,084,865 ("the '865 patent"), on the other hand. (Dkt. 428-1, at 4-6). Because these theories and assumptions were untimely—presented for the first time in the Motion—Mylan moves for appropriate relief pursuant to FED. R. CIV. P. 56(d). In support of such relief, Mylan relies upon the facts set forth in the accompanying Affidavit of Heinz J. Salmen in Support of Rule 56(d) Motion ("Salmen Affidavit"), filed as Exhibit 1 hereto.

I. BACKGROUND.

Over a year ago, in its Detailed Statement disclosures, Mylan Pharmaceuticals Inc. ("Mylan") disclosed to Regeneron the prior art it proposed using to challenge the validity of the '865 patent, including for obviousness under 35 U.S.C. § 103. (Mylan's Detailed Statement for

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the 865 Patent, Ex. H to Mylan's Memorandum in Opposition to Regeneron's Motion for Summary Judgment ("Mylan's Response")). Over five months ago, in discovery requests, Mylan asked Regeneron for the factual basis for any challenge it would mount against Mylan's prior art. (Mylan's Interrogatory No. 6, Ex. J to Mylan's Response; *see also* Dkt. 237). Regeneron never contended during discovery that Dix '546, Dix '226, or Wiegand cannot be used to show obviousness under § 103, because they purportedly can only be classified as § 102(e) references.

Now, just six weeks before trial, Regeneron has introduced a new theory that it never disclosed or substantiated during discovery, a theory for which Regeneron has the burden of production. Mylan therefore was deprived the opportunity to take discovery it requires to present facts to justify its opposition, including the opportunity to discover or explore at least the following issues:

- Documents concerning the roles of each individual named as an inventor on the Dix Prior Art and Wiegand;
- Documents concerning assignment of rights by each named inventor of the '546, '226, and '865 patents.
- Documents concerning employment agreements for each inventor of the '546, '226, and '865 patents.
- Documents concerning priority dates, written description support, and joint activity to support Regeneron's arguments concerning which formulations were purportedly invented by whom, and when; and what testing characteristics were made by whom, and when, and to whom such information was communicated, before or after any publication dates involving Dix '226; the Dix '546; and/or Wiegand.

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- Documents concerning written support for each asserted claim, not only in the June 16, 2006 provisional application, but in each of the ten (10) further filings in the chain of applications that led to Patent Application No. 16/739,559 from which the '865 patent actually issued.
- Documents concerning claim-by-claim basis for common ownership by Regeneron for each asserted claim in the '865 patent.
- Documents concerning claim-by-claim basis for reduction to practice by Regeneron for each asserted claim in the '865 patent.
- A deposition of Regeneron and each named inventor to (1) inquire about the facts contained in Regeneron's Motion for Summary Judgment, dated April 20, 2023; (2) authenticate and explain the documents newly produced and/or referenced in Regeneron's motion for summary judgment; (3) inquire about the discovery topics outlined above; and (4) state the factual basis for why Regeneron withheld its disclosure of the invalidity challenges set forth in its Motion until April 2023.

(Ex. 1, Salmen Affidavit at 9-10).

II. LEGAL STANDARDS.

Federal Rule 56(d) provides:

> If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:
> (1) defer considering the motion or deny it;
> (2) allow time to obtain affidavits or declarations or to take discovery; or
> (3) issue any other appropriate order.

FED. R. CIV. P. 56(d).

The Fourth Circuit has interpreted the requirements of Rule 56(d) to require an affidavit that "particularly specifies legitimate needs for further discovery" and identifies "which aspects of

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discovery required more time to complete." *Nguyen v. CNA Corp.*, 44 F.3d 234, 242 (4th Cir. 1995). Indeed, the Fourth Circuit places "great weight on the [Rule 56(d)] affidavit" and, to that end, "[a] party may not simply assert in its brief that discovery was necessary and thereby overturn summary judgment when it failed to comply with the requirement of [Rule 56(d)] to set out reasons for the need for discovery in an affidavit." *Evans v. Techs. Apps. & Serv. Co.*, 80 F.3d 954, 961 (4th Cir. 1996) (quoting *Nguyen*, 44 F.3d at 242 (internal citations omitted)).

Further, Rule 56(d) requires the district court to refuse to grant summary judgment when the non-movant "has not had the opportunity to discover information that is essential to [its] opposition." *Works v. Colvin*, 519 F. App'x 176, 181–82 (4th Cir. 2013) (internal quotations omitted). It is incumbent upon the nonmovant that it must show through affidavits that it cannot yet properly oppose a motion for summary judgment. FED. R. CIV. P. 56(d); *Evans*, 80 F.3d at 961. "The purpose of the affidavit is to ensure that the nonmoving party is invoking the protections of [Rule 56(d)] in good faith and to afford the trial court the showing necessary to assess the merits of a party's opposition." *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244 (4th Cir. 2002) (quotation marks omitted). Importantly, because the rule "is intended as a safeguard against a premature grant of summary judgment[,] [courts] should construe the rule liberally[.]" *Works*, 519 F. App'x at 182 (internal quotations omitted); *accord Harrods*, 302 F.3d at 245 n. 18 (citing with approval sources applying the rule liberally).

III. ARGUMENT

As set forth in Mylan's Response, and in view of the facts set forth in the Salmen Affidavit, Mylan (the nonmovant) cannot present facts essential to justifying its opposition to Regeneron's Motion for Summary Judgment without first engaging in a period of discovery, because Regeneron's Motion presents a previously undisclosed theory in the case. *See* FED. R. CIV. P. 56(d). Further, the undisclosed theory rests on factual assumptions that Mylan contests. For

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example, Regeneron's theory presumes that the '865 patent will secure a June 16, 2006 priority date. (Dkt. 428-1, Regeneron Motion at 2). Regeneron has the burden of production to assert that *each asserted claim* deserves the benefit of a June 2006 priority date so as to limit Dix '546, Dix '226, or Wiegand to § 102(e) prior art. *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (2008). But Regeneron never disclosed, or tried to meet, that burden of production. (Dkt. 428-1).

As fully set forth in the Salmen Affidavit, Mylan's Response, and Mylan's FED. R. CIV. P. 56(c) and LR Civ P 7.02 Statement of Contested Facts in Opposition to Regeneron's Motion for Summary Judgment in order to adequately defend against Regeneron's previously undisclosed contentions, Mylan requires discovery on numerous issues and the allegations of fact upon which such arguments are premised, that Regeneron has advanced as grounds for summary judgment regarding at least the following issues:

- What is the "inventive entity" of the Dix '226, Dix '546, and '865 patents?
- Did each inventor of the "inventive entity" of the Dix '226, Dix '546, and '865 patents sign over their rights to Regeneron?
- When did each inventor of the "inventive entity" of the Dix '226, Dix '546, and '865 patents sign over their rights to Regeneron?
- Was signing over of their rights of the Dix '226, Dix '546, and '865 patents to Regeneron part of any valid employment agreement?
- What are the priority dates, where is the written description support, and was there any joint activity that supports Regeneron's arguments concerning which formulations were purportedly invented by whom, and when?

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