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INDIVIOR INC., INDIVIOR UK LTD. and  
and AQUESTIVE THERAPEUTICS, INC.

Plaintiffs,

Civil Action No. 17-cv-7111 (KM)(CLW)  
Civil Action No. 18-cv-1775 (KM)(CLW)  
Civil Action No. 18-cv-5288 (KM)(CLW)

v.

DR. REDDY'S LABORATORIES S.A. and  
DR. REDDY'S LABORATORIES, INC.,

Defendants,

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INDIVIOR INC., INDIVIOR UK LTD. and  
and AQUESTIVE THERAPEUTICS, INC.

Plaintiffs,

Civil Action No. 17-cv-7106 (KM)(CLW)  
Civil Action No. 18-cv-5285 (KM)(CLW)

v.

ALVOGEN PINE BROOK, LLC.

Defendants,

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## **OPINION & ORDER**

### **I. INTRODUCTION**

Before the Court are two separate Motions for Leave to File First Amended Answer, Affirmative and Separate Defenses, and Counterclaims brought by Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") and Alvogen Pine Brook, LLC ("Alvogen") against Plaintiff Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics (collectively "Indivior") in the 17-7106 consolidated action ("Dkt. No. 7106") and 17-7111 consolidated action ("Dkt. No. 7111")<sup>1</sup>. (Dkt. No. 7106 at DE 174; Dkt. No. 7111 at

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<sup>1</sup> Unless otherwise noted, all docket references are related to Civil Action Nos. 17-7106 and 17-7111.

DE 262.) The Court has considered all submissions on the Docket, and the October 29, 2019 oral argument, including the detailed power point presentations and **GRANTS** the Defendants' Motions to Amend Answers, Affirmative and Separate Defenses and Counterclaims.

## **II. BACKGROUND**

The Court will limit the procedural discussion to relevant events of the above motions. Following a related patent infringement litigation in the District of Delaware wherein DRL and Alvogen prevailed, Indivior obtained U.S. Patent Nos. 9,931,305 and 9,687,454 (the “305 patent” and the “454 patent,” respectively) and subsequently asserted patent infringement claims against DRL and Alvogen in various cases in the District of New Jersey, which have since been consolidated. (Dkt. Nos. 7106 and 7111.) On June 14, 2018, DRL received approval on a generic film product that led Plaintiff to file a motion for preliminary injunctive relief against DRL on June 15, 2018 (Dkt. No. 7111 at DE 70), which was granted by the District Court on July 13, 2018 (Dkt. Nos. 121-22). DRL subsequently appealed the District Court's ruling to the Federal Circuit, which on November 20, 2018, issued an opinion reversing and remanding the Preliminary Injunction against DRL because Indivior was unlikely to succeed on the merits of its patent infringement claim. *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 F. App'x 1024 (Fed. Cir. 2018).

On January 22, 2019, two days prior to Alvogen's expected approval for its generic film, Indivior filed a motion for a temporary restraining order (“TRO”) to prevent Alvogen from launching its generic product (Dkt. No. 7106 DE 83-84). The District Court granted the TRO on January 24, 2019, which remained in effect until February 19, 2019, the date the Federal Circuit issued its mandate vacating the DRL preliminary injunction and the District Court

subsequently vacated the TRO (Dkt. Nos. 7106 DE 119 and 7111 DE 242). Shortly thereafter, both DRL and Alvogen entered the generic market along with several other generics.

On April 9, 2019, Indivior was indicted by a federal grand jury on various counts of health care fraud; wire fraud; and mail fraud. There is also notice of forfeiture, which would require, if convicted, not less than 3 billion dollars in judgment and forfeiture of various trademarks, patents, assets and receivables.

### **III. DISCUSSION**

The grant of a motion to amend is within the discretion of the District Court. See *Foman v. Davis*, 371 U.S. 178, 182 (1962). Federal Rule of Civil Procedure 15(a)(2) directs courts to “freely give leave” to amend “when justice so requires.” The Third Circuit has adopted a liberal approach to the amendment of pleadings to ensure that a claim will be decided on its merits rather than on technicalities. See *Dole v. Acro Chem. Co.*, 921 F. 2d 484, 487 (3d Cir. 1990). Denial of leave to amend is warranted in certain circumstances. These include “undue delay,” “dilatatory motive on the part of the movant,” “undue prejudice to the opposition party,” and “futility of amendment.” *Id.* (quoting *Foman*, 371 U.S. at 182).

Plaintiffs argue that the motions are untimely, and therefore Defendants must make a “good cause” showing to the Court pursuant to Rule 16. Defendants argue that good cause exists because, among other things, the specifics of the indictment were previously unknown, and within a month of the indictment, Defendants’ proposed the amendments to Indivior. Thereafter, within two months of the indictment, DRL filed this motion (Dkt. No. 7106 at DE 262), followed by Alvogen’s motion in August (Dkt. No. 7111 at DE 174).

The Court notes that the last amended scheduling order in the DRL consolidated action Dkt. No. 7111 and the Alvogen consolidated action Dkt. No. 7106, both called for an Amend date of

August 24, 2018 (Dkt. Nos. 7111 DE 84-1 and 7106 DE 48-1). This was in fact the last scheduling order entered in both cases and, as cited above in the procedural background, the cases went off track by way of various injunction proceedings, and therefore, in June of 2018, off of the scheduling order, prior the expiration of the parties deadline to amend the pleadings.

Accordingly, intermittent proceedings resulting in preliminary injunctive relief and TROs, led by the Federal Circuit Appeals, interrupted any scheduling order in these two consolidated cases. For this reason, the Court will consider a Rule 16(b)(3)(A) “good cause” application, as well as Rule 15.

This Court has wide discretion in the degree of “good cause” that must be addressed. *Wyeth v. Medtronic, Inc.* No. 08-1021(JAP), 2011 at \*4 (D.N.J. May 3, 2011). “The moving party must show that, despite its diligence, the deadlines set forth in the scheduling order could not reasonably be met.” *Korow v. Aaron’s, Inc.*, 300 F.R.D. 215, 220 (D.N.J. 2014). The occurrence of an indictment detailing allegations that include e-mails and documents not the subject of discovery in the Hatch Waxman cases at bar, which were exposed long after the interrupted scheduling order amend date, is more than good cause, and despite any due diligence by the Defendants could not have been known prior to the August 24, 2018 amend date. Therefore, Defendants have presented more than sufficient support to meet the Rule 16(b)(3)(A) “good cause” requirement because the indictment, albeit allegations, changes the landscape.

The Court now addresses the Rule 15 analysis, wherein the court should “freely give leave” to amend a pleading “when justice so requires.” Rule 15(a)(2). Plaintiffs bear the burden of demonstrating why the Court should not grant leave to amend. *Luppino v. Mercedes-Benz, USA, LLC* No. 09-5582, 2012 WL 850743 at \*2 (D.N.J. Mar. 8, 2012). Here, Indivior argues that there is no good faith basis for DRL and Alvogen’s anti-trust counterclaims while they also

argued to the trial Court the superiority of their film product. The Court determines that this will be disclosed and explored in full and fair discovery. In the same breath Plaintiffs argue that the amendments will be futile however, it is far too early to declare the futility of such proposed amendments. Plaintiff's argue that the Noerr-Pennington Doctrine bars the proposed counterclaims, as the Defendants cannot show the sham litigation exception to avoid Noerr-Pennington doctrine. That will also be explored in the discovery exchange and the Court will not make any findings on the Noerr-Pennington Doctrine without having the parties engage in full discovery.

Finally, Indivior argues that it will suffer a general prejudice from extended discovery, based upon the delay in the proceeding, without citing to any specifics. The Court finds no merit in Plaintiff's prejudice argument.

#### **IV. CONCLUSION**

The Court **grants** Defendants' Leave to File First Amended Answer, Affirmative and Separate Defenses, and Counterclaims

Accordingly, it is on this 19th day of November 2019,

**ORDERED** that Defendants' Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc., Motion to File their First Amended Answer, Affirmative and Separate Defenses, and Counterclaims (Dkt. No. 7111 at DE 261-62) is **GRANTED**; and

**ORDERED** that Defendant Alvogen Pine Brook LLC's Motion to File their First Amended Answer, Affirmative and Separate Defenses, and Counterclaims (Dkt. No. 7106 at DE 174) is **GRANTED**.

Date: 11-19-2019

s/Cathy L. Waldor  
**CATHY L. WALDOR**  
United States Magistrate Judge