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DATE FILED: 9/3/15

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----- X
FERA PHARMACEUTICALS, LLC,

Plaintiff,

12 Civ. 7694 (LLS)

- against -

MEMORANDUM AND ORDER

AKORN, INC., SEAN BRYNJELSEN, and MICHAEL
STEHN,

Defendants.

----- X
AKORN, INC.,

Counterclaim-Plaintiff,

- against -

FERA PHARMACEUTICALS, LLC, ALFERA
PHARMACEUTICALS, LLC, FERANDA, LLC, BACI
007, LLC, FERA HOLDINGS, LLC, PERRIGO
COMPANY OF TENNESSEE, and PERRIGO COMPANY
PLC,

Counterclaim-Defendants.

----- X

Counterclaim-defendants Fera Pharmaceuticals, LLC, Alfera
Pharmaceuticals, LLC, Feranda, LLC, Baci 007, LLC, and Fera
Holdings LLC (collectively, "Fera") and Perrigo Company of
Tennessee and Perrigo Company PLC (collectively, "Perrigo") move
to dismiss counterclaim-plaintiff Akorn's counterclaims pursuant
to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon
which relief can be granted. For the reasons that follow, the
motions are denied.

BACKGROUND

As fairly summarized in Akorn's opposition papers, the somewhat complex relationships and acts are alleged to be as follows:

Akorn began developing generic Bacitracin in the late 1990s, utilizing sterile API acquired from non-party Xellia. (Counter. ¶ 22.) At the time, Xellia provided Akorn with a Letter of Authorization ("LOA") authorizing Akorn to reference Xellia's Drug Master File for sterile Bacitracin API, a required component of the Abbreviated New Drug Application ("ANDA") that Akorn was preparing for submission to the FDA to obtain approval to market and sell Bacitracin legally in the U.S. (Id. ¶ 23.) Akorn chose not to submit its ANDA at that time for purely commercial reasons. (Id.)

In 2009, Fera purchased the rights to eight generic ophthalmic products, including Bacitracin. (Id. ¶ 26.) On July 13, 2009, Fera entered into a Contract Manufacturing and Supply Agreement ("CMS") with Akorn pursuant to which Akorn agreed to manufacture the ophthalmic drugs that Fera had just acquired, including Bacitracin. (Id. ¶ 27; Ex. B.) Of note, the CMS had an initial term of seven years, but permitted Akorn to terminate the agreement at any time, "in its sole discretion," if Fera failed to meet the CMS's minimum annual purchase requirements. (Id.)

Fera began selling Bacitracin in the U.S. in 2009. Around the same time, other companies that had previously sold Bacitracin in the U.S. exited the market and let their ANDAs lapse. Thus, Fera found itself as the only company with an active ANDA (which permitted it to legally market and sell Bacitracin in the U.S.) that was selling Bacitracin in the U.S. market. (Id. ¶ 29.) Fera exploited its new-found monopoly by increasing the price of Bacitracin from a few dollars per unit - the price in a competitive market - to the supracompetitive price of approximately \$50 per unit, an increase of over 1,000% (Id. ¶¶ 29, 71.) Confirming that Fera held monopoly power in the U.S. Bacitracin market, in the wake of this astounding price increase, Fera was still able to increase its volume of Bacitracin sales year after year, with sales between August 2010 and July 2011 of [REDACTED] units for revenues of

██████████ (average price of \$47.25/unit), and sales between August 2011 and July 2012 of ██████████ units for revenues of ██████████ (average price of \$47/unit). (Id. ¶ 72.) The dramatic price increase did not result in significant switching to competing products; to the contrary, Fera grew the market and maintained its monopoly price. (Id.)

In 2010, Akorn decided to finalize its Bacitracin ANDA. (Id. ¶ 30.) On December 16, 2010, in order to make a small "exhibit batch" of Bacitracin for its ANDA submission, Akorn purchased Bacitracin API from Xellia pursuant to the Xellia LOA (Id.) Akorn made clear its intention to use the API to support Akorn's "core product launch." (Id.) On June 8, 2011, Akorn submitted to the FDA its Bacitracin ANDA, which referenced and relied upon the LOA from Xellia. (Id. ¶ 31.)

During this time, Fera failed to fulfill its minimum annual purchase requirements under the CMS for the calendar year 2011, which gave Akorn the right, "in its sole discretion," to terminate the CMS. (Id. ¶ 32.) After Akorn exercised that right in May 2012 (extinguishing the exclusivity provision as well), Fera responded by filing this lawsuit in September 2012, baselessly accusing Akorn of fraudulently inducing Fera to enter into the CMS, breaching the CMS, and misappropriating its trade secrets. (Id.) Paranthetically, Akorn's Counterclaim details many of the facts that directly refute all of these claims: (i) Akorn developed its own Bacitracin ten years before Fera even existed as a company, (ii) the formulation of Akorn's Bacitracin was required by law to match the formulation of the "Referenced Listed Drug" (which is the product Fera purchased in 2009) to obtain FDA approval, (iii) Fera did not have any patent protections or other intellectual property protections that otherwise prevented competitive entry, and (iv) Akorn used its own proprietary techniques to manufacture Fera's Bacitracin. (Id. ¶¶ 22, 26, 28, 30-31, 35, 38-39.)

In or around November 2012, Fera and Perrigo began discussing the sale of Fera's portfolio of ophthalmic products to Perrigo. (Id. ¶¶ 40-41.) During its diligence, Perrigo recognized that Fera's Bacitracin was not protected by trade secrets or other intellectual property that could lawfully block competitors from entering the market. Thus, Perrigo would not proceed

unless Fera could preserve the monopoly in the U.S. Bacitracin market well into the future. (Id. ¶ 42.) Fera agreed to help do just that. (See id. ¶¶ 43-66.)

Having agreed to restrain trade in the Bacitracin market, Fera and Perrigo made various misrepresentations about Akorn. For instance, they falsely claimed that Akorn had misappropriated Fera's confidential information, that it had illicitly developed an ANDA based on Fera's confidential information, and that it had obtained API from Xellia under false pretenses. (Id. ¶ 45.) To further entice Xellia's participation in their scheme, Fera and Perrigo offered a lucrative financial incentive. On top of a fixed per unit cost of the API, they agreed to pay Xellia a significant royalty for every unit of Bacitracin they sold in the U.S., which would allow Xellia to share in the windfall profits that Fera and Perrigo would make over the course of the extended monopoly. (Id. ¶ 46.)

The strong-arm tactics and financial incentive worked as planned. Once Xellia was on board, Fera, Perrigo, and Xellia carefully orchestrated a set of contractual agreements to implement their scheme. On June 14, 2013, Fera and Xellia entered into an exclusive supply agreement (the "Exclusivity Agreement"), pursuant to which Xellia agreed that it would only sell its sterile Bacitracin API to Fera for use in Bacitracin sold in the U.S. (Id. ¶ 48; Ex. H.) The Exclusivity Agreement also prohibited Xellia from issuing any future LOAs for Bacitracin API, and it required Xellia to revoke any active LOAs issued to third parties, including Akorn's. (Id. ¶¶ 48-49.) The parties also agreed to keep their agreement secret by means of a strict confidentiality requirement, which prevented Akorn from learning of the agreement's existence until it obtained a copy during discovery in this litigation. (Id. ¶ 51).

Contemporaneous with the Exclusivity Agreement, Fera and Perrigo also executed an Asset Purchase Agreement ("APA") on June 14, 2013, pursuant to which Fera sold its rights to Bacitracin and seven other ophthalmic products to Perrigo, and transferred its rights under the Exclusivity Agreement to Perrigo. (See id. ¶ 52; Ex. I.) In return, Perrigo agreed to pay Fera approximately \$90 million in cash. (Id. Ex. I § 2.5(a).) On top of that, Perrigo agreed to pay Fera a multimillion dollar "earn-out" contingent on Akorn not entering the Bacitracin market. Specifically, the APA

provides that Perrigo will pay Fera an additional \$20 million - referred to as the "Akorn Holdback Amount" - if Akorn does not enter the Bacitracin market for two years following execution of the APA. (Id. ¶ 54; Ex. I § 2.8.) Fera can earn this money either by obtaining an injunction that precludes Akorn from selling Bacitracin, or otherwise keeping Akorn from entering the market within two years of the APA's closing. (Id. ¶¶ 54-55.) Notably, this holdback is paid if Akorn is blocked from the market, and not if any other competitor comes into the market. This fact undercuts any argument that the holdback provision was a value allocation between the parties, as opposed to what it actually is, a payment for blocking out Akorn.

After entering into the Exclusivity Agreement, Xellia had second thoughts about its agreement to participate in Fera and Perrigo's scheme, but those were quickly squelched by Fera and Perrigo. On June 17, 2013, just three days after both the Exclusivity Agreement and the APA were signed, Fera sent Xellia step-by-step instructions for revoking Akorn's LOA. (Id. ¶ 59.) On June 20, 2013, Fera's founder and CEO, Frank Della Fera, contacted Xellia and repeated the false claim that Akorn had misappropriated Fera's confidential information and demanded that Xellia revoke Akorn's LOA. (Id. ¶ 60.) Xellia responded by explaining that it had a pre-existing business relationship with Akorn and faced potential legal exposure by revoking Akorn's LOA. (Id. ¶ 62.) On June 24, 2013, seven days after Fera's rights to Bacitracin had been transferred to Perrigo under the APA, Fera and Perrigo jointly sent a letter to Xellia repeating the false claim about Akorn's business practices and demanding that Xellia withdraw Akorn's LOA as soon as possible. (Id. ¶ 63.) In that letter, they expressly recognized Xellia's relationship with Akorn and threatened Xellia with "serious" consequences if it did not comply with their demands: "We assure you that the consequences to Xellia of not complying with the [Exclusivity] Agreement will be far more serious and costly than any claim Akorn could possibly have." (Id., Ex. J.)

On August 5, 2013, Xellia fell into line and withdrew Akorn's LOA. (Id. ¶ 65.) Xellia did not provide Akorn with a copy of the communication revoking the LOA and, as noted, Akorn was unaware of the Exclusivity Agreement because of its confidentiality provisions. (Id. ¶ 66.) Thus, Akorn waited for the FDA to approve its pending ANDA, believing that it would be able to enter the market in the

first quarter of 2014. (Id.) Although the FDA approved Akorn's ANDA on December 13, 2013, it rescinded that approval on February 19, 2014 when it became aware of Xellia's withdrawal of the LOA. (Id. ¶¶ 67-68.) Without an approved ANDA and without access to sterile Bacitracin API, Akorn has been unable to enter the Bacitracin market, as it had planned. (Id. ¶¶ 69, 85-86.) Moreover, by preventing Akorn and any other would-be competitors from entering the Bacitracin market, Fera and Perrigo directly harmed competition. (Id. ¶ 87.) This, in turn, has stymied competitive pricing of Bacitracin that would have lowered prices from their current supracompetitive level. Ultimately, this harmed consumers because they are forced to continue paying artificially inflated prices for Perrigo's Bacitracin. (Id.) In other words, Fera and Perrigo's anticompetitive conduct has allowed Perrigo to maintain the supracompetitive price (1000% higher than the pre-monopoly price) that Fera was charging consumers because there are no competitors in the market whose presence would create competition and lower prices. (Id.)

Akorn Opp. pp. 5-11 (footnotes omitted).

DISCUSSION

The above allegations from Akorn's opposition are supported by additional facts, but represent a fair summary of Akorn's counterclaims. The counterclaims articulate claims of antitrust injury caused by conspiracy and monopolization.

Fera and Perrigo attack the counterclaims on the grounds that (1) Akorn lacks standing because it has not alleged a valid antitrust injury and is not an efficient enforcer of the antitrust laws; (2) Akorn fails to state a claim under Sections 1 and 2 of the Sherman Act; and (3) Akorn fails to state a claim for tortious interference with a business relationship.

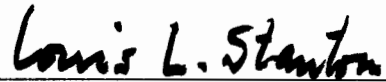
Each of those assertions rests upon a different view of the facts than that alleged by Akorn and depends upon the resolution in Fera and Perrigo's favor of a flotilla of factual issues, and thus paradigmatically presents a case not for dismissal, but for trial. Accordingly, the motions to dismiss Akorn's counterclaims are denied.

CONCLUSION

Counterclaim-defendants Fera and Perrigo's motions to dismiss counterclaim-plaintiff Akorn's counterclaims (Dkt. Nos. 75 and 79) are denied.

So ordered.

Dated: New York, New York
August 31, 2015

A handwritten signature in black ink that reads "Louis L. Stanton". The signature is written in a cursive, slightly slanted style. Below the signature is a horizontal line.

Louis L. Stanton
U.S.D.J.