UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Natco Pharma Ltd.,

Plaintiff,

v.

Gilead Sciences, Inc.; Accredo Health Group, Inc.; and Express Scripts Holding Co.,

Defendants.

Civil No. 14-3247 (DWF/JSM)

MEMORANDUM OPINION AND ORDER

Christopher A. Pinahs, Esq., Peter Kohlhepp, Esq., and Jeffer Ali, Esq., Carlson Caspers Vandenburgh Lindquist & Schuman PA, counsel for Plaintiff.

Eric Stops, Esq., F. Dominic Cerrito, Esq., and Steig D. Olson, Esq., Quinn Emanuel Urquhart & Sullivan, LLP; and Richard A. Duncan, Esq., Faegre Baker Daniels LLP, counsel for Defendant Gilead Sciences, Inc.

Alfred C. Pfeiffer, Jr., Esq., Amanda P. Reeves, Esq., and Andrew J. Robinson, Esq., Latham & Watkins, LLP; and Steve W. Gaskins, Esq., Gaskins Bennett Birrell Schupp, LLP, counsel for Defendant Express Scripts Holding Co. and Accredo Health Group, Inc.

INTRODUCTION

This matter is before the Court on Defendant Gilead Sciences, Inc.'s ("Gilead") Motion to Dismiss First Amended Complaint (Doc. No. 55), Accredo Health Group, Inc. ("Accredo") and Express Scripts Holding Co.'s ("Express Scripts") Motion to Dismiss (Doc. No. 61),[1] and Plaintiff Natco Pharma Ltd.'s ("Natco") Motion to File Supplemental

[1] Defendants are collectively referred to as "Defendants."

Pleading (Doc. No. 76). For the reasons set forth below, the Court grants the motions to dismiss and denies Natco's motion to file a supplemental pleading.

BACKGROUND

Natco seeks relief for alleged antitrust violations under Sections 1 and 2 of the Sherman Act and under state law for allegedly anti-competitive conduct on the part of Defendants for excluding generic competition in the market for the prescription pharmaceutical ambrisentan, which is used for the treatment of pulmonary arterial hypertension ("PAH"), a chronic disease affecting the functions of the heart and lungs.

Gilead manufactures and markets the prescription drug ambrisentan in the United States under the name Letairis. (Doc. No. 52, Am. Compl. ¶¶ 1, 2.) Gilead has several patents on Letairis, one of which does not expire until July 28, 2018. (*Id*. ¶¶ 29, 31.) Natco alleges that Letairis is the only Federal Drug Administration ("FDA")-approved ambrisentan product indicated for PAH, and therefore Gilead controls 100% of the U.S. market for ambrisentan. (*Id*. ¶¶ 2, 102.) Letairis is distributed exclusively by specialty pharmacies, which dispense medications for certain conditions that require ongoing patient education and monitoring.. (*Id*. ¶ 37.) Accredo, a subsidiary of Express Scripts, is a specialty pharmacy. (*Id*. ¶¶ 2, 8.)

Before marketing a new drug in the United States, a manufacturer must obtain FDA approval for its new drug application ("NDA"). *See* 21 U.S.C. § 355(a). An NDA application must provide full reports on safety and efficacy studies and also must specify the drug's components and composition, the methods of manufacture, proposed drug labeling, and patents pertaining to the drug's composition or method of use. *Id.*

§ 355(b)(1). Prior to 1984, most drug manufacturers seeking to market any drug, including a generic drug, had to file an NDA to obtain FDA approval. In 1984, Congress passed the Hatch-Waxman Act, which created an abbreviated approval process for generic drugs (an "ANDA"). *See* 21 U.S.C. § 355(j)(2)(A)(iv). A generic manufacturer could file an ANDA without conducting preclinical and clinical trials, but instead it could demonstrate that its generic drug is "bioequivalent" to the already approved brand-name drug. *Id.* A generic manufacturer must obtain samples in order to demonstrate bioequivalence to a brand-name drug. *See* 21 U.S.C. §§ 355(b)(1)(A), 355(j)(2)(A).

Letairis poses known safety risks and, specifically, is a teratogen, meaning it can cause serious birth defects if taken during pregnancy. (*Id.* ¶ 32.) As a result, Letairis is only available through the FDA-mandated Risk Evaluation and Mitigation Strategy ("REMS") program.[2] The REMS program applies to new and previously approved drug products that are known to or have the potential for serious side effects and may require certain certifications for practitioners, pharmacies, or health care settings that dispense the drug. (*Id.* ¶¶ 26, 32.) The Letairis REMS program outlines two goals: (1) informing prescribers, patients, and pharmacies about the serious risk of teratogenicity and conditions for the safe use of Letairis; and (2) minimizing the risk of fetal exposure and adverse fetal outcomes in women taking Letairis. (Am. Compl. ¶ 34; Letairis REMS at I.) Further, under the Letairis REMS program, Letairis is to be distributed exclusively

[2] The Court takes judicial notice of *NDA 22-081 Letairis® (ambrisentan), Risk Evaluation and Mitigation Strategy (REMS)*, Ref. ID: 3650027, Gilead Sciences, Inc., available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientandProviders/UCM164969.pdf (last modified October 2014) (the "Letairis REMS").

by specialty pharmacies, including Express Scripts (Accredo). (Am. Compl. ¶ 37.) In addition, under the Letairis REMS, Gilead is obligated to ensure that "physicians and other appropriately licensed healthcare professionals who prescribe Letairis are specially certified . . . and agrees [] that he or she has read the full prescribing information [], the *Letairis Medication Guide*, and the *Prescriber Guide to the Letairis REMS Program*." (Letairis REMS at II.B.) Physicians may become certified, at no cost, by filling out a form on the Letairis REMS program website. (Letairis REMS at II.B.1.a.)

Natco is an Indian Company that develops, manufactures, and sells generic pharmaceuticals. (*Id*. ¶¶ 3, 6, 42.) Natco identified an opportunity and need in the United States for a generic version of Letairis. (*Id*. ¶ 44.) Natco developed a generic drug that it believes is bioequivalent to Letairis. (*Id*. ¶ 45.) Before Natco can obtain FDA approval to sell its proposed generic version of Letairis, Natco must demonstrate that its ambrisentan drug product is bioequivalent to Letairis. (*Id*. ¶¶ 46-47.) To demonstrate bioequivalence, Natco must purchase a "sufficient quantity of Letairis to perform its bioequivalent testing." (*Id*. ¶ 48.) Natco therefore seeks samples of Letairis "to conduct bioequivalent testing as a prerequisite to submitting an ANDA to the FDA." (*Id*. ¶ 4.)

Natco alleges that it has made numerous unsuccessful attempts to purchase samples of Letairis. (*Id*. ¶ 50.) For example, on June 6, 2014, Natco sent Gilead a letter, asking to purchase Letairis samples for bioequivalence testing. (*Id*. ¶ 52.) Specifically, Natco offered to pay the market rate and shipping for 530 tablets of Letairis to an address in India, indicating that the tablets would "be used solely for development purposes to

meet FDA requirements" and that "[a]ll necessary precautions w[ould] be put in place to limit the access and handling of these samples." (*Id*. ¶ 53, Ex. A.) Natco stated: "Natco understands that distribution of Letairis is normally restricted as part of Gilead's [REMS], which is why Natco requests to purchase Letairis tablets directly from Gilead." (*Id*.) Natco did not indicate whether it had secured a REMS-certified physician to oversee the administration of the drug.

In a letter dated June 23, 2014, Gilead denied Natco's request, explaining:

> As you are likely aware, the current [REMS] for Letairis does not require male patients to be enrolled in the REMS to receive the product. Therefore, Natco should be able to obtain samples of Letairis for male subjects through commercial channels. Accordingly, Gilead does not believe it is necessary to fulfill your purchase request in order for you to be able to obtain the product.

(*Id*. ¶ 54, Ex. B.)

In a letter dated July 22, 2014, Natco attempted to purchase Letairis from Express Scripts. (*Id*. ¶ 56, Ex. C.) Natco stated that it would use the samples to conduct bioequivalence testing in male subjects. (*Id*.) Natco also explained that it had previously attempted to obtain Letairis from Gilead, and that Gilead had advised that Natco should be able to obtain the samples through commercial sales. (*Id*.) Natco further explained:

> Today, following the direction of Gilead, Natco attempted to purchase Letairis® through [Accredo]—the commercial channel through which it is sold. However, Accredo refused to sell Letairis® to Natco. Specifically, on July 22, 2014, Prasad Ravipati of Natco contacted Accredo via its customer service number. Mr. Ravipati spoke with Ms. Carmen Wilkis of the pharmacy department and attempted to purchase Letairis® on behalf of Natco. Mr. Ravipati was informed that Accredo will not dispense Letairis® without a prescription or patient name. . . . Of course, Natco does not have a prescription because it wishes to purchase Letairis® for the

> purpose of FDA-required bioequivalence testing, not for the purpose of treating any patient.
>
> Because Natco has thus far been unable to obtain Letairis® for the purpose of bioequivalence testing, we are writing, as legal counsel for Natco, to again request that Express Scripts (through [Accredo]) sell Natco samples of Letairis® for the purpose of bioequivalence testing in support of Natco's abbreviated new drug application for the generic form of Letairis®. Specifically, Natco requests 30 tablets of 5 mg and 500 tablets of 10 mg Letairis®, preferably from the same lot. Natco is willing, of course, to pay market rate and shipping for these samples . . .

(*Id*. 56, Ex. C.) Again, Natco did not present a prescription from a REMS-certified doctor. Express Scripts did not respond to Natco's request before Natco initiated this action. (Am. Compl. ¶ 59.)

Natco alleges that it continued to attempt to obtain Letairis. (Am. Compl. ¶ 60.) For example, Natco alleges that it made "other attempts . . . to purchase Letairis® through normal commercial channels" but that all attempts failed, "with specialty pharmacies refusing to sell the samples without prior approval of Gilead." (*Id*.) Natco also alleges that it contacted "numerous contract research organizations ('CROs')" in an effort to obtain Letairis samples, but that these attempts were unsuccessful. (*Id*. ¶¶ 61-62.) Natco further alleges that "at least one of these CRO's has specifically informed Natco that it was told by a specialty pharmacy" that it cannot distribute drug samples without Gilead's prior written permission. (*Id*. ¶ 63.) With respect to Express Scripts, Natco alleges that it was told it could not purchase Letairis without a prescription. (*Id*. ¶ 64.) Natco alleges that Gilead has entered into contracts with its specialty pharmacies, including Express Scripts, to prevent the pharmacies from selling

Letairis to generic drug companies without regard for these companies' ability to mitigate safety concerns relating to the administration of Letairis. (Am. Compl. ¶ 39.)

Natco filed its original Complaint on August 22, 2014. (Doc. No. 1, Compl.) Defendants separately filed motions to dismiss. (Doc. Nos. 23, 34.) Natco then filed a motion to amend its Complaint. (Doc. No. 39.) Defendants consented to the filing and service of the First Amended Complaint. (Doc. Nos. 49, 51.) On January 7, 2015, Natco filed its First Amended Complaint. (Doc. No. 52.) As amended, Natco's Complaint contains the following causes of action: (I) Violation of Section 1 of the Sherman Act: Contract, Combination or Conspiracy in Restraint of Trade; (II) Violation of Section 2 of the Sherman Act—Monopolization, Attempted Monopolization and Conspiracy to Monopolize; (III) Violation of Section 2 of The Sherman Act—Essential Facilities; (IV) Violation of the Minnesota Antitrust Act § 325D.52; (V) Violation of the Minnesota Antitrust Act §§ 325D.51 and 53; and (VI) Declaratory Relief. (Am. Compl. ¶¶ 107-178.)

Defendants move to dismiss Natco's claims in their entirety. In addition, Natco seeks to file a supplemental pleading and asks the Court to consider new facts contained in that pleading in denying the motions to dismiss.

DISCUSSION

I. Motions to Dismiss

In deciding a motion to dismiss pursuant to Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th

Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged. *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6). *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id*. at 555. As the United States Supreme Court reiterated, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556. "The essential elements of a private antitrust claim must be alleged in more than vague and conclusory terms to prevent dismissal of the complaint on a defendant's [Rule] 12(b)(6) motion." *Double D Spotting Serv., Inc. v. Supervalu, Inc.*, 136 F.3d 554, 558 (8th Cir. 1998) (quotation omitted); *see also Am. Channel, LLC v. Time Warner Cable, Inc.*, Civ. No. 06-2175, 2007 WL 142173, *7 (D. Minn. Jan. 17, 2007) (explaining that bare bones accusations of conspiracy is insufficient to state an antitrust claim).

A. Section 2 of the Sherman Act (Counts II and III)

In Counts II (Monopolization and Attempted Monopolization and Conspiracy to Monopolize) and III (Essential Facilities) of the First Amended Complaint, Natco alleges violations of Section 2 of the Sherman Act. (Am. Compl. ¶¶ 119-144.) Under Section 2 of the Sherman Act, it is unlawful to "monopolize, or attempt to monopolize, or combine or conspire with another person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2.

To state a claim for unlawful monopolization under Section 2 of the Sherman Act, a plaintiff must establish that: (1) the defendant possessed monopoly power in the relevant market, and (2) the defendant willfully acquired or maintained this monopoly power by anticompetitive conduct as opposed to gaining that power as a result of a superior product, business acumen, or historical accident. *Concord Boat Corp v. Brunswick Corp.*, 207 F.3d 1039, 1060 (8th Cir. 2000) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). To establish a claim for unlawful attempt to monopolize, a plaintiff must prove: "(1) a specific intent by the defendant to control prices or destroy competition; (2) predatory or anticompetitive conduct undertaken by the defendant directed to accomplishing the unlawful purpose; (3) a dangerous probability of success; and (4) an injury reflecting the anticompetitive effect." *Gen. Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795, 801 (8th Cir. 1987) (emphasis added). To establish a claim under the "essential facilities" doctrine, a plaintiff must allege: "(1) control of an essential facility by a monopolist; (2) the inability to practically or economically duplicate the facility; and (3) the unreasonable denial of the use of the facility to a

competitor when such use is economically and technically feasible." *City of Malden, Mo. v. Union Elec. Co.*, 887 F.2d 157, 160 (8th Cir. 1989). The "indispensable requirement for invoking the doctrine is the unavailability of access to the 'essential facilities'; where access exists, the doctrine serves no purpose." *Verizon Commc'ns Inc. v. Law Offices of Curtis Trinko*, 540 U.S. 398, 411 (2004).

"Anticompetitive conduct is conduct without legitimate business purpose that makes sense only because it eliminates competition." *Morgan v. Ponder*, 892 F.2d 1355, 1358 (8th Cir. 1989). The anti-competitive conduct Natco alleges is a refusal to deal. A refusal to deal does not constitute anticompetitive conduct if valid business reasons exist for the refusal. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp*., 472 U.S. 585, 507, 605 (1985). In addition, a refusal to deal claim requires a showing that the requested assets are completely unavailable. *See, e.g.*, Phillip E. Areeda & Herbert Hovencamp, *Antitrust Law* § 772d3 (2d ed. 2008) ("The doctrine must be strictly limited to circumstances where the requested assets are completely unavailable.").

The parties dispute whether Natco has adequately alleged that Gilead engaged in anticompetitive conduct—specifically, whether Gilead's actions amount to a refusal to deal or the denial of access necessary to establish anticompetitive or exclusionary conduct.

Natco asserts that it has adequately alleged that it has been denied access to Letairis. In particular, Natco argues that the Letairis REMS program is a scheme designed to preclude access to Letairis. Natco argues that submission of a prescription is not necessary to allege an antitrust violation and that Gilead explicitly refused the deal by

refusing Natco's request for Letairis samples. Natco claims it has adequately pled a claim for exclusionary conduct by alleging Gilead has designed its REMS program in such a way so as to eliminate generic competition by precluding access to Letairis and thereby allowing Gilead to control prices and destroy competition. Natco also alleges that Gilead entered into distribution agreements with specialty pharmacies that preclude the distribution of Letairis to Natco for use in bioequivalence studies.

Defendants argue that Natco's Section 2 claims all fail for the failure to plead predatory or anticompetitive conduct.[3] Defendants contend that the basic REMS protocols in place require Gilead to ensure that Letairis is prescribed and administered by a REMS-certified physician who can ensure the drug is used safely. Defendants maintain that Natco can obtain samples of Letairis but that it must present a prescription from a REMS-certified physician to do so. Defendants argue that because Natco can obtain Letairis with a prescription from a REMS-certified physician, Letairis is not completely unavailable to Natco and, therefore, there is no anticompetitive or exclusionary conduct to give rise to an antitrust claim.

The Court concludes that Natco has failed to plead facts supporting its refusal to deal claim. Natco's claim that Gilead refused to deal with Natco by requiring a REMS-certified physician to write a prescription does not support a refusal to deal claim. The FDA restricts distribution of Letairis through the REMS protocol and requires a prescription from an enrolled physician with a REMS certification. Gilead accepted the

[3] Arguments made by Gilead in support of its motion to dismiss are joined by Express Scripts and Accredo. (Doc. No. 63 at 2 n.1.)

conditions and restrictions on distribution as a condition to being able to market Letairis. In addition, as authorized distributors of pharmaceuticals, Express Scripts and its subsidiaries, such as Accredo, who dispense prescription drugs as a specialty pharmacy, are prohibited by law from dispensing prescription medication to a buyer without a prescription. 21 U.S.C. § 353(b)(1)(A). Even accepting Natco's allegations as true, Natco has failed to allege anticompetitive conduct based on a refusal to deal. First, Natco is able to obtain samples by engaging a REMS-certified physician to write a prescription. Thus, Letairis is not completely unavailable. Second, complying with FDA requirements requiring a valid prescription before dispensing Letairis constitutes a valid business reason to refuse to dispense Letairis outside of the REMS requirements. Thus, Natco fails to state an actionable claim under Section 2.[4]

In its opposition to the present motions, Natco argues that Gilead is engaged in a "scheme" to prevent generic manufacturers from obtaining Letairis even if they comply with the REMS protocol. The allegations of an agreement between Gilead and specialty pharmacies, however, are conclusory in nature. (*See* infra.) In addition, the allegations are belied by the fact that another generic drug manufacturer has obtained Letairis for a bioequivalence study, conducted the study, and filed an ANDA with the FDA. (*See* U.S. Food & Drug Admin., Paragraph IV Patent Certifications 2 (Feb. 19, 2015), http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevel

[4] The Court does not reach Defendants' alternative arguments in support of their motions to dismiss.

opedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf.)[5]

For the above reasons, Counts II and III fail to state a claim and are dismissed.

B. Section 1 of the Sherman Act (Count I)

In Count I of the First Amended Complaint, Natco asserts a claim under Section 1 of the Sherman Act. To establish a claim under Section 1 of the Sherman Act, Natco must demonstrate that: (1) there was a contract, combination, or conspiracy; (2) the agreement unreasonably restrained trade under either a per se rule of illegality or a rule of reason analysis; and (3) the restraint affected interstate commerce. *Reg'l Multiple Listing Serv. of Minn. v. Am. Home Realty Network, Inc.*, 960 F. Supp. 2d 958, 979 (D. Minn. 2013). In addition, Natco must allege that each participant in the alleged conspiracy possessed "a conscious commitment to a common scheme designed to achieve an unlawful objective." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984) (quotation omitted).

In its First Amended Complaint, Plaintiff alleges the existence of a conspiracy "on information and belief" in the following paragraphs:

> 38. On information and belief, Gilead restricts the abilities of these pharmacies, including Express Scripts, to sell Letairis® on the condition that they not sell Letairis® to generic drug company competitors for the

[5] The Court takes judicial notice of this document. *See Axcan Scandipharm Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1072 n.6 (D. Minn. 2007) (citing *Great Plains Trust Co. v. Union Pac. R.R. Co.*, 492 F.3d 986, 995-96 (8th Cir. 2007) (taking judicial notice of court documents in other cases and an FDA webpage). In addition, in a post-hearing letter, counsel for Gilead informed the Court that another generic manufacturer had filed an ANDA with the FDA for a generic version of Letairis. (Doc. No. 93.)

> purpose of clinical (including bioequivalence) testing, without Gilead's prior approval.
>
> 39. On information and belief, Gilead has entered into contracts with its specialty pharmacy distributors, including Express Scripts, that prevent them from selling Letairis® to generic drug company competitors without regard for these competitors' ability to adequately mitigate safety concerns relating to the administration of Letairis®, even refusing to sell the drug to generic drug company competitors who intend to conduct bioequivalence testing only in males, who fall outside of the REMS program for Letairis®.
>
> 40. On information and belief, Express Scripts has agreed with Gilead, absent Gilead's prior approval, not to sell or supply Letairis® to Natco for Natco's bioequivalence testing in male subjects for FDA-approval purposes.
>
> . . .
>
> 51. On information and belief, Letairis® distributor specialty pharmacies, including Express Scripts, have not supplied and will not supply samples of Letairis® to Natco for bioequivalence studies without prior approval by Gilead.
>
> . . .
>
> 78. On information and belief, Gilead and Express Scripts have knowingly and intentionally engaged in this anticompetitive activity to unlawfully "block or delay approval,". . . of an AB-rated generic version of Gilead's Letairis® and to willfully maintain Gilead's monopoly power.

(Am. Compl. ¶¶ 38-40, 51 & 78.) While Natco generally alleges a conspiracy, Natco does not specify any facts supporting the existence of a conspiracy or any basis for the allegations made on "information and belief." For example, Natco does not identify anyone who was denied Letairis after presenting a valid prescription. Nor does Natco allege any facts that would explain how a specialty pharmacy could discern that an individual prescription was written for a bioequivalence study. Natco's allegations are

insufficient to suggest an agreement or conspiracy between the Defendants or between Gilead and specialty pharmacies and, therefore, the allegations fail to state a claim. *See, e.g., Tatone v. SunTrust Mortg., Inc.*, 857 F. Supp. 2d 821, 839 (D. Minn. 2012) (explaining with respect to conspiracy claim that a plaintiff must allege facts with sufficient particularity); *In re Elevator Antitrust Litig*., 502 F.3d 47, 50-51 (2d Cir. 2007).

Moreover, as discussed above, Defendants' refusal to sell Letairis to Natco was in compliance with the legal obligation *not* to sell Letairis without a prescription and does not suggest an unlawful agreement to restrain the trade of Letairis. *See, e.g., Uhr v. Responsible Hospitality Inst., Inc.*, Civ. No. 10-4945, 2011 WL 4091866, *7-8 (D. Minn. Sept. 14, 2011) (dismissing price-fixing conspiracy claims related to drink specials at bars under *Twombly* because "bars and restaurants face potentially ruinous liability under dram shop laws if they serve alcohol to underage or intoxicated patrons"); *Kramer v. Pollock-Krasner Found*., 890 F. Supp. 250, 256 (S.D.N.Y. 1995) (dismissing conspiracy claims where defendants' allegedly conspiratorial actions could equally have been prompted by lawful goals). Instead, Defendants had plausible, lawful reasons not to dispense Letairis without a prescription or outside the REMS protocol. *See, e.g.*, *Blomkest Fertilizer, Inc. v. Potash Corp. of Saskatchewan*, 203 F.3d 1028, 1037 (8th Cir. 2000) ("[W]here there is an independent business justification for the defendants' behavior, no inference of conspiracy can be drawn.").

For the above reasons, Count I is dismissed.

D. Remaining Claims

There is no dispute that Natco's remaining state-law antitrust claims are analyzed consistently with claims under the Sherman Act. (Doc. No. 68 at 44 (citing *Minn. Made Hockey, Inc. v. Minnesota Hockey, Inc.*, 789 F. Supp. 2d 1133, 1141 n.2 (D. Minn. 2011).) Accordingly, these claims similarly fail and Counts IV and V are dismissed.

III. Natco's Motion to Supplement Pleading

Natco contends that the allegations in its First Amended Complaint are sufficient to survive Defendants' respective motions to dismiss, but nonetheless seeks to amend its pleading in order to update the Court on Natco's continued attempts to obtain Letairis.

"On motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). Supplemental pleading can be allowed even where the original pleading fails to state a claim or defense. *Id*. Supplemental pleadings are intended to cover matters occurring after the original complaint is filed and are permitted pursuant to exercise of the court's discretion. *United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 673 n.4 (8th Cir. 2003). A district court may deny leave to amend "where there are compelling reasons such as undue delay, bad faith, or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment." *Streambend Props II v. Ivy Tower Minneapolis, LLC*, 781 F.3d 1003, 1015 (8th Cir. 2015) (quotation omitted).

Natco submits that there are additional factual developments in this case that warrant supplementation. For example, Natco alleges that on April 2, 2015, a Letairis REMS-certified physician obtained by Natco's CRO submitted a prescription for Letairis on behalf of Natco. (Doc. No. 76, Ex. 1 (Proposed "First Supplemental Pleading") ¶ 63, Ex. D.) Natco claims that it was informed that its prescription request had been forwarded to Gilead's legal team. (*Id*. ¶ 65, Ex. E.) Natco also claims that Gilead has not yet contacted Natco regarding this request. (*Id*. ¶ 66.) According to Natco, the same REMS-certified physician submitted a prescription to a CVS specialty pharmacy. (*Id*. ¶ 67.) On April 3, 2015, CVS denied Natco's prescription request explaining that "[we] will not be able to provide Letairis because we are not licensed as a wholesaler. We can dispense FDA approved medications to persons with prescriptions who live in the states where we are licensed as a pharmacy" and suggested that "[s]ince the study is conducted in New Jersey, [Natco] might consider obtaining the product directly from the manufacturer." (*Id*. ¶ 68, Ex. F.) Natco further claims that on April 16, 2015, Accredo explained to Natco that a prescription was not honored because the physician was not the physician that will conduct the bioequivalence study and (citing to Natco's attorney's letter to Accredo's attorney) that Accredo represented that it would not fill a prescription written by the REMS-certified physician who will conduct Natco's bioequivalence study. (*Id*. ¶¶ 69-70, Ex. G.) In a letter dated May 22, 2015, Natco informed the Court that the physician who will be conducting its bioequivalence study had been REMS-certified and that the physician had submitted a prescription for Letairis to Accredo and Express Scripts, as well as several other specialty pharmacies. (Doc. No. 86.)

Natco seeks to supplement its pleading to address these new facts. Natco argues that: the amendment will not prejudice Defendants; Natco sought leave to file a supplemental pleading in a diligent and timely fashion; the proposed supplemental pleading is brought in good faith; and the supplemented pleading is not futile because it would withstand a motion to dismiss. Specifically, Natco argues that Defendants' pending motions to dismiss are premised on the assertion that Natco has not been denied access to Letairis. Natco submits that counsel for Defendants made assurances at oral arguments that a prescription for Letairis would be filled if written by a REMS-certified physician, and further that its REMS-certified physician submitted such a prescription, but that the prescription was not honored. Natco argues that this refusal supports its Section 2 refusal to deal claim. Natco also alleges that after Natco submitted a prescription request to Accredo, that request was forwarded to Gilead's legal team. Natco submits that this supports Natco's Section 1 conspiracy claim. Finally, in anticipation of the argument that the prescription is not valid because the REMS-physician who wrote it is not the same physician who will oversee the bioequivalence study, Natco indicated that it would submit a prescription once the physician for the bioequivalence study is certified. Natco has since informed the Court that its physician who will conduct the bioequivalence study has become REMS certified, that a Letairis prescription was submitted, and that, as of the notification to the Court, the prescription was yet to be filled. (Doc. No. 86.)

Defendants oppose Natco's motion separately but make similar arguments. Gilead argues that Natco has waited too long to follow the procedures set out in the Letairis

REMS. First, Gilead submits that it repeatedly informed Natco since June 2014 that Letairis could not be dispensed legally without a valid prescription from a REMS-certified physician, but rather than working to properly obtain Letairis, Natco filed this lawsuit. Second, Gilead argues that this antitrust case is not the appropriate vehicle for Natco to familiarize itself with the regulatory framework. Third, Defendants argue that Natco's motion to supplement the Amended Complaint is futile. Defendants contend that Natco still has not plausibly alleged a claim for refusal to deal or denial of access. Defendants argue that, at a minimum, the case should be dismissed without prejudice unless and until Natco diligently pursues all avenues for obtaining Letairis. Accredo and Express Scripts argue separately that the motion should be denied because Natco cannot allege an antitrust injury, Natco's conspiracy allegations still fail as a matter of law, and Natco's allegations underscore that Express Scripts should not be a party to this action.

The Court denies Plaintiff's motion to supplement the Amended Complaint. The allegations and attached exhibits in the proposed supplemental complaint demonstrate that Natco did not have a REMS-certified physician engaged for its study and, therefore, its various attempts to obtain Letairis samples were defective. Indeed, it is apparent that Natco is only now beginning to attempt to obtain samples under the regulatory framework and has not offered a reasonable basis to conclude that it will be unsuccessful. Therefore, the Court denies the motion to supplement and, based on the reasoning above, dismisses this action. The Court does so without prejudice. Thus, should Natco pursue

all appropriate avenues to obtain samples of Letairis and still maintain that Defendants are liable for antitrust violations, Natco can again file an action.

ORDER

Based upon the parties' submissions and arguments, and for the reasons set forth above, **IT IS HEREBY ORDERED** that:

1. Gilead's Motion to Dismiss (Doc. No. [55]) is **GRANTED**.

2. Express Scripts' and Accredo's Motion to Dismiss (Doc. No. [61]) is **GRANTED**.

3. All counts in the Amended Complaint (Doc. No. [52]) are **DISMISSED WITHOUT PREJUDICE**.

4. Natco's Motion to File Supplemental Pleading (Doc. No. [76]) is **DENIED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: September 29, 2015

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge