IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC., Plaintiffs/Counterclaim Defendants, v. APOTEX INC., APOTEX CORP. ROXANE LABORATORIES, INC. and ACTAVIS ELIZABETH LLC, Defendants/Counterclaim Plaintiffs.	Case No: 1:12-cv-05743 (NLH) (AMD) CIVIL ACTION MOTION DATE: APRIL 1, 2013

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS/COUNTERCLAIM PLAINTIFFS' OPPOSITION TO PLAINTIFFS/COUNTERCLAIM DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS AND TO DISMISS COUNTERCLAIMS

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PRELIMINARY STATEMENT

Actelion Pharmaceuticals Ltd. and Actelion Clinical Research, Inc. ("Actelion") have highly lucrative brand-name drug monopolies over bosentan and miglustat (marketed under the brand names Tracleer and Zavesca) which are threatened by potential generic competition. When Actelion's patents expire and generic competitors enter the market, Actelion's monopolies will end and its profits will fall precipitously. Rather than accept and adapt to this commercial reality, Actelion has designed an anticompetitive scheme to foreclose generic competition. It has intentionally crafted restricted distribution systems that bar Tracleer and Zavesca sales to potential generic competitors who seek limited quantities of the drugs only for scientific testing purposes. It has precluded third parties from selling Tracleer and Zavesca to potential generic competitors. And it has refused to sell directly to potential generic competitors at any price and under any conditions.

In furtherance of these brazen attempts to stifle generic competition, Actelion now asks this Court to dismiss the claims brought by Defendants/Counterclaim Plaintiffs Apotex Inc., Apotex Corp., Roxane Laboratories, Inc., and Actavis Elizabeth LLC ("Counterclaim Plaintiffs"), and declare its anticompetitive conduct per se lawful. Such a declaration, if granted, will give brand-name drug manufacturers carte blanche to obstruct the only pathway for generic competition that has stood in place for nearly 30 years, and threaten the very existence of the generic drug industry. Fortunately for the patients, hospitals, insurers, and others who benefit from the low prices that generic drug entry brings, Actelion's Motion for Judgment on the Pleadings and to Dismiss Counterclaims ("Actelion's Motion" or "Actelion Mot.") is without any merit.

Counterclaim Plaintiffs state a claim against Actelion under Section 2 of the Sherman Act, which precludes a firm with monopoly power from engaging in exclusionary conduct that has an anticompetitive effect. Actelion refuses to even address this claim directly and does not cite any of the numerous Third Circuit cases that discuss the standards for Section 2 liability. This is a remarkable omission, but it is not a mistake. Section 2 requires a fact-intensive inquiry that asks, among other things, whether there is a plausible procompetitive business justification for a defendant's exclusionary conduct. Actelion's actions to date leave no doubt that its conduct is motivated not by any cognizable business justification, but by a desire to maintain its monopolies by any means necessary. Knowing full well that discovery will confirm Actelion's violation of Section 2, Actelion hopes to nip this case in the bud by incorrectly framing the issues raised herein as pure questions of law and by requesting a declaration that its anticompetitive scheme is per se lawful.

Actelion thus largely abandons any independent arguments in support of its Fed. R. Civ. P. 12(b)(6) motion and wagers all of its chips on its Fed. R. Civ. P. 12(c) motion, which seeks an extraordinary declaration that, as a matter of law, the antitrust laws give a firm with monopoly power a "right to refuse to deal" with any – and in this case *all* – potential generic competitors, regardless of the circumstances and effects. Because Counterclaim Plaintiffs allege a course of conduct with a refusal to deal being just one of Actelion's many exclusionary acts, this is no defense at all. It is also not the law. Actelion cites no statute or case that creates any such blanket "right." The Sherman Act *expressly prohibits* exclusionary tactics by firms with

monopoly power. Likewise, the Supreme Court has long held that such conduct by an unregulated monopolist violates Section 2 when it has anticompetitive effects.

Actelion contends that the Supreme Court's decision in *Verizon Communications, Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U.S. 398 (2004), reversed this rule and created a common law "right" for monopolists to engage in anticompetitive conduct, provided they couch that conduct as a "refusal to deal." As an initial matter, Actelion's conduct goes beyond a "refusal to deal." Actelion not only refuses to sell to potential generic competitors itself, but has prohibited *other* distributors from selling to generics. In any event, *Trinko* rejects Actelion's "refusal to deal" argument and says a monopolist's right to refuse to deal is not "unqualified." *Id.* at 408. In *Trinko*, the Court held that when Congress authorizes regulators to *enforce* a monopolist's affirmative obligation to deal with its competitors through a comprehensive set of substantive, procedural, and remedial requirements, a plaintiff cannot use antitrust law to attack the already regulated anticompetitive conduct. At that point, antitrust law offers little additional benefit.

The circumstances here are entirely different in four respects. *First*, Counterclaim Plaintiffs state a Section 2 claim for monopolization based on Actelion's exclusionary course of conduct, of which a refusal to deal is just one component. Because Actelion's conduct goes well beyond a textbook refusal to deal, the 12(c) motion that seeks immunity solely on this basis cannot resolve the case.

Second, even if the Court analyzes Actelion's conduct as a simple refusal to deal, Actelion cannot show that *Trinko* creates a blanket rule of per se legality which (absent two

exceptions) immunizes its otherwise exclusionary conduct. The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or "Hatch-Waxman") creates a framework for expedited generic entry, with a focus on ensuring that safe and effective generic drugs come to market as quickly as possible. Unlike the Federal Communications Commission and state public utility commissions (the agencies at issue in *Trinko*), however, the Food and Drug Administration ("FDA"), which implements Hatch-Waxman, has no authority to regulate the competitive process or compel a course of dealing. Actelion readily *concedes* as much through its repeated insistence that Hatch-Waxman does not impose a mandatory requirement that brand-name drug manufacturers make samples available to generic manufacturers.

Third, even if *Trinko* did create Actelion's bright-line rule (which it did not), Counterclaim Plaintiffs sufficiently allege facts that bring this case within *Trinko*'s two "exceptions." As to the first exception, Counterclaim Plaintiffs state a Section 2 claim for an anticompetitive refusal to deal under *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), and *Trinko*. *Trinko* did not overturn the century-old prohibition on such anticompetitive conduct; if anything, as its discussion of *Aspen Skiing* confirms, *Trinko* affirmed it. As to the second exception, Counterclaim Plaintiffs state a Section 2 claim for an anticompetitive refusal to deal based on denial of Tracleer and Zavesca samples, which constitute essential facilities.

And *fourth*, Roxane states a viable Section 1 claim based on Actelion's agreements with its distributors, which unreasonably restrain trade by prohibiting the distributors from selling

drug samples to Roxane for use in the bioequivalence testing necessary to support an application to market generic versions of Actelion's drug products.

Here, antitrust law must play its traditional role as the "*Magna Carta* of free enterprise." *United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972). If competition is to have any protection from private aggrandizement and help to enhance consumer welfare, there is no other regulatory scheme that can serve this function. The relief Counterclaim Plaintiffs seek will facilitate generic drug entry by denouncing Actelion's exclusionary plans. Enforcing the antitrust laws to address Actelion's anticompetitive conduct will incentivize innovation without infringing on any valid patent rights, and it will ensure that consumers obtain the benefits of generic drug competition, as Congress intended. Actelion offers no basis in law or fact to hold otherwise.

BACKGROUND

I. THE HATCH-WAXMAN ACT AND ITS REGULATORY FRAMEWORK

To understand how and why Actelion's conduct halts generic drug entry and the ensuing price competition in a manner that undermines congressional intent, it is important to understand the framework that Congress crafted to ensure and expedite such generic entry.

The Federal Food, Drug, and Cosmetic Act ("FDC Act") requires that pharmaceutical firms obtain FDA approval to market new prescription drugs. 21 U.S.C. § 355(a). Under the FDC Act, applicants for a new drug that is not based on a previously marketed drug, must complete a new drug application ("NDA") which requires that they (i) provide full reports on safety and efficacy studies and (ii) specify the drug's components and composition; the methods

and facilities used in its "manufacture, processing and packaging"; the proposed drug labeling; and patents pertaining to the drug's composition or methods of use. *Id.* at § 355(b)(1). Originally, with limited exceptions, anyone seeking to market any drug – including a generic version of an already approved drug – had to meet these requirements and undertake its own lengthy and costly studies to establish the drug's safety and efficacy. The result was a nearly insurmountable barrier to generic entry resulting in extremely high drug prices.

In 1984, Congress passed the Hatch-Waxman Act to relieve consumers from these crushing pharmaceutical costs by creating a framework to bring low-cost generic drugs to market more quickly. *See* H.R. Rep. No. 98-857(I) (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, at 14-15 (explaining that the purpose of Hatch-Waxman was "to make available more low cost generic drugs"). Hatch-Waxman created an abbreviated approval process for generic drugs by eliminating the requirement that generic applicants conduct lengthy preclinical and clinical trials to re-demonstrate the drug's safety and efficacy to the FDA. Instead, a generic manufacturer can file an abbreviated new drug application (an "ANDA"), under which it must demonstrate that its generic drug is "bioequivalent" to the already approved brand-name drug (termed the "reference listed drug" ("RLD")). *See* 21 U.S.C. § 355(j)(2)(A)(iv).

Congress's creation of the ANDA pathway addressed two tactics that brand-name drug manufacturers had deployed to limit generic entry. *First*, brand-name drug manufacturers used the patents that covered their brand-name drugs to lock generic entrants out of the market by (1) asserting patents that may have been invalid, and (2) challenging non-infringing generic drugs. To prevent such tactics, Hatch-Waxman permits generic entry prior to patent expiry

provided (1) a generic manufacturer certifies that the patent claimed to cover the brand-name drug is invalid, unenforceable, and/or not infringed by the generic drug, and the brand-name drug manufacturer does not sue to enforce its patent, *see* 21 U.S.C. § 355(j)(2)(A)(vii) (describing a "Paragraph IV certification"); (2) following a stay of FDA approval after a brand-name drug manufacturer sues in response to a Paragraph IV certification, the ANDA filer launches at risk while the patent litigation is ongoing; or (3) the ANDA filer prevails in the patent litigation brought by brand-name drug manufacturer in response to a Paragraph IV certification.[1]

Second, Congress recognized that brand-name patent holders were claiming that the mere act of testing patented products for the purposes of preparing an NDA constituted infringement. Potential generic competitors therefore could not even begin the testing process until ***after*** patent expiration, effectively further delaying generic competition beyond the brand-name drug's statutory patent right. Hatch-Waxman therefore provides that use of a patented drug solely to engage in testing needed to satisfy the FDA approval requirements does not constitute patent infringement. *See* 35 U.S.C. 271(e)(1) (known as the "Bolar Amendment").[2]

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[1] Under Hatch-Waxman, the first filer of an ANDA containing a Paragraph IV certification is granted a 180-day exclusivity period, during which it is the only generic to receive FDA approval to market its product. Congress created this 180-day exclusivity period to incentivize generic drug manufacturers to challenge invalid or non-infringed patents. During this exclusivity period, the generic manufacturer can establish its own market share and erode that of the brand-name manufacturer by attracting consumers with its lower price.

[2] The statute provides: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." This amendment overturned *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), which held that such conduct constituted infringement.

The issue in this case arises out of Actelion's attempt to design a new strategy for thwarting generic entry. Following Hatch-Waxman, a generic manufacturer must show that its drug is "bioequivalent" to the brand-name drug. *See* 21 U.S.C. §§ 355(b)(1)(A), 355(j)(2)(A). As a result, the generic manufacturer must first obtain samples of the FDA-approved brand-name drug. *See* 21 U.S.C. § 355(j)(8)(B). Generic manufacturers typically obtain these samples through normal distribution channels, such as from a wholesaler. In September 2007, however, Congress authorized the FDA to require a Risk Evaluation and Mitigation Strategy ("REMS") for new and previously approved drug products that are known or have the potential to cause serious side effects. 21 U.S.C. § 355-1(f)–(g). In addition to requirements such as a medication guide and package insert, a REMS program can include potential restrictions on a drug's distribution, such as requiring special certifications for practitioners, pharmacies, or health care settings that dispense the drug. *Id.* (*See, e.g.*, Roxane Answer & Counterclaim ("Roxane Countercl.") ¶ 28.)[3] These restrictions are termed "elements to assure safe use." *Id.*

Anticipating that Actelion and other brand-name drug manufacturers would seize on the REMS program to, again, block or delay generic entry, Congress made it clear that brand-name drug manufacturers ***shall not use*** a REMS program to block or delay generic entry. 21 U.S.C. § 355-1(f)(8) ("No holder of an approved covered application shall use any element to assure safe use required by [the FDA] . . . to block or delay approval of an [ANDA]."). As a result, the FDA

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[3] Other components of a REMS program can include a requirement that (1) the drug be dispensed only to patients engaged in patient monitoring or to patients enrolled in a registry or (2) the drug only be dispensed to patients in certain health care settings such as hospitals.

has stated that a REMS program shall not provide a brand-name drug manufacturer with a basis for refusing to provide a generic manufacturer with samples to conduct bioequivalence studies. (Roxane Countercl. ¶ 36); *see also* February 12, 2007 letter from FDA to a generic drug maker (Ex. A hereto)[4] ("[I]t is not the agency's intention to permit the restrictions of the [REMS] program to prevent manufacturers of generic drugs from obtaining [RLD samples] for use in bioequivalence testing necessary to obtain approval of an abbreviated new drug application.").

II. FACTUAL BACKGROUND

Counterclaim Plaintiffs develop, manufacture, and sell low-priced generic drugs. (Apotex Answer & Counterclaim ("Apotex Countercl.") ¶ 7; Roxane Countercl. ¶ 64; Actavis Answer & Counterclaim ("Actavis Countercl.") ¶ 6.) This case involves Counterclaim Plaintiffs' efforts to create generic competition for Tracleer (Apotex Countercl. ¶¶ 33-34; Roxane Countercl. ¶ 64; Actavis Countercl. ¶ 3) and Roxane's efforts to create generic competition for Zavesca (Roxane Countercl. ¶ 64), which are two of the four brand-name drugs that Actelion manufactures and sells in the United States.

Tracleer contains the active ingredient bosentan, which is the first FDA-approved oral treatment for pulmonary arterial hypertension ("PAH"), a chronic and potentially life-threatening disease that severely compromises lung and heart function. (Apotex Countercl. ¶ 1; Roxane Countercl. ¶¶ 4, 44; Actavis Countercl. ¶¶ 29-30.) Tracleer is the only FDA-approved drug containing bosentan and Actelion is the only company presently approved by the FDA to manufacture and sell it. (Apotex Countercl. ¶¶ 1, 28; Roxane Countercl. ¶¶ 5, 48; Actavis

[4] References to exhibits hereto refer to the exhibits attached to the Declaration of Jason B. Lattimore accompanying this Memorandum of Law.

Countercl. ¶¶ 28-30.) Accordingly, Actelion controls one-hundred percent of the market for bosentan in the United States and is able to charge an extraordinarily high price (approximately $3,000 per month) that is well in excess of its production costs. (Apotex Countercl. ¶¶ 1, 31; Roxane Countercl. ¶¶ 5, 42, 84; Actavis Countercl. ¶¶ 31-32.) In the first nine months of 2012, Tracleer accounted for $1.2 billion of Actelion's $1.4 billion in worldwide revenue, forty-two percent of which came from the United States. (Apotex Countercl. ¶ 32; Roxane Countercl. ¶ 50.)

The patent listed in the FDA's "Orange Book" for Tracleer, U.S. Patent No. 5,292,740 (the "'740 Patent") (which was not developed by Actelion but is exclusively licensed to it), was issued on March 8, 1994 and was initially scheduled to expire on June 9, 2012.[5] (Apotex Countercl. ¶ 29; Roxane Countercl. ¶ 52; Actavis Countercl. ¶¶ 27-28.) However, the patent holder obtained a 1,259-day extension under a Hatch-Waxman provision that allows brand-name manufacturers to obtain extensions of their patent terms under certain conditions. (Roxane Countercl. ¶ 52.) As a result, the '740 Patent is set to expire on November 20, 2015. (Apotex Countercl. ¶ 29; Roxane Countercl. ¶ 52.)

Zavesca contains the active ingredient miglustat, which is the first FDA-approved oral treatment for mild-to-moderate forms of type 1 Gaucher's disease, a rare and debilitating metabolic disorder. (Roxane Countercl. ¶¶ 4, 57.) It is used by patients who cannot be treated with enzyme replacement therapy. (*Id.* ¶ 4.) Zavesca is the only FDA-approved drug product containing miglustat and Actelion is the only company approved by FDA to manufacture and sell

[5] Counterclaim Plaintiffs make no admission as to the validity of the patents underlying Tracleer or Zavesca or the enforceability of the patents against any potential generic products.

it, giving Actelion complete control over the market for miglustat in the United States. (*Id.* ¶¶ 4-5, 57-59.) In the first nine months of 2012, Zavesca accounted for nearly $67 million of Actelion's worldwide revenue. (*Id.* ¶ 60.) The listed patents for Zavesca, U.S. Patent Nos. 5,472,969 and 5,525,616, expire on May 13, 2013 and June 11, 2013, respectively. (*Id.* ¶ 62.) Therefore, even assuming the validity and enforceability of these patents, Zavesca should be subject to generic competition beginning on June 11, 2013.

A. Actelion Has Prevented Generic Competition By Blocking Counterclaim Plaintiffs' Access To Tracleer And Zavesca Samples

To manufacture and sell generic bosentan and miglustat products in the United States, Counterclaim Plaintiffs must acquire Tracleer and Zavesca samples to perform bioequivalence testing. Actelion's course of conduct has prevented them from doing so.

Actelion Blocks Its Distributors From Selling To Counterclaim Plaintiffs. Typically, Counterclaim Plaintiffs purchase samples of a brand-name drug through normal distribution channels, such as from a brand-name manufacturer's distributor, rather than buying directly from a competitor. (Roxane Countercl. ¶ 7; Actavis Countercl. ¶ 4.)

Due to its potential side effects, however, Tracleer is currently subject to a REMS program (the Tracleer Access Program or "TAP"), which Actelion designed, adopted, implemented, and enforces. (Apotex Countercl. ¶ 30; Actavis Countercl. ¶¶ 4, 33.) Under the guise of TAP, Actelion distributes Tracleer only to "specially certified" wholesalers that specifically agree not to sell Tracleer to generic drug manufacturers such as Counterclaim Plaintiffs. (Roxane Countercl. ¶ 51; Actavis Countercl. ¶ 4.) Accordingly, although the law prohibits a brand-name manufacturer from using a REMS to "block or delay" approval of a

potential generic drug, 21 U.S.C. § 355-1(f)(8), Actelion has deployed TAP to prohibit its wholesalers from selling Tracleer samples to potential generic competitors and therefore block them from obtaining FDA approval.

Actelion has similarly blocked Roxane from purchasing FDA-approved Zavesca samples from Actelion's exclusive wholesaler for the drug. (Roxane Countercl. ¶ 74.) Actelion prohibits the wholesaler, Curascript, from selling Zavesca samples to Roxane even though the FDA does not require Zavesca to have a formal REMS program. (*Id.* ¶¶ 61, 76.)

Actelion's conduct has left Counterclaim Plaintiffs with no choice but to purchase samples of Tracleer and Zavesca directly from Actelion.[6] Ordinarily, this would not pose any issues if Actelion would sell the samples to Counterclaim Plaintiffs as they do to every other customer willing to purchase the drugs for a lawful, safe use. As described below, however, Actelion has refused to do so.

Actelion Denies Apotex Samples. On January 21, 2011, Apotex wrote Actelion seeking to purchase Tracleer samples. (Apotex Countercl. ¶ 40.) Apotex informed Actelion that (1) it was willing to pay market prices for the samples; (2) the samples would be used to develop a generic bosentan product and would not be sold in the United States to any patient; and (3) it would implement all reasonably necessary restrictions to control access to the samples in

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[6] Counterclaim Plaintiffs cannot obtain samples from other possible sources. Although TAP does not restrict sales of a version of Tracleer approved for marketing in another country, the FDA will not approve a bioequivalence study that uses such versions of Tracleer. 21 C.F.R. § 3.14.94(a)(3) (requiring bioequivalence be proven based on the FDA-approved "listed drug"); (*see, e.g.*, Apotex Countercl. ¶¶ 48-53 (describing FDA's refusal to allow generic firms to use Canadian samples for bioequivalence testing)). Additionally, through TAP, Actelion also requires that any patient who purchases Tracleer agree not to resell it to "unapproved" buyers, including potential generic competitors. (Roxane Countercl. ¶ 85.)

compliance with the REMS. (*Id.* ¶ 41.) On April 12, 2011, Apotex repeated its request. (*Id.* ¶¶ 42-46.) Actelion ignored both letters. (*Id.* ¶¶ 43, 47.)

On June 26, 2012, counsel for Apotex reprised its request for a third time, explaining that (1) it had been 17 months since Apotex first attempted to purchase samples from Actelion, and (2) Actelion's stonewalling was causing Apotex economic harm by delaying Apotex's ANDA submission for a generic bosentan product. (*Id.* ¶¶ 55-56.) On July 2, 2012, counsel for Actelion refused Apotex's request and stated that while the Tracleer REMS "does not provide for the sale of Tracleer tablets to Apotex," Actelion had a right "independent[] of the REMS program for Tracleer" to refuse Apotex's requests because Actelion "has the right to choose with whom it does business and to whom it will sell its products." (*Id.* ¶¶ 57-58.)

On August 1, 2012, counsel for Apotex responded that Actelion's right to choose with whom it does business "is not unlimited." (Ex. B hereto.) Counsel for Apotex enclosed a draft complaint and asked for Actelion's response by August 16, 2012. (*Id.*) On August 9, 2012, counsel for Actelion responded that "among" Actelion's concerns with selling samples of Tracleer to Apotex were "complying with its REMS program's strict limitations on distribution and protecting its intellectual property." (Ex. C hereto.) Counsel for Actelion asked four questions related to those issues, but noted that he could not "promise that Apotex's responses to the[] questions will necessarily change Actelion's position" that it would not sell samples to Apotex. (*Id.*) On August 17, 2012, counsel for Apotex answered Actelion's questions, including describing how Apotex's proposed bioequivalence protocol complied with the Tracleer REMS.

(Ex. D hereto.) Thereafter, counsel for Apotex unsuccessfully attempted to resolve the dispute through negotiations with Actelion's counsel. (Actelion Complaint. ¶ 28.)

Actelion Denies Roxane Samples. Roxane's experience with Actelion followed a similar pattern. On January 12, 2012, Roxane sent Actelion a letter seeking to purchase samples of Tracleer solely for developmental purposes. (Roxane Countercl. ¶ 67.) On February 10, 2012, Actelion responded with a refusal to sell Tracleer samples, claiming that Actelion "has the right to choose with whom it does business." (*Id.* ¶ 68.)

On August 1, 2012, Roxane's counsel urged Actelion to reconsider its position and assured Actelion that Roxane would "comply with all legitimate safety concerns." (Ex. E hereto.) Although Roxane's counsel warned that it intended to pursue all available legal options, counsel for Roxane also expressed a willingness "to explore alternatives to such legal options, including arrangements that we have successfully negotiated in previous situations with other brand-name pharmaceutical companies." (*Id.*) On August 9, 2012, Actelion's counsel responded with a letter that was virtually identical to his August 9, 2012 letter to Apotex, asking the same questions about the Tracleer REMS and intellectual property issues. (Ex. F hereto.) Sensing that the only purpose of Actelion's questions was to further delay Roxane's efforts to obtain samples and to submit an ANDA for generic bosentan (Roxane Countercl. ¶ 72), Roxane did not respond.

As to Zavesca, beginning on April 19, 2010, Roxane sent three letters to Actelion requesting to purchase samples of Zavesca for development of a generic product. (*Id.* ¶¶ 74-75.) After Actelion refused these requests, counsel for Roxane proposed in a follow-up letter on June

6, 2011 a meeting to discuss a resolution of their dispute. (Ex. G hereto.) Counsel for Actelion responded by suggesting that Roxane purchase Zavesca samples in Europe or "elsewhere." (Roxane Countercl. ¶ 75.) After counsel for Roxane reminded Actelion that FDA regulations prohibit the use of foreign samples in bioequivalence studies, counsel for Actelion explained in a letter on November 9, 2011 that Actelion would not sell Zavesca samples to Roxane because Actelion "has the right to choose with whom it does business." (*Id.* ¶¶ 75-76.)

Actelion Denies Actavis Samples. Actelion took the same absolutist position in response to Actavis's requests. On September 6, 2011, Actavis sent Actelion a letter seeking to purchase samples of Tracleer for the development of a generic bosentan product. (Actavis Countercl. ¶ 34.) Actavis explained that it would "pay Actelion for the fair market value of these products and reimburse Actelion for all reasonable shipping, handling and other costs associated with this request." (Ex. H hereto.) Actavis also informed Actelion that it "has established and will follow procedures that fully comply with FDA requirements for conducting any required testing involving bosentan." (*Id.*) On September 20, 2011, Actelion refused Actavis's request, explaining that it has the "right to choose with whom it does business," which "exists independently of the restricted distribution program for Tracleer." (Ex. I hereto.)

Actelion Provides Samples To Firms That Do Not Pose A Competitive Threat. In stark contrast to this pattern of denying potential generic competitors access to samples of its drugs, Actelion has frequently provided Tracleer and Zavesca samples for testing purposes to companies and organizations that are not potential competitors. (Roxane Countercl. ¶ 89.) Over the past twenty years, Actelion has allowed other entities to use Tracleer samples in at least

forty-seven different publicly disclosed clinical studies. (*Id.* ¶ 87.) Some of these studies were performed by large brand-name drug manufacturers, including an ongoing study by Novartis. (*Id.*) Likewise, during this same period, Actelion allowed other entities to use Zavesca samples in at least eight publicly disclosed clinical studies, including five studies by large brand-name drug manufacturers such as G.D. Searle (now a part of Pfizer) and Glaxo Wellcome (now GlaxoSmithKline). (*Id.* ¶ 88.) Notably, none of the entities performing these studies obtained the Tracleer samples through TAP or the Zavesca samples through Actelion's restricted distribution program. (*Id.* ¶ 90.) And none of these companies used the samples for the purposes of developing competing generic versions of the drugs.

B. Actelion's Conduct Has Harmed Both Counterclaim Plaintiffs And Consumers Who Must Pay Higher Prices For Tracleer And Zavesca

As Counterclaim Plaintiffs allege, Actelion's conduct has precluded Counterclaim Plaintiffs from conducting the bioequivalence testing required to develop and submit ANDAs to the FDA and, as a result, has substantially delayed the introduction of their generic bosentan and miglustat products. (Apotex Countercl. ¶ 59; Roxane Countercl. ¶¶ 78-79; Actavis Countercl. ¶ 42.) This delay has caused (and will continue to cause) Counterclaim Plaintiffs to lose profits from sales of their competing generic products. (Apotex Countercl. ¶¶ 67, 77, 83, 89, 95; Roxane Countercl. ¶¶ 135, 154, 172, 186, 199, 213, 226; Actavis Countercl. ¶¶ 52, 60, 66, 71, 80.) Actelion's conduct also has harmed purchasers of Tracleer and Zavesca, including patients and third-party payors, such as insurance companies and federal and state governments, who have paid and will continue to pay artificially high, supra-competitive prices for bosentan and

miglustat products. (Apotex Countercl. ¶¶ 66, 76, 82, 88; Roxane Countercl. ¶¶ 41, 115, 136, 155, 173; Actavis Countercl. ¶¶ 51, 59.)

III. PROCEDURAL HISTORY

On September 14, 2012, Actelion filed a complaint for declaratory judgment against Apotex and Roxane seeking a declaration that it has no legal duty or obligation to sell samples of Tracleer to them. (Dkt. No. 1.) On November 27, 2012, Apotex and Roxane each answered the complaint and filed counterclaims, and Actavis moved to intervene in the case. (Dkt. Nos. 24, 25, 27.) On December 19, 2012, the Court granted Actavis's motion (Dkt. No. 39), and on December 26, 2012, Actavis filed its answer and counterclaim with the Court. (Dkt. No. 40.)

Counterclaim Plaintiffs allege that Actelion's refusal to sell, or to permit its wholesalers to sell, samples of Tracleer to them violates Section 2 of the Sherman Antitrust Act and Section 56:9-4 of the New Jersey Antitrust Act because it constitutes unlawful monopolization, attempted monopolization, and the denial of an essential facility. They also allege state law claims for tortious interference. Roxane alleges the same claims with respect to Actelion's refusal to sell, or to permit its wholesalers to sell, Zavesca samples and also alleges that Actelion's distribution arrangements with respect to both Tracleer and Zavesca violate Section 1 of the Sherman Act and Section 56:9-3 of the New Jersey Antitrust Act. Counterclaim Plaintiffs seek treble damages, a declaration that Actelion's refusal to sell Tracleer and Zavesca samples is unlawful, and an injunction requiring Actelion to sell Tracleer and Zavesca samples to them.

ACTELION'S BURDEN UNDER FED. R. CIV. P. 12(C) AND 12(B)(6)

Actelion has moved for judgment on the pleadings under Fed. R. Civ. P. 12(c), seeking a declaration that it cannot be held liable for its anticompetitive conduct under any of Counterclaim Plaintiffs' causes of action. Granting judgment on the pleadings is a drastic action that "results in a determination on the merits at an early stage in the litigation." *Inst. for Scientific Info., Inc. v. Gordon & Breach, Sci. Publishers, Inc.*, 931 F.2d 1002, 1005 (3d Cir. 1991). It is thus incumbent on the movant to "clearly establish that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Id.*; *see also Allstate Prop. & Cas. Ins. Co. v. Squires*, 667 F.3d 388, 390 (3d Cir. 2012). That high threshold is only satisfied in circumstances where "no relief can be granted under any set of facts that could be proved." *Allah v. Al-Hafeez*, 226 F.3d 247, 250 (3d Cir. 2000).

Actelion also has moved to dismiss Counterclaim Plaintiffs' counterclaims under Rule 12(b)(6). When reviewing a motion to dismiss, a court must accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief. *D.B. v. Div. of Youth & Family Servs.*, No. 12-1559, 2012 WL 5406079, at *3 (D.N.J. Nov. 5, 2012) (citations omitted). The factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). Stating a claim requires a complaint with enough factual matter (taken as true) to suggest the required elements and raise a reasonable expectation that discovery will reveal evidence of the elements necessary to state a claim. *See D.B.*, 2012 WL 5406079, at *3.

As discussed below, Actelion's Motion fails under both legal standards. First, Actelion fails to show that, as a matter of law, it has a right to refuse to sell Counterclaim Plaintiffs the samples they need to undertake the FDA approval process. Second, Actelion fails to show that, when all the factual allegations are taken as true, it is not reasonable to expect that discovery will reveal evidence of the necessary elements of Counterclaim Plaintiffs' claims.

ARGUMENT

I. COUNTERCLAIM PLAINTIFFS SUFFICIENTLY ALLEGE THAT ACTELION'S CONDUCT VIOLATES SECTION 2 OF THE SHERMAN ACT

A. To Prevail On Its Motion, Actelion Must Show That, As A Matter Of Law, Its Conduct Cannot Be Regarded As Exclusionary

Liability for monopolization under Section 2 of the Sherman Act requires proof of two elements: (1) the possession of monopoly power in the relevant market and (2) willful acquisition or maintenance of that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 343 (3d Cir. 2012) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). Actelion does not dispute that Counterclaim Plaintiffs have adequately pled that Actelion has monopoly power in the market for FDA-approved bosentan tablets to treat PAH. (Apotex Countercl. ¶ 62; Roxane Countercl. ¶ 84; Actavis Countercl. ¶¶ 39, 44.)[7] As a result, the only issue for the Court is whether Counterclaim Plaintiffs sufficiently

[7] Actavis and Roxane also allege that Actelion is engaged in attempted monopolization of this same market. "The elements of attempted monopolization are (1) that the defendant has a specific intent to monopolize, and (2) that the defendant has engaged in anticompetitive conduct that, taken as a whole, creates (3) a dangerous probability of achieving monopoly power." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 108 (3d Cir. 2010) ("*West Penn*"). Actelion offers no argument as to why Actavis's and Roxane's attempted monopolization claims

allege the "conduct" element by alleging that Actelion engaged in "anticompetitive" (or "exclusionary") conduct. *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 308 (3d Cir. 2007).

Although such "conduct may take a variety of forms," it "is generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits," *id*. (citing *LePage's, Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003) (emphasis added)), or an "attempt[] to exclude rivals on some basis other than efficiency." *ZF Meritor*, 696 F.3d at 343 (quoting *Aspen Skiing*, 472 U.S. at 605 (1985)). Anticompetitive conduct "is too dependent upon context, for any court or commentator ever to have enumerated all the varieties." *LePage's*, 324 F.3d at 152. The Third Circuit has repeatedly observed that the Section 2 analysis is inherently fact-intensive and context-dependent, and that it must be guided by the "economic realities" of the relevant industry. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005).

Actelion's suggestion that Supreme Court precedent delineates broad exemptions from Section 2 liability without regard to the nuances of "context" and "economic realities" is a familiar tactic to the Third Circuit, but it has yet to prevail. In *ZF Meritor*, for example, the defendant claimed that under *Brooke Group, Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993), its exclusive dealing agreements were "*per se* lawful [under Section 2] because it priced its products above-cost." *Id.* at 263. The Third Circuit disagreed, holding that *Brooke Group* did not establish "a per se rule of non-liability under the antitrust laws for *all* contractual

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should be dismissed and, indeed, does not so much as even reference these elements let alone dispute that Actavis and Roxane have sufficiently alleged them. As discussed herein, both Actavis's and Roxane's complaints allege sufficient facts to plead each of these elements.

practices that involve above-cost pricing." *Id*. at 278 (refusing to impose an "unduly simplistic and mechanical rule" because doing so "would place a significant portion of anticompetitive conduct outside the reach of the antitrust laws"). Instead, the court held that the defendant's conduct could create liability, provided the plaintiffs demonstrated an anticompetitive effect that was not outweighed by a legitimate business reason. After weighing the evidence, the court agreed with the plaintiffs, noting that "there was more than sufficient evidence for a jury to conclude that ***the cumulative effect*** of [the defendant] Eaton's conduct was to adversely affect competition." *Id.* at 289 (emphasis added); *see also LePage's*, 324 F.3d at 152 (rejecting the defendant's attempt to categorize its conduct as per se lawful, and observing that "[n]othing in any of the Supreme Court's opinions in the decade" since *Brooke Group* suggest that the Court "overturned decades of Supreme Court precedent that evaluated a monopolist's liability under § 2 by examining its exclusionary, i.e., predatory, conduct").

Contrary to Actelion's assertions, the Third Circuit also has not hesitated to hold that anticompetitive conduct premised on abuse of intellectual property rights can violate Section 2. In *Broadcom*, the plaintiff Broadcom alleged that the defendant engaged in exclusionary conduct when it failed to disclose to a private industry standard setting organization ("SSO") that it held patents encompassed by a standard that the SSO ultimately selected for industry-wide use. 501 F.3d at 304. The Third Circuit held that the plaintiff stated a Section 2 claim, reasoning that the SSO's selection of the defendant's patents put the defendant in a "unique position of bargaining power" whereby it could "extract supracompetitive royalties from the industry participants" as a result of its control of access to an essential input. *Id*. at 310. By abusing the exclusionary

power conferred by its patent to exclude rivals who otherwise would have lawfully licensed (i.e., not infringed) the defendant's patents, the Court held that Broadcom sufficiently alleged exclusionary conduct.

As discussed below, under controlling Third Circuit monopolization precedent (which Actelion does not even cite), Actelion cannot carry its burden under Fed. R. Civ. P. 12(b)(6) or 12(c). First, Counterclaim Plaintiffs sufficiently allege that Actelion is engaged in an overall anticompetitive scheme which violates Section 2. *Trinko's* narrow limitation on pure refusal to deal claims does not immunize that conduct. Second, with respect to Actelion's refusal to sell product samples to Counterclaim Plaintiffs, Actelion fails to demonstrate that *Trinko* established a bright-line rule that immunizes its otherwise unlawful conduct. Third, even if such a rule were to apply, Counterclaim Plaintiffs sufficiently allege facts to come within *Trinko*'s two exceptions: (1) conduct lacking a cognizable business justification (as in *Aspen Skiing*, among other cases) and (2) the denial of access to an essential facility.

B. Actelion's Overall Scheme To Prevent Potential Generic Competitors From Obtaining Tracleer And Zavesca Samples From Any Potential Source Constitutes Exclusionary Conduct Under Section 2

Actelion's entire argument rests on its belief that *Trinko* immunizes a firm from antitrust scrutiny for refusing to deal with its would-be competitors. (Actelion Mot. at 1-3.) Although this interpretation of *Trinko* is incorrect (*see* Parts I. C-D, *infra*), Actelion's argument fails in any event because its refusal to sell Counterclaim Plaintiffs drug samples is merely *one component* of the larger exclusionary scheme challenged here. Put simply, this case involves much more than an unadorned refusal to deal. Counterclaim Plaintiffs allege that Actelion is engaged in multiple unlawful acts and practices that cannot be couched as "competition on the merits." Collectively,

this scheme amounts to ***a calculated strategy to eliminate or cripple all generic competition***. (*See, e.g.*, Actavis Countercl. ¶¶ 36, 46; Roxane Countercl. ¶¶ 34, 81, 105; Apotex Countercl. ¶¶ 63-64.) This conduct goes far beyond a typical "refusal to deal" and falls well within the classic definition of unlawful monopolization.

To review, the facts alleged by Counterclaim Plaintiffs – which must be taken as true for present purposes – establish the following scheme. First, Actelion designed a REMS and a restricted distribution program that preclude potential generic competitors (but only potential generic competitors) from obtaining Tracleer and Zavesca samples for testing purposes, *regardless of whether the generic manufacturers can adequately mitigate safety concerns for these drugs*. (Actavis Countercl. ¶ 36; Roxane Countercl. ¶¶ 34, 85, 105, 126; Apotex Countercl. ¶¶ 54-59, 63.) Second, Actelion entered into contracts with wholesalers that prevent them from selling Tracleer or Zavesca to potential generic competitors for bioequivalence testing with no regard for their ability to adequately mitigate safety concerns. (Actavis Countercl. ¶ 4; Roxane Countercl. ¶¶ 9, 51, 67; Apotex Countercl. ¶ 39.) Third, having made itself the sole source from which Counterclaim Plaintiffs can purchase the samples that are necessary for them to compete, Actelion refused their requests to directly purchase those samples at market prices. (Apotex Countercl. ¶¶ 39, 57; Actavis Countercl. ¶¶ 34-35; Roxane Countercl. ¶¶ 67-68, 74). Fourth, Actelion has made clear that, with or without the REMS, it is not obligated to sell Counterclaim Plaintiffs samples, ensuring that ***generic entry can never occur*** unless and until Actelion itself so chooses. (Actelion Mot. at 21.)

The problem with Actelion's heavy reliance on *Trinko* is that it at best only addresses Actelion's liability for refusing to sell drug samples directly to Counterclaim Plaintiffs. The Third Circuit, however, has held that the proper inquiry is whether the defendant's alleged actions "***considered together***" evidence an overall anticompetitive scheme. *LePage's*, 324 F.3d at 162 ("The relevant inquiry is the anticompetitive effect of [defendant's] exclusionary practices considered together. . . . [T]he courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."); *see also In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009) ("Courts have routinely upheld the validity of 'overall monopolization scheme' claims in the patent context, even in the absence of allegations that any one of the scheme's predicate actions was independently violative of antitrust laws."); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (same).

Counterclaim Plaintiffs adequately allege that Actelion is engaging in an overall monopolization scheme which includes drafting intentionally over-restrictive distribution programs,[8] entering into restrictive agreements with distributors, and refusing to sell product to Counterclaim Plaintiffs at market price (or any price). Each element of its scheme is designed to guarantee that Counterclaim Plaintiffs will be unable to engage in non-infringing bioequivalence testing in time to obtain FDA approval to enter the market at patent expiration for Zavesca

[8] The fact that the FDA has accepted the REMS drafted by Actelion does not constitute evidence of its lawfulness under antitrust law, as FDA's mandate in evaluating proposed REMS extends only to a consideration of whether they adequately ensure patient safety. *See* 21 U.S.C. § 355-1(a)(1) (stating that the FDA may require a REMS when it determines that a REMS is "necessary to ensure that the benefits of the drug outweigh the risks of the drug").

(2013) and Tracleer (2015).[9] Moreover, Actelion's claim that it can prevent potential generic competitors from purchasing Tracleer or Zavesca samples for as long as it chooses, including permanently, means that, if permitted, Actelion could prevent generic competition indefinitely. As a result, Actelion's argument addressing only the third element of this scheme (its unilateral refusal to sell samples) is insufficient to support dismissal of Counterclaim Plaintiffs' Section 2 monopolization claims. *See SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702-703 (E.D. Pa. 2004) (denying motion to dismiss counterclaims based on a "larger scheme to maintain [a] monopoly," even though certain elements of the scheme did not independently cause antitrust injury, because it was necessary to "consider the anticompetitive effect of [plaintiff's] acts as a whole").

In addition to alleging anticompetitive conduct, Counterclaim Plaintiffs also sufficiently allege "that the cumulative effect" of Actelion's conduct is "to adversely affect competition." *ZF Meritor*, 696 F.3d at 289. Generic entry creates competition by bringing less costly alternatives to market. Generic drugs bring down drug prices, provide significant savings to consumers, make treatment available to more patients/users, and reduce overall health care costs.

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[9] Actelion's conduct also ensures that there will not be lawful competition from generics before patent expiry. By refusing to provide samples as the clock ticks towards the expiration of its patents, Actelion has disincentivized Counterclaim Plaintiffs from making a Paragraph IV certification (and therefore attempting to challenge the validity of the Tracleer patent or otherwise enter the market by showing that their products do not infringe the Tracleer patent). Assuming Actelion were to sue to defend its patents, the lawsuit would trigger a 30-month stay of the ANDA approval process to allow the litigation to run its course, meaning generic entry could not occur prior to that date unless a Counterclaim Plaintiff obtained expeditious injunctive relief. The unlikelihood of that timing means there is little incentive for Counterclaim Plaintiffs to assume the requisite litigation costs needed to attempt the early entry that Hatch-Waxman encourages.

On average, the retail price of a generic drug is *75 percent lower than the retail price of a brand-name drug*. *See* U.S. Gov't Accountability Office, GAO-12-371R, Drug Pricing: Research on Savings from Generic Drug Use, at 1 (2012), *available at* http://www.gao.gov/assets/590/588064.pdf. So long as Actelion engages in its exclusionary conduct (to say nothing of what other brand-name manufacturers will do if Actelion prevails on this Motion), it will indefinitely block *any* lower-priced generic versions of Tracleer and Zavesca from coming to market (Actavis Countercl. ¶ 47; Roxane Countercl. ¶ 3; Apotex Countercl. ¶ 66), which is the quintessential anticompetitive effect. *West Penn*, 627 F.3d at 100 ("Anticompetitive effects include increased prices, reduced output, and reduced quality.").

In response, Actelion does not even suggest that this conduct is "competition on the merits"[10] or "efficiency enhancing." Instead, Actelion attempts to defend its exclusionary conduct on statutory grounds, contending that it falls within the scope of its intellectual property rights, which Counterclaim Plaintiffs, by demanding samples for bioequivalence testing, allegedly infringe. The Bolar Amendment, however, makes clear that Counterclaim Plaintiffs' planned use of the requested samples *does not infringe Actelion's patent* but is *an essential lawful step in enabling competition on the merits*. *See* 35 U.S.C. § 271(e)(1) (stating that it is not "an act of infringement to make, use, offer to sell, or sell within the United States" any patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary

[10] "Competition on the merits" means competition based on the merits of the product or service provided and includes conduct that leads to increased functionality, better service, and reduced prices. *See, e.g., Cal. Computer Prods., Inc. v. IBM*, 613 F.2d 727, 743-744 (9th Cir. 1979).

biological products"). Actelion also suggests that it is immune from antitrust attack because Hatch-Waxman does not prohibit its conduct. But Hatch-Waxman on its face states that brand-name drug manufacturers (like Actelion) cannot use restricted distribution systems to block generics. 21 U.S.C. § 355-1(f)(8).[11]

At bottom, Actelion does not credibly dispute that Counterclaim Plaintiffs plausibly allege the existence of a multi-pronged scheme designed to foreclose all competition in the markets for bosentan and miglustat. Actelion's attempt to justify certain elements of this scheme in a piecemeal fashion is unavailing. Because this Court must "consider the anticompetitive effect of [Actelion's] acts as a whole" and must credit all of Counterclaim Plaintiffs' well-pleaded factual allegations detailing this overall scheme, Actelion's Motion must be denied. *SmithKline*, 383 F. Supp. 2d at 702.

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[11] Actelion argues that because Congress considered but did not enact legislation requiring companies with drugs subject to REMS to provide samples to generic competitors, its refusal to do so cannot be subjected to antitrust scrutiny. But when Congress leaves conduct in the first instance to private commercial arrangements, antitrust has always been regarded as the governing legal system. *See Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973). In *Otter Tail*, the defendant, Otter Tail Power Company, barred towns that it had previously served from setting up their own municipal power distribution systems by refusing to wheel power to those towns. The defendant argued that because the Federal Power Commission had the authority to compel interconnections (but not wheeling), Congress's silence evinced an intent to insulate the defendant from antitrust liability when it engaged in conduct that was otherwise anticompetitive. *Id.* at 374. The Supreme Court rejected the defendant's position, holding that that "there [was] no basis for concluding that the limited authority of the Federal Power Commission to order interconnections was intended to be a substitute for, or to immunize Otter Tail from, antitrust regulation" for more generally "refusing to deal with municipal corporations." *Id.* at 374-75. To hold otherwise would mean, perversely, that a predicate cause of action in some other body of law must first exist before there can be any antitrust liability for exclusionary conduct.

C. *Trinko* Does Not Render Actelion's Anticompetitive Conduct Per Se Lawful

Even if this were a pure refusal to deal case, Actelion's Motion would still fall short of demonstrating that Counterclaim Plaintiffs' claims fail as a matter of law. The root justification for Actelion's refusal to sell product samples to Counterclaim Plaintiffs is its claim that, following *Trinko*, it is per se lawful for any firm to refuse to deal with competitors under any circumstances, unless an antitrust plaintiff meets one of two "exceptions." (Actelion Mot. at 11-13, 22.) Although, as discussed *infra* in Section I.D., Counterclaim Plaintiffs plead facts sufficient to fit within both of those exceptions, there is a threshold problem with Actelion's position: *Trinko* does not create such a bright-line rule.

Trinko arose in the context of the 1996 Telecommunications Act ("Telecommunications Act" or "Act"). To encourage the transition from a historically monopolized telecommunications market to a competitive one, the Telecommunications Act required incumbent local exchange carriers ("LECs") to share their local access networks with new competitors. Verizon was the incumbent LEC serving New York State and, before the Telecommunications Act, it enjoyed an exclusive franchise within its local service area. *Trinko*, 540 U.S. at 402-03. As a result, the Act required Verizon to fill new competitor LECs' orders for access to the system so that they could compete. *Id.* at 403.

Congress extensively regulated this process through a series of compulsory provisions which provided an independent federal regulatory agency (the FCC) and the state public utility commissions with extensive enforcement authority to ensure that new competition would emerge and take root. Significant provisions included (1) a requirement that Verizon provide new competitor LECs with access to the systems it used to provide service to customers; (2) provision

of authority to the FCC and state public service commissions to impose weekly or daily reporting requirements to monitor compliance; (3) grants of authority to the FCC to impose substantial penalties for noncompliance with these statutory access obligations; and (4) grants of authority to state public service commissions to enforce any voluntary agreements between new LECs and incumbent LECs and to demand arbitration of disputes under such agreements, and judicial review of any state commission action. *Id.*. at 413.

After the new LECs complained that Verizon was not filling their orders, the FCC opened an investigation into Verizon's conduct. Verizon subsequently entered into a consent decree with the FCC that imposed a $3 million fine, heightened reporting requirements, and increased penalties for noncompliance. *Id.* at 403-04. This was in addition to an investigation of Verizon by, and a settlement with, the New York Public Service Commission, which levied a $10 million financial penalty and heightened state reporting requirements as well. *Id.*

After Verizon entered into the consent decree, customers of the new competitor LECs filed a follow-on antitrust class action suit and alleged that Verizon's failure to fill competitor LEC orders – in essence *its failure to comply with pre-existing statutory obligations which the FCC had already enforced* – violated Section 2 of the Sherman Act. *Id.* at 404. On these facts, the Supreme Court declined to find Section 2 liability and articulated three reasons why requiring Verizon *under the antitrust laws* to allow rivals to interconnect was inconsistent with both the Telecommunications Act and the objectives of federal antitrust law. None of those concerns (let alone all of them) supports Actelion's position here.

First, the Court found it persuasive – if not dispositive – that the plaintiffs' antitrust claim rested entirely on allegations that Verizon was failing to engage in conduct *already mandated by the Telecommunications Act and compelled by FCC enforcement*. *Id.* at 412 ("One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm.").[12] The Court ruled that "where a state or federal agency has effective power to compel [access] . . . and to regulate its scope and terms," *id*. at 411, then there is nothing for the antitrust laws to require because the relevant conduct is already regulated. Concluding that "the [regulatory] regime was an effective steward of the antitrust function" and that no additional harm to antitrust interests would result if Verizon remained subject only to the existing regulatory procedures and penalties for any refusal to deal with the plaintiff, the Court refused to also hold Verizon liable for this same conduct under Section 2. *Id.* at 413-14.

As Actelion repeatedly emphasizes, the FDA *lacks authority to require it to provide samples* as Counterclaim Plaintiffs have requested. (Actelion Mot. at 19 ("Congress did not, however, include any requirement that a pharmaceutical innovator . . . provid[e] a generic competitor with samples for bioequivalence testing.").) In doing so, Actelion concedes the absence of any regulations like those found dispositive in *Trinko*. Thus, unlike *Trinko*, where there was already a scheme of regulation in place to safeguard the public interest which was "much more ambitious than the antitrust laws," *Trinko*, 540 U.S. at 415, no such regulatory

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[12] Indeed, the explicit issue before the Court was whether a refusal to deal gave rise to an antitrust claim where a competing regulatory scheme provided adequate protections against the resulting competitive harms. *Id.* at 401 (framing the question presented as concerning "whether a complaint alleging ***breach of the incumbent's duty under the 1996 Act*** to share its network with competitors states a claim under § 2 of the Sherman Act") (emphasis added).

scheme exists to serve as "an effective steward of the antitrust function" here. *Id.* at 413.

Second, the Court in *Trinko* was concerned that supplementing the extensive regulatory scheme with an overlay of potential antitrust liability would alter a firm's incentive to innovate. *Id.* at 407-08 (noting that compelled sharing "may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities"). This concern is simply not present here because Hatch-Waxman already protects a brand-name manufacturer's patent rights.[13] Counterclaim Plaintiffs' *use of samples prior to patent expiration* does not infringe Actelion's patent rights because "testing" does not constitute entry and does not provide any actual competition. 35 U.S.C. § 271(e)(1). Counterclaim Plaintiffs' *entry into the market prior to patent expiration* would not infringe Actelion's patent rights because such early entry could occur only if Counterclaim Plaintiffs were to prove that any Orange Book-listed patents were invalid, unenforceable, or not infringed by Counterclaim Plaintiffs' proposed formulations.[14] And Counterclaim Plaintiffs' *entry into the market after patent expiration* would not infringe Actelion's patent rights.

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[13] *See* H.R. Rep. 98-857, pt. 2, at 2714 (Aug. 1, 1984) (noting that Congress enacted the Hatch-Waxman Act to "balance the need to stimulate innovation against the goal of furthering the public interest"). In striking this balance, the Act provides patent and exclusivity provisions to incentivize brand-name drug manufacturers to innovate by allowing them to recoup the research and development costs required to find new and useful drugs. It provides holders of patents covering new approved drugs with up to five additional years of patent protection. *See* 35 U.S.C. § 156(g)(6). It also provides brand-name manufacturers with five years of exclusivity for new chemical entities regardless of patent protection. *See* 21 U.S.C. § 355(c)(3)(E)(ii).

[14] At this point, Actelion's refusal to sell Counterclaim Plaintiffs samples combined with the expiration dates for the Zavesca and Tracleer patents (June 2013 and November 2015, respectively) means that generic entry via a launch at risk is impossible. This is because a Paragraph IV certification, a lawsuit, and a 30-month stay of that litigation would all need to take place before such a launch could occur.

Third, the Court was concerned about putting antitrust courts in the position of "central planners." *Trinko*, 540 U.S. at 408. By finding Verizon's conduct unlawful under antitrust law, the Court would impose mandatory sharing obligations as part of an ongoing course of dealing between Verizon and new competitor LECs, which would have "require[d] continuing supervision of a highly detailed decree." *Id.* at 415. Actelion does not (and cannot) allege any concern that an antitrust remedy would require ongoing supervision of the course of dealing between Actelion and Counterclaim Plaintiffs, as the Court feared in *Trinko*. Here, Counterclaim Plaintiffs simply want to make a one-time purchase of samples. They have zero interest in engaging in an ongoing course of dealing with their future competitor. Additionally, there is no need for the court to define (let alone supervise) the market parameters because Actelion already sells Tracleer and Zavesca through an independent distribution channel at established prices. As in *Aspen Skiing*, Counterclaim Plaintiffs simply want to purchase the product that Actelion sells for the full market price that it already charges (or to purchase samples from third-party wholesalers who already sell the products). 472 U.S. at 593-94.[15] Yet Actelion refuses to allow Counterclaim Plaintiffs to purchase the product at *any* price.

California Computer Products, which Actelion relies on in support of its broad-based claim, underscores the gaps in Actelion's arguments. There, plaintiff alleged that defendant instituted design changes that delayed plaintiff's ability to reverse engineer defendant's product

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[15] Given that Actelion is already in the business of selling these drugs at established prices, the sale of samples would not lead to a long-term relationship between Actelion and the Counterclaim Plaintiffs requiring court management, any potential burden on the court would be insignificant and would not be an obstacle to any remedy if Counterclaim Plaintiffs prevail on their claims.

and thus develop compatible competitive products. 613 F.2d at 731. In reviewing a directed verdict, the Ninth Circuit found that the undisputed evidence at trial showed that the defendant's design change was solely a cost saving step that enabled it to offer its customers the same functions at reduced prices. *Id.* at 744. The court thus held that where it is ***uncontroverted*** that the effect of defendant's conduct ***is to provide consumers with lower prices***, that conduct is not anticompetitive merely because it harms specific competitors in some way. *Id.* Actelion makes no allegations (let alone "uncontroverted" ones, as it must to prevail on its Fed. R. Civ. P. 12(c) motion) that would support such a finding here. Nor can it where, as here, the sole purpose and effect of its conduct is to continue charging consumers artificially high, supra-competitive prices.[16]

Fundamentally, because Actelion's scheme to eliminate generic competition has nothing to do with benefitting consumers and because Actelion cannot point to another legal framework that affirmatively protects the competitive process here, Actelion cannot hold up *Trinko* (or any other refusal-to-deal case) as immunizing it from Section 2 scrutiny. Nothing in the case law suggests that a refusal to deal, no matter what the circumstances, is an automatic and complete

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[16] Actelion also relies on a trio of Seventh Circuit cases, none of which supports the outcome that Actelion seeks. *Schor v. Abbott Labs.*, 457 F.3d 608 (7th Cir. 2006), the only post-*Trinko* decision that Actelion cites, explicitly states that there was no refusal to deal involved. 457 F.3d at 610. *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 400 (7th Cir. 2000), in contrast, involves a refusal to deal in a fact pattern identical to *Trinko*, but was decided *before Trinko*. As such, it would be improper for this Court to rely on the Seventh Circuit's analysis in lieu of the Supreme Court's decision. Finally, in holding that exclusionary conduct did not occur where the defendant stopped helping the plaintiff but did not hinder it, the court in *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370 (7th Cir. 1986), explained that a "monopolist may be guilty of monopolization if it refuses to cooperate with a competitor *in circumstances where some cooperation is indispensable to effective competition*." *Id.* at 379 (emphasis added). Here, generic manufacturers' ability to purchase samples is indispensable to generic competition.

defense to any Section 2 claim. And nothing in Actelion's pleadings or its brief demonstrates that it has any procompetitive justification for its conduct.

D. Counterclaim Plaintiffs Allege Facts That Meet Both *Trinko* "Exceptions"

Actelion contends that post-*Trinko*, Counterclaim Plaintiffs can prevail on their Section 2 claims only if they satisfy one of two alleged "exceptions" to *Trinko*'s ostensible ban on refusal-to-deal claims: the first based on *Trinko*'s reaffirmation of its *Aspen Skiing* decision (which itself declared a refusal to deal unlawful), and the second based on the essential facilities doctrine. Although Counterclaim Plaintiffs reject this narrow reading of *Trinko*, they allege facts sufficient to satisfy both purported exceptions.

1. Counterclaim Plaintiffs Sufficiently Allege An Unjustified Refusal To Deal Under *Trinko* And *Aspen Skiing*, Neither Of Which Require A Prior Voluntary Course Of Dealing Between The Specific Parties

Counterclaim Plaintiffs allege sufficient facts under the refusal-to-deal framework applied in *Aspen Skiing* and reaffirmed in *Trinko*. Although Actelion contends that *Trinko* and *Aspen Skiing* closed the door on all duty-to-deal claims absent allegations of a preexisting, voluntary course of dealing between the parties (Actelion Mot. at 13-14), that assertion rests on a flawed reading of controlling Supreme Court precedent.

Trinko does not, as Actelion claims, construe *Aspen Skiing* as requiring cessation of a voluntary course of conduct between the parties as a predicate for refusal-to-deal liability. (Actelion Mot. at 13.) To the contrary, *Trinko*'s discussion of *Aspen Skiing* begins by first *endorsing Aspen Skiing*'s core holding; namely, that the "high value that [the Court] ha[s] placed on the right to refuse to deal with other firms does not mean that the right is unqualified." 540 U.S. at 408 (quoting *Aspen Skiing*, 472 U.S. at 601); *see also United States v. Colgate & Co.*,

250 U.S. 300, 307 (1919) ("***In the absence of any purpose to create or maintain a monopoly***, the act does not restrict the . . . right of trader or manufacturer . . . to exercise his own independent discretion as to parties with whom he will deal.") (emphasis added). The Court then distinguishes the facts in *Trinko* from those in *Aspen Skiing*, "the leading case for § 2 liability based on refusal to cooperate with a rival," and in the process highlights aspects of *Aspen Skiing* that made imposition of antitrust liability for refusal to deal appropriate in that case. *Id*. at 408-09.

In *Aspen Skiing*, defendant had a history of dealing profitably with its rival company. When it abruptly changed course and locked the plaintiff out of the venture, that conduct "support[ed] an inference that the monopolist made a deliberate effort to discourage its customers from doing business with its smaller rival." 472 U.S. at 610. Similarly, the putative monopolist in *Aspen Skiing* refused to sell a product it offered to others (ski lift tickets) to its competitor, despite the fact that the competitor was offering to pay full retail price for the product – conduct the *Trinko* Court described as "reveal[ing] a distinctly anticompetitive bent." *Trinko*, 540 U.S. at 409; *Aspen Skiing*, 472 U.S. at 608. While the facts in *Aspen Skiing* suggested that the refusal to deal was motivated by a desire to quash competition, Verizon's failure in *Trinko* to live up to its regulatory obligation to provide network access to rivals did not. 540 U.S. at 414. This led the Court to conclude that imposing liability on Verizon based upon a bare refusal to deal, without more, would be of "slight benefit" when weighed against the risk of "false positives." *Id.*

Trinko's reaffirmation of *Aspen Skiing* therefore does not stand for the rule that a plaintiff must plead facts identical to those in *Aspen Skiing* to state a Section 2 claim. Rather, consistent with a long line of Section 2 case law which *Trinko* did not overrule, the Court held that (1) a complaint must allege facts beyond a bare refusal to deal which suggest that the motivation for the refusal is a desire to acquire or maintain a monopoly, and (2) a complaint can satisfy this test by alleging a change in prior conduct that evinces such a motivation, *or* by showing that a putative monopolist has refused to sell to its rival, at retail price, a product which it sells to other customers that are not its competitors. *See Trinko*, 540 U.S. at 408-09; s*ee also Otter Tail*, 410 U.S. at 378 (holding that a defendant who was in the business of selling power to customers violated Section 2 by refusing to sell power to potential competitors because there were no engineering factors (i.e., business justifications) that prevented the defendant from making the sales, and the defendant's refusal to sell was solely to protect its monopoly).

Several courts have endorsed this interpretation of *Trinko*. In *Helicopter Transport Services, Inc. v. Erickson Air-Crane, Inc.*, No. CV-06-3077, 2008 WL 151833 (D. Or. Jan. 14, 2008), for example, the court held that defendant's conduct, including a refusal to sell parts even at retail, more closely resembled the conduct in *Aspen Skiing* and *Otter Tail* than in *Trinko*. Contrary to Actelion's argument here, the court observed that the "Supreme Court has never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim." *Id.* at *9. Instead, the court noted, such conduct "was merely one of several facts in *Aspen Skiing* that supported a finding that the refusal to deal was intended to exclude competition rather than to advance a legitimate business interest." *Id*. The court noted that *Trinko* did not effect a "sea

change in antitrust law," but instead "recited and applied the same antitrust standards the Supreme Court has articulated for years." *Id.* In other words, *Trinko* recognized that the decision by the defendant in *Aspen Skiing* to depart from a prior course of dealing with its competitor was significant not on its own merits but because it suggested an exclusionary motive underlying the monopolist's decision. *See Broadcom*, 501 F.3d at 316-17 (a complaint alleging that a company refused to sell technology to a rival that it actively marketed and licensed to other customers states a claim for refusal to deal under *Trinko*).[17]

Consistent with these cases, Counterclaim Plaintiffs allege facts demonstrating a marked departure from Actelion's prior conduct. Counterclaim Plaintiffs allege that drugs like those at issue here are typically available for purchase from wholesalers, but that Actelion has intentionally entered into agreements with wholesalers and distributors of Tracleer and Zavesca that prohibit them from selling the drugs to potential generic competitors like Counterclaim Plaintiffs. (Apotex Countercl. ¶ 39; Actavis Countercl. ¶¶ 34, 45; Roxane Countercl. ¶¶ 23, 51.[18]) In addition, Counterclaim Plaintiffs allege that Actelion has engaged in a course of voluntary conduct whereby it has repeatedly provided Tracleer and Zavesca samples to others for clinical studies, yet has refused to provide the same samples to Counterclaim Plaintiffs because it fears potential competition. (Roxane Countercl. ¶¶ 86-90.)

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[17] *See also Stand Energy Corp. v. Columbia Gas Transmission Corp.*, 373 F. Supp. 2d 631, 641 (S.D.W. Va. 2005) (denying defendants' motion to dismiss and holding that *Trinko* does not foreclose refusal-to-deal claims where no regulatory structure exists to remedy the harm and factual allegations demonstrate the refusal to deal is "predicated on anticompetitive goals").

[18] Similarly, Roxane alleges that Actelion has entered into an exclusive agreement with its distributors of Zavesca that prevents the distributors from selling product to potential generic rivals like Roxane. (Roxane Countercl. ¶ 61.)

Counterclaim Plaintiffs also allege that Actelion's refusal to deal with its competitors represents a willingness to sacrifice potential sales for which the only rational justification is its anticipated exclusionary effect. Counterclaim Plaintiffs allege that they have offered to purchase Actelion's products at full market prices, but that these offers have been refused. (Apotex Countercl. ¶¶ 39-47; Actavis Countercl. ¶¶ 34-36; Roxane Countercl. ¶¶ 67-69, 72-76.) Actelion has ignored Counterclaim Plaintiffs' proffered assurances that they would comply with any reasonable safety protocols in handling product samples, conduct which further demonstrates that Actelion's supposed safety concerns are pretextual. (Apotex's Countercl. ¶¶ 41, 54-59; Actavis Countercl. ¶¶ 36-37; Roxane Countercl. ¶ 105.)

Actelion *does not deny* any of these facts. To the contrary, as Counterclaim Plaintiffs allege, Actelion has entered into restrictive agreements with its distributors, it has provided drug samples for clinical studies to others, it has rebuffed Counterclaim Plaintiffs' offers to purchase Tracleer and Zavesca at market prices or any price, and it has ignored Counterclaim Plaintiffs' assurances of proper safety protocols. Nor does Actelion even argue that this conduct is motivated by any concern other than the desire to suppress generic competition. Instead, Actelion has embraced the reality that all of the above conduct is motivated solely by a desire to maintain its monopoly.

This case is therefore nothing like *Trinko*, where the unadorned refusal-to-deal allegations left the Court to conclude that the conduct alleged "tells us nothing about [Verizon's] dreams of monopoly." *Trinko*, 540 U.S. at 409. Here, by contrast, the conduct alleged – and Actelion's explicit acknowledgment of its anticompetitive aims – tells us *everything* about

Actelion's "dreams of monopoly." *See id.* Actelion's claim that, under *Trinko* and *Aspen Skiing*, it can refuse to deal with Counterclaim Plaintiffs for anticompetitive reasons without being subjected to any antitrust scrutiny is simply wrong. As a result, Actelion's Motion must be denied.

2. Counterclaim Plaintiffs Sufficiently Allege A Section 2 Violation Under The Essential Facilities Doctrine

Counterclaim Plaintiffs also state a Section 2 claim based on the denial of access to essential facilities (here, the Tracleer and Zavesca samples). To plead an essential facilities claim, a competitor must allege: "(1) control of the essential facility by a monopolist; (2) a competitor's inability practically or reasonably to duplicate the essential facility; (3) denial of the use of the facility to a competitor; and (4) the feasibility of providing the facility." *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 748 (3d Cir. 1996) (citations omitted). Counterclaim Plaintiffs sufficiently allege each of these elements. (*See* Apotex Countercl. ¶¶ 70-74; Roxane Countercl. ¶¶ 146-49, 164-67; Actavis Countercl. ¶¶ 55-57.) Actelion does not dispute the applicable standard or contest the sufficiency of Counterclaim Plaintiffs' allegations. Indeed, reminiscent of its other arguments, Actelion offers four broad reasons why its anticompetitive behavior is categorically exempt from scrutiny under the essential facilities doctrine. None is persuasive.

a. The Essential Facilities Doctrine Applies Post-*Trinko*

Actelion suggests that the essential facilities doctrine did not survive *Trinko*, pointing out that the doctrine "has been questioned" by some law professors. (Actelion Mot. at 15.) But in *Trinko*, the Supreme Court explicitly declined an invitation to hold the doctrine invalid. 540

U.S. at 411 (finding "no need either to recognize . . . or to repudiate [the doctrine] here"). In so holding, *Trinko* noted that "[t]he 1996 [Telecom] Act's extensive provision for access makes it unnecessary to impose a judicial doctrine of forced access." *Id.* at 411. As discussed *infra*, no such "extensive provision for access" exists here.

Unsurprisingly then, lower courts have recognized that the essential facilities doctrine survived *Trinko*. *See, e.g.*, *Metronet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1128-30 (9th Cir. 2004); *Morris Commc'ns Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1294 (11th Cir. 2004). In particular, courts in this Circuit have treated the essential facilities doctrine as good law both before *Trinko*, *see, e.g.*, *Monarch Entertainment Bureau, Inc. v. New Jersey Highway Authority*, 715 F. Supp. 1290, 1300 (D.N.J. 1989) (the doctrine "attempts to address the situation where a monopolist controls a facility that its competitors need access to if they are to compete effectively"), and after. Order Den. Def.'s Mot. to Dismiss, *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920, (E.D. Pa. Mar. 31, 2011), Dkt. No. 42 (Ex. J hereto); Lannett Mem. in Opp'n to Renewed Mot. to Dismiss, *Lannett Co.*, No, 2:08-cv-03920, (E.D. Pa. June 18, 2010), Dkt. No. 34, (Ex. K hereto). Indeed, in *Lannett*, the plaintiffs brought only one claim: that a brand-name drug manufacturer's refusal to provide access to samples for bioequivalence testing violated Section 2 of the Sherman Act, under the essential facilities doctrine. *Id.* Much like Actelion here, the brand-name manufacturer argued that the essential facilities doctrine's "validity . . . [was] seriously questioned" by *Trinko* and moved to dismiss the complaint for failure to state a claim. Def.'s Renewed Mot. to Dismiss at 14, *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920, (E.D. Pa. May 28. 2010), Dkt. No. 29 (Ex. L hereto). The court rejected this argument, and

denied the brand manufacturer's motion to dismiss, confirming that the generic manufacturer had stated a claim for relief based solely on its essential facilities argument. (*See* Ex. J.)

b. There Is No Requirement That A Monopolist's Control Of An Essential Facility Deny A Competitor Access To A Different Market

Actelion next contends that "this case simply does not fit within the contours of the essential facilities doctrine" because the doctrine governs only a monopolist's denial of access to an essential facility "necessary to compete in a *different* market with a *different* service or product." (Actelion Mot. at 15.) These so-called "contours" are entirely of Actelion's own making, as no court has ever limited the doctrine's application to cases in which a monopolist's control of an essential facility denies a competitor access to a different market. In fact, courts apply the doctrine in cases where a monopolist's control of an essential facility denies a competitor access to the *same* market because the touchstone of an essential facilities claim *is the competitive relationship between the parties*, not the relationship between the essential facility and the relevant market. *See Mid-South Grizzlies v. NFL*, 550 F. Supp. 558, 570 (E.D. Pa. 1982) ("The doctrine is applicable only where a party is being denied access to something necessary for that party to engage in business which is controlled by his *competitors*."), *aff'd*, 720 F.2d 772 (3d Cir. 1993).

Although Actelion relies on *MCI Communications Corp. v. AT&T*, 708 F.2d 1081 (7th Cir. 1983), *MCI* simply does not limit the essential facilities doctrine to cases in which a monopolist's control of an essential facility denies a competitor access to a different market. The sentence that Actelion partially quotes (Actelion Mot. at 15) from *MCI* states in its entirety: "[A] refusal [to deal] may be unlawful because a monopolist's control of an essential facility

(sometimes called a 'bottleneck') can extend monopoly power from one stage of production to another, and from one market into another." *Id.* at 1132. This sentence in no way imposes any requirement that a monopolist's control of an essential facility deny a competitor access to a different market – a point which is underscored by the fact that, almost immediately following the sentence relied on by Actelion, the court sets out the same four elements set forth above. *Id.* None of those elements includes any requirement that a competitor's control of an essential facility deny a competitor access to a different market.

c. Actelion's Claim That The Essential Facilities Doctrine Does Not Apply To Patented Products Is Irrelevant And Incorrect

Actelion's argument that "patented products . . . cannot be considered essential facilities" (Actelion Mot. at 16) is equally unsupported. The basic premise underlying this argument is that it would fly in the face of a patent holder's intellectual property rights for a court to compel the patent holder to share its intellectual property. For three reasons, however, the concerns implicated by that premise are not applicable here.

First, as discussed *infra* Section I.C., Actelion's patent rights are not at risk here because the Bolar Amendment, 35 U.S.C. § 271(d)(1), already establishes that those rights are not infringed by bioequivalence testing. The patents for Tracleer and Zavesca therefore do not provide Actelion with protection as part of its intellectual property rights against Counterclaim Plaintiffs' proposed use of samples for bioequivalence testing.

Second, even if there were some argument that Counterclaim Plaintiffs' essential facility claim implicates Actelion's intellectual property rights, no court has ever held that a patent grants blanket immunity from the antitrust laws. As Justice Harlan explained in his landmark

concurrence in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 179-80 (1965), when a patent holder defends against a claim of anticompetitive conduct, the correct approach is to evaluate the patent holder's conduct in light of the aims of the patent laws (which foster innovation) and the antitrust laws (which foster competition). *Id.* (noting that the antitrust analysis hinges on whether subjecting conduct that implicates a patent's exclusionary power would undermine the patent system's incentive to induce innovation). Justice Harlan concluded that, if the patent holder's conduct does not further either of those objectives, application of the antitrust laws to the patent holder's conduct would not undermine the patent laws because, quite simply, the patent holder's conduct was already inconsistent with both of those laws.

Here, there is no deference that needs to be accorded to Actelion's patent rights in Tracleer and Zavesca because Congress has already concluded that when a brand-name drug manufacturer facilitates bioequivalence testing, it does not harm innovation (which Hatch-Waxman already protects) but incentivizes competition. The generic manufacturer's use of those samples (and its inherent need for the samples to engage in the testing) is therefore consistent with the objectives of both the antitrust and intellectual property laws.

Third, Actelion's argument also fails because it prematurely raises the issue of its patent rights, an issue that Hatch-Waxman decreed would not be addressed until *after* the filing of an ANDA. If one or more of Counterclaim Plaintiffs obtains Tracleer or Zavesca samples and files an ANDA for generic bosentan or miglustat with a Paragraph IV certification stating that Actelion's patents are invalid, unenforceable, or non-infringed, then Actelion could sue and

trigger the Hatch-Waxman provision that provides for a 30-month stay of approval for any related ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Actelion's attempt to use its patents as a defense to antitrust liability assumes that it would prevail in any such patent litigation and simultaneously ensures that it will never have to actually fight this battle because Counterclaim Plaintiffs cannot file an ANDA without first obtaining Tracleer and Zavesca samples.

Actelion does not cite any case that supports its sweeping proposition that, as a matter of law, its intellectual property rights confer blanket immunity from Section 2 liability under the essential facilities doctrine. Actelion's citation to *Applera* (Actelion Mot. at 16) underscores the problems with its argument. *Applera* only rejected the plaintiff's essential facilities claim *after* a jury had determined that the plaintiff had infringed the defendant's patent. *Applera Corp. v. MJ Research, Inc.*, 349 F. Supp. 2d 338, 348 (D. Conn. 2004). In other words, in *Applera* the plaintiff was clearly impinging on the defendant's intellectual property rights and, notwithstanding that, sought a declaration that it could do so under the essential facilities doctrine. This case is entirely different because, as a matter of law, bioequivalence testing is unambiguously ***not an act of patent infringement***. 35 U.S.C. § 271(e)(1). *Applera*'s observation that finding a patent to be "an 'essential facility' to which [a patent holder] must provide access would subvert the plain meaning and purpose of the Patent Act" (Actelion Mot. at 16) therefore makes no sense here. Allowing Counterclaim Plaintiffs to use Tracleer and Zavesca samples for bioequivalence testing is entirely consistent with Congress's "plain meaning and purpose" in Hatch-Waxman, which establishes that such use does *not* violate a brand-name manufacturer's patent, even assuming validity.

Actelion's claim that *Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, 486 F. App'x 186 (2d Cir. 2012), is "directly on point" also is inaccurate. *Eatoni* did not hold that the existence of a patent itself made the plaintiff's essential facilities claim untenable. Instead, on the facts presented, the court affirmed the dismissal of an essential facilities claim where the plaintiff admitted that there were "other competitor mobile phone producers capable of creating a reduced QWERTY keyboard model," such that the plaintiff could "not plausibly assert that [the defendant was] the *only* mobile phone manufacturer with which [it] feasibly [could] do business." *Id.* at 190. Counterclaim Plaintiffs make no such admission here. To the contrary, as discussed *infra*, they vigorously dispute Actelion's suggestion that other means of entry are viable. Moreover, while the patent in *Eatoni* gave the defendant the "lawful power to exclude," the Bolar Amendment means that Actelion's patents covering Tracleer and Zavesca do not provide Actelion with any such power where, as here, Counterclaim Plaintiffs seek to use Tracleer and Zavesca samples for bioequivalence testing.

d. Actelion Fails To Show That Undisputed Facts Demonstrate That Access to Samples of Tracleer and Zavesca Is Not Essential to the Generics' Ability to Compete

The *only* element of the four-prong essential facilities test that Actelion contests is the first element – i.e., whether or not samples of Tracleer and Zavesca are truly "essential." Actelion's argument that "[t]here are alternate ways in which Apotex, Roxane and Actavis can compete" (Actelion Mot. at 17), however, simply creates a disputed fact by contesting Counterclaim Plaintiffs' allegations that Tracleer and Zavesca samples are an essential facility. The Court should not even consider this argument, as contested issues of fact cannot be decided at this stage and certainly cannot be resolved in favor of the moving party. *See Ohio Bell*

Telephone Co. v. CoreComm Newco, Inc., 214 F. Supp. 2d 810, 818 (N.D. Ohio 2002) (noting that although the defendant may eventually be able to defeat plaintiff's allegation as to each essential facilities element, "these defenses are issues of fact which cannot be decided on a 12(b)(6) motion to dismiss"). As one court stated in responding to a similar argument, although the defendant "contends that [the plaintiff] has not set forth facts confirming that there were no reasonable alternatives to the stadiums alleged to be essential," an antitrust plaintiff "is not required to bolster its allegations with particularized facts, . . . let alone to negate in its complaint factual challenges that the defendant might raise." *JamSports & Entertainment, LLC v. Paradama Productions, Inc.*, No. 02 C 2298, 2003 WL 1873563, at *12 (N.D. Ill. Apr. 15, 2003). Because "[a]n essential facilities claim, like relevant market definition, requires factual development," the court declined at the pleading stage "to look beyond the pleadings to take notice of alternative" sources that the plaintiff identified. *Id.*

In any event, Actelion's assertion is wrong because Tracleer and Zavesca samples are essential to competition in the relevant markets. The suggestion that Counterclaim Plaintiffs could "practically and reasonably" compete with Tracleer or Zavesca by developing new "drug products with the exact same formulation as Tracleer and . . . file an NDA" is nonsensical. (Actelion Mot. at 17.) Actelion holds the NDA for Tracleer and Zavesca, which are patented drugs. That means that no other manufacturer may lawfully develop and seek FDA approval of drug products with the exact same formulations as these products outside of the ANDA pathway,

and bioequivalence studies (and samples of the patented drugs) are an essential predicate to an ANDA.[19]

Actelion's claim that potential competitors can instead enter the Tracleer and Zavesca markets via a Section 505(b)(2) application is simply wrong. The FDA has stated unequivocally that generic manufacturers should not submit Section 505(b)(2) applications "for duplicates of approved products that are eligible for approval under 505(j) [the statutory provision that governs ANDAs] . . . ." FDA, *Draft Guidance for Industry: Applications Covered by Section 505(b)(2)* at 3-4 (Oct. 1999). This is because Section 505(b)(2) governs applications that seek to market an already approved drug with certain slight changes, such as a new dosage form or new indication. *Id.* at 4-5. An application submitted under section 505(b)(2) is therefore still an NDA and, as such, must demonstrate the safety and effectiveness of the proposed new drug. The only difference is that a Section 505(b)(2) applicant may rely on either published literature or

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[19] If Actelion's position is that Counterclaim Plaintiffs could compete with Actelion by developing entirely new drugs to treat PAH instead of seeking to bring a generic competitor to market, then it illustrates the extent to which Actelion's purported relief would profoundly undermine Hatch-Waxman. Moreover, none of these suggestions are "practical[] and reasonabl[e]" alternatives given the differences between filing an NDA and an ANDA. The lengthy process of developing a new drug and filing an NDA would allow Actelion to extend its statutorily granted monopoly well past its expiration. And because they would face immediate competition from Tracleer or Zavesca, there would be no exclusionary period available to generic entrants to recoup the costs associated with the NDA process.

The difference between these two forms of entry is exemplified by their costs. According to some estimates, a single clinical trial (required for an NDA) can cost up to $100 million. *See* Matthew Herper, The Truly Staggering Cost of Inventing New Drugs, Forbes, Feb. 10, 2012, *available at* http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/. By contrast, the total cost of developing a generic drug for ANDA approval, including bioequivalence studies, has been estimated by some to cost between $1–$2 million. Henry Grabowski, et al., The Market For Follow-On Biologics: How Will It Evolve?, 25 Health Aff. 1291, 1293 (2006), *available at* http://fds.duke.edu/db/attachment/219.

FDA's findings of safety and efficacy for a drug that has already been approved to fulfill some of the requirements for approval, as opposed to conducting all of the referenced studies itself. This process has hardly anything in common with the ANDA pathway that Congress created in Hatch-Waxman to facilitate generic entry of bioequivalent drugs to compete directly with their more expensive, brand-name counterparts.

Beyond these arguments, Actelion cites several cases for the noncontroversial proposition that a facility is not "essential" merely because it is the most economical route for a competitor to take. (Actelion Mot. at 17.) Counterclaim Plaintiffs do not dispute this point and note that, in each of Actelion's cited essential facilities cases, there were other "reasonable" means to obtain the alleged essential facility. Here, in contrast, Counterclaim Plaintiffs cannot "practically or reasonably" duplicate the samples of Tracleer or Zavesca. To the extent Actelion disagrees, it is free to put forth factual evidence on this point at the summary judgment and trial stages – but it cannot gain the benefit of such factual inferences at the pleadings stage.

II. ROXANE ADEQUATELY ALLEGES THAT ACTELION'S DISTRIBUTION AGREEMENTS VIOLATE SECTION 1 OF THE SHERMAN ACT

In Counts V and VI of its counterclaims, Roxane alleges that Actelion's restrictive agreements with the wholesalers, distributors, and/or pharmacies that distribute Tracleer and Zavesca are agreements in restraint of trade that violate Section 1 of the Sherman Act.[20]

[20] Roxane also alleges that these agreements amount to a conspiracy to monopolize in violation of Section 2 of the Sherman Act. (Roxane Countercl. ¶¶ 106-108, 127-130.) Because of the substantial overlap between Section 1 "agreement" claims and Section 2 conspiracy claims, Roxane will primarily address Actelion's arguments for dismissal through the lens of Section 1 precedent. However, for the same reasons that Roxane has adequately pled the existence of agreements that unreasonably restrain trade in violation of Section 1, Roxane has

Actelion offers only two arguments in support of its Motion to Dismiss these claims: (1) Roxane "cannot show that the distribution arrangements for Tracleer and Zavesca are illegal," (Actelion Mot. at 22), and (2) because "Actelion and its distributors are not independent sources of economic power," (Actelion Mot. at 23-24), agreements between them are subject to no antitrust scrutiny whatsoever. Both arguments demonstrate severe misunderstandings of well-settled antitrust doctrine, and neither justifies a dismissal of Roxane's counterclaims.

A. Actelion's Assertion That Distribution Agreements Are Not Inherently Unlawful Does Not Immunize Those Agreements From Antitrust Scrutiny

The gravamen of Roxane's Section 1 claims is that Actelion has intentionally entered into overly-restrictive distribution agreements with distributors of Tracleer and Zavesca in order to, and with the effect of, unreasonably restraining trade by preventing potential generic competitors from obtaining these products through normal distribution channels. (Roxane Countercl. ¶¶ 178-202.) Actelion argues that since "proof of an illegal agreement" is an essential element of a Section 1 claim, Roxane's claims fail because Actelion's agreements with its distributors are not illegal. (Actelion Mot. at 22.) In other words, Actelion argues that the agreements in question are not unlawful because they are not unlawful. (*See id.*) But this circular reasoning merely begs the question – it does not even begin to attempt to answer it.

There is no requirement in antitrust law that a plaintiff challenging a putatively unlawful agreement show that the mere existence of such an agreement makes it unlawful on its face. Contracts setting the prices of goods and services are not in and of themselves "illegal," but when used to facilitate a price-fixing cartel, they violate Section 1 of the Sherman Act. *United*

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also adequately pled a conspiracy to monopolize under Section 2. *See, e.g.*, *West Penn*, 627 F.3d at 99 n.7.

States v. Socony-Vacuum Oil Co., 310 U.S. 150, 218 (1940). Nor are agreements setting professional standards for dentists inherently "illegal," but when they limit "the package of services offered to customers," and have no "countervailing procompetitive virtue," they too violate Section 1. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 459 (1986). Collectively marketing intellectual property may be legal and "perfectly sensible" in some cases, but it "is still concerted activity under the Sherman Act that is subject to § 1 analysis." *Am. Needle, Inc. v. NFL*, 130 S. Ct. 2201, 2216 (2010).

Actelion appears to be claiming that because its distribution agreements are not per se illegal, the Court's inquiry is at an end. But this argument simply ignores the requisite analysis applied in Section 1 cases, where only "limited categories" of agreements are considered facially unlawful, *Toledo Mack Sales & Service, Inc. v. Mack Trucks, Inc.*, 530 F.3d 204, 224-25 (3d Cir. 2008), and most are evaluated under the "fact intensive" rule-of-reason test in order to evaluate whether they unreasonably restrain trade. *West Penn*, 627 F.3d at 99. Roxane's allegations are more than sufficient to survive a motion to dismiss under the pleading standards applicable to rule of reason claims. To plead an actionable agreement in restraint of trade under a rule-of-reason theory, a claimant must allege: "(1) that the defendants contracted, combined, or conspired among each other; (2) that the combination or conspiracy produced adverse, anti-competitive effects within relevant product and geographic markets; (3) that the objects of and the conduct pursuant to that contract or conspiracy were illegal; and (4) that the plaintiffs were injured as a proximate result of that conspiracy." *Franco v. Conn. Gen. Life. Ins. Co.*, 818 F.

Supp. 2d 792, 834 (D.N.J. 2011). Roxane has adequately alleged each element of this test. (*See* Roxane Countercl. ¶¶ 51, 61, 67, 69, 74, 77-80, 81-84, 95-99, 181-188, 192-201.)

Actelion also mentions in passing that "Actelion's distribution arrangements . . . are currently required by the FDA for purposes of patient safety." (Actelion Mot. at 22 (emphasis removed).) But Actelion cannot claim protection from antitrust liability based on FDA regulatory provisions, since there is no "clear repugnancy between the antitrust laws and the regulatory system." *United States v. Nat'l Ass'n of Sec. Dealers, Inc.*, 422 U.S. 694, 719 (1975). In fact, in this particular case, the two statutory schemes are completely consistent. Just as the Sherman Act prohibits "***every contract*** . . . in restraint of trade," 15 U.S.C. § 1 (emphasis added), the Food and Drug Administration Amendments Act ("FDAAA") prohibits these particular agreements, declaring that: "No holder of an approved covered application shall use ***any element*** to assure safe use required by [FDA] under [FDC Act § 505-1(f)] to ***block or delay approval*** of an application under Section 505(b)(2) or (j) [an ANDA]." FDC Act § 505-1(f)(8) (emphasis added). The Sherman Act, the FDAAA, and the Hatch-Waxman Act are working toward the same goal: greater competition and easier generic entry. Actelion's assertion that it is "required" to "block or delay" generic entry, FDC Act § 505-1(f)(8), flies in the face of this "anti-gaming" provision, designed to prevent this exact behavior.[21]

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[21] Actelion's attempt to invoke its REMS program is further undercut by the FDA's interpretation of the statutory scheme. The FDA has ***never*** exercised any claimed authority to prohibit a brand-name company subject to a REMS program from providing bioequivalence samples to a potential generic applicant. The FDA has in fact explicitly stated the opposite – that it will not take any enforcement action against brand-name manufacturers that agree to provide samples to a generic applicant that gives adequate assurances of safety. (*See* Roxane Countercl. ¶ 36.)

Furthermore, given the limited purpose for which such samples would be used – bioequivalence testing using FDA-approved safety protocols – any purported "patient safety" concern (Actelion Mot. at 22), is disingenuous and plainly pretextual. This is particularly so where Actelion has a long history of providing Tracleer and Zavesca samples for clinical testing purposes to brand-name manufacturers and research hospitals. (*See* Roxane Countercl. ¶¶ 86-90.) Actelion's failure to respond to these allegations of differential treatment between brand and generic manufacturers speaks volumes about the legitimacy of this purported "patient safety" concern. And of course, the fact that prescription drugs can have serious side-effects does not insulate Actelion's anticompetitive behavior: "Exceptions to the Sherman Act for potentially dangerous goods and services would be tantamount to a repeal of the statute." *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978); *see also United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993) ("A restraint on competition cannot be justified solely on the basis of social welfare concerns.").

In sum, Actelion simply cannot use its REMS program as a justification for its anticompetitive conduct. Actelion is not "required" by the FDA to extend its monopolies well beyond patent expiration through use of the REMS program Actelion itself drafts and enforces. (*See* Roxane Countercl. ¶ 34.) Moreover, any legitimate safety concerns could easily be addressed by tailoring Actelion's extremely restrictive agreements more narrowly. For example, Actelion could permit its wholesalers to sell bioequivalence samples to licensed generic manufacturers or to research organizations that provide adequate assurances of safety. Instead, Actelion asserts the "right" to prevent all generic manufacturers from ever obtaining any

bioequivalence samples, *directly or indirectly*, under any circumstances, in any quantity, at any time. Whatever legitimate reasons there may be for some limitations on distribution, they do not stretch this far. *See Brown*, 5 F.3d at 679 ("To determine if a restraint is reasonably necessary, courts must examine first whether the restraint furthers the legitimate objectives, and then whether comparable benefits could be achieved through a substantially less restrictive alternative."). These arguments apply even more strongly to Actelion's restrictive distribution agreements for Zavesca, which is not subject to a formal REMS program at all. (*See* Roxane Countercl. ¶ 61.)

B. Vertical Agreements Between Manufacturers And Distributors Are Not Immune From Antitrust Scrutiny

Actelion's final argument is that because "Actelion and its distributors are not independent sources of economic power, or independent sources of access to Tracleer and Zavesca," they are "not legally capable of conspiring for antitrust purposes." (Actelion Mot. at 23.) This argument fails for two simple reasons: (1) no federal court has ever issued such a holding, and (2) adopting such a rule would require this Court to ignore controlling Supreme Court and Third Circuit decisions that hold precisely the opposite.

Actelion offers three citations to support its argument. The first is to *Copperweld Corp. v. Independence Tube Corp.*, which stands for the proposition that a corporation "and its wholly owned subsidiary . . . are incapable of conspiring with each other for purposes of § 1 of the Sherman Act." 467 U.S. 752, 777 (1984). Actelion's agreements with wholesalers, distributors, and pharmacies do not fit within the *Copperweld* exception, since those entities are not wholly-

owned subsidiaries of Actelion. Indeed, those distribution partners are not subsidiaries at all. Thus, *Copperweld* does not remove Actelion's distribution agreements from antitrust scrutiny.

Actelion also cites to two decisions from other districts, *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2550835 (D. Del. June 10, 2011), and *Levi Case Co. v. ATS Products, Inc.*, 788 F. Supp. 428, 430 (N.D. Cal. 1992). Both of those cases stand for the narrow proposition that a patent owner and its exclusive licensee are incapable of conspiring with each other under the Sherman Act. *See Shionogi*, 2011 WL 2550835, at *5 (citing *Levi Case*, 788 F. Supp. at 431-32). Again, these cases are inapposite since Actelion's distribution agreements are not licensing agreements between a patent owner and its exclusive licensee. There is a "complete unity of interest," *Shionogi*, 2011 WL 2550835, at *5 (quoting *Copperweld*, 467 U.S. at 771), between a patent owner and its sole, exclusive licensee that simply does not exist with respect to Actelion's relationship with its multiple and unaffiliated distribution partners. Even if these extensions of *Copperweld* were appropriate, they do not apply to the facts of this case.

Since *Copperweld* does not apply, Actelion essentially asks this court to be the first one to hold that vertical agreements between a manufacturer and a distributor are ***subject to no antitrust scrutiny whatsoever***. This would be nothing short of an antitrust revolution. The most recent Supreme Court decision rejecting this approach is *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007). *Leegin* holds that it can be "illegal under § 1 of the Sherman Act . . . for a manufacturer to agree with its distributor to set the minimum price the distributor can charge for the manufacturer's goods," but such "vertical price restraints are to be judged by the rule of reason." 551 U.S. at 881-82. *Leegin* instructed the lower courts to apply the rule of

reason to all vertical agreements between manufacturers and distributors, so that courts can "distinguish[] between restraints with anticompetitive effects that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." *Id.* at 886. The fact that the leather belt distributors in *Leegin* were not "potential independent sources," of leather belts (Actelion Mot. at 24), played no role in the analysis.

Indeed, a long history of Supreme Court authority confirms that vertical agreements between a manufacturer and a distributor *are* subject to rule-of-reason scrutiny, and thus violate the Sherman Act if they are unreasonably anticompetitive. *See, e.g.*, *State Oil Co. v. Khan*, 522 U.S. 3 (1997) (vertical maximum price-fixing agreement between oil company and gas station subject to rule of reason analysis); *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 37 (1977) (applying rule of reason to "[f]ranchise agreements between manufacturers and retailers" that "include[d] provisions barring the retailers from selling franchised products from locations other than those specified in the agreements"); *see also Klor's Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207 (1959) (boycott accomplished via agreement and conspiracy between "manufacturers, distributors, and a retailer" violates sections 1 and 2 of the Sherman Act). The Third Circuit has applied these principles without controversy. *Toledo Mack*, 530 F.3d at 224-25 ("In contrast to horizontal price-fixing agreements between entities at the same level of a product's distribution chain, the legality of a vertical agreement that imposes a restriction on the dealer's ability to sell the manufacturer's product is governed by the rule of reason.") (citing *Leegin*, 551 U.S. at 907). Actelion ***does not cite to a single decision*** holding that vertical

agreements between a manufacturer and a distributor are wholly exempt from antitrust scrutiny for this reason alone. Nor could they – this is simply not the law.

III. COUNTERCLAIM PLAINTIFFS STATE A CLAIM FOR A VIOLATION OF NEW JERSEY'S STATE ANTITRUST LAW

For the same reasons articulated in Sections I and II, above, Counterclaim Plaintiffs have also stated claims under New Jersey's antitrust laws. New Jersey's Antitrust Act explicitly provides that interpretations of the federal antitrust laws should be followed so as to "effectuate, insofar as practicable, a uniformity in the laws." N.J. Stat. Ann. § 56:9-18; *see also TransWeb, LLC v. 3M Innovative Props. Co.*, No. 10-4413, 2011 WL 2181189, at *20 (D.N.J. June 1, 2011) ("Because New Jersey's antitrust statutes are construed in harmony with federal antitrust statues, the Court need not separately analyze the state law claims."). Actelion's Motion to Dismiss these counts should also be denied.

IV. COUNTERCLAIM PLAINTIFFS STATE A CLAIM FOR TORTIOUS INTERFERENCE WITH PROSPECTIVE BUSINESS RELATIONS

Counterclaim Plaintiffs allege that Actelion's anticompetitive conduct constitutes tortious interference with prospective business relations and economic advantage under New Jersey common law. (Roxane Countercl. ¶¶ 216-229; Apotex Countercl. ¶¶ 90-95; Actavis Countercl. ¶¶ 73-80.) Actelion correctly identifies the relevant elements of a properly-pled tortious interference claim, which are: (1) a reasonable expectation of economic benefit or advantage; (2) intentional interference therewith by the defendant without valid justification, i.e., with malice; (3) loss of a prospective gain; and (4) damages. (Actelion Mot. at 24-25 (citing *Syncsort, Inc. v. Innovative Routines Int'l, Inc.*, No, 04-cv-3623, 2008 WL 1925304, at *19 (D.N.J. Apr. 30,

2008))); *see also Platinum Mgmt., Inc. v. Dahms*, 666 A.2d 1028, 1043-33 (N.J. Super. Ct. Law Div. 1995).

Actelion challenges the adequacy of Counterclaim Plaintiffs' pleadings only with respect to the malice element, asserting that its interference with Counterclaim Plaintiffs' potential economic gains was per se justified because it had a lawful right to prevent Counterclaim Plaintiffs from obtaining samples of its drug products. (Actelion Mot. at 25.) But as Counterclaim Plaintiffs have explained at length, Actelion's multi-pronged efforts to unlawfully prevent generic competition are not protected by its claimed right to refuse to deal. *See* Part I, *supra*. Similarly, nothing in the applicable statutory framework requires Actelion to prohibit its distributors from selling Tracleer or Zavesca to Counterclaim Plaintiffs; rather, the law is clear that a REMS program or other safety measures cannot be used as a pretext for preventing generic entry into the marketplace. 21 U.S.C. § 355-1(f)(8). Thus, Actelion's argument for dismissal of Counterclaim Plaintiffs' tortious interference claims fails for the same reason its Motion fails with respect to Counterclaim Plaintiffs' claims brought under Section 2 of the Sherman Act.

Moreover, courts in New Jersey and this district have repeatedly recognized that the presence of malice – or, put another way, lack of a valid business justification – is a fact-intensive inquiry that focuses on both the ***motive*** for the interferer's conduct and the ***means*** by which the interference is accomplished. *HowMedica Osteonics Corp. v. Zimmer, Inc.*, No. 11-1857, 2012 WL 5554543, at *12 (D.N.J. Nov. 14, 2012) (denying defendant's summary judgment motion premised on a valid business justification because "a defendant claiming a business-related excuse must justify not only its motive and purpose, but also the means used")

(quoting *Lamorte Burns Co. v. Walters*, 770 A.2d 1158, 1171 (N.J. 2001)); *Dahms*, 666 A.2d at 1043 ("The question of 'malice,' or 'improper means' is factual, to be determined on a case-by-case basis."). In assessing whether a proffered justification is valid, New Jersey courts employ an eight-factor balancing test derived from the Restatement (Second) of Torts § 767. *MB Imports, Inc. v. T&M Imports*, LLC, No. 10-3445, 2012 WL 5986454, at *9 (D.N.J. Nov. 28, 2012).[22] Actelion's Motion does not even attempt to address the application of this test to Counterclaim Plaintiffs' allegations – a tacit admission that such a fact-specific examination into its motivations cannot be accomplished via a motion to dismiss or judgment on the pleadings. *See Alston v. Countrywide Fin. Corp.*, 585 F.3d 753, 758 (3d Cir. 2009) (in considering a motion to dismiss under Rule 12(b)(6), the court must accept as true all of the plaintiff's factual allegations and construe the complaint in a light most favorable to plaintiff); *Inst. for Scientific Info*, 931 F.2d at 1005 (a Rule 12(c) motion requires the movant to demonstrate that there are no material issues of fact).

In any event, Counterclaim Plaintiffs allege sufficient facts to plausibly show that Actelion is *motivated* by a bare desire to suppress competition and that it has used improper *means* to accomplish this end. (*See, e.g.*, Roxane Countercl. ¶¶ 51-54, 61-63 (alleging that Actelion has entered into overly-restrictive distribution agreements with distributors in order to prevent potential competitors from purchasing its drugs), ¶¶ 67-85 (alleging that Actelion refuses

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[22] This test examines: "(a) the nature of the actor's conduct; (b) the actor's motive; (c) the interests of the other with which the actor's conduct interferes; (d) the interests sought to be advanced by the actor; (e) the social interests in protecting the freedom of action of the actor and the contractual interests of the other; (f) the proximity or remoteness of the actor's conduct to the interference and (g) the relations between the parties." *MB Imports*, 2012 WL 5986454, at *9.

to sell its products to Counterclaim Plaintiffs at market price and that its reasons for refusing to do so are mere pretext), ¶¶ 85-90 (alleging that Actelion provides its products to various entities to conduct studies but has refused to allow Counterclaim Plaintiffs similar access despite assurances of compliance with safety protocols).)

Such allegations are more than sufficient to withstand a Rule 12(b)(6) motion to dismiss because under New Jersey law even a legally-protected right to interfere must be asserted in good faith and through appropriate means. *Brown & Brown, Inc. v. Cola*, No. 10-3898, 2010 WL 5258067, at *7 (E.D. Pa. Dec. 22, 2010) (refusing to dismiss a tortious interference claim based on defendant's claimed right to enforce a non-compete agreement because "a party relying on such a claim must prove both that the restrictive covenant is valid and the party used proper means to protect its interest") (applying New Jersey law). Accordingly, Actelion's Motion to Dismiss Counterclaim Plaintiffs' tortious interference claims must be denied.

CONCLUSION

For the foregoing reasons, Actelion has failed to carry its burden to show that its dispositive motions seeking extraordinary relief should be granted. Actelion's motion for judgment on the pleadings and its motion to dismiss Counterclaim Plaintiffs' complaints must be denied.

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