Beth S. Rose
Charles J. Falletta
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102
Telephone: (973) 643-7000
brose@sillscummis.com
cfalletta@sillscummis.com

-and-

Of Counsel:
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
Telephone: (202) 879-5000

Attorneys for Defendant Roxane Laboratories, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. AND ACTELION CLINICAL RESEARCH, INC.	Civil Action No.: 12-05743-NLH-AMD
	Honorable Noel L. Hillman
Plaintiffs and Counterclaim Defendants,	*Document electronically filed.*
v.	**ROXANE LABORATORIES, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIM COMPLAINT**
APOTEX, INC., APOTEX CORP., and ROXANE LABORATORIES, INC.,	
Defendants and Counterclaim Plaintiffs.	**JURY TRIAL DEMANDED**

Defendant and Counterclaim Plaintiff Roxane Laboratories, Inc. ("Roxane") answers the declaratory judgment complaint of and brings this action against plaintiffs and counterclaim defendants Actelion Pharmaceuticals Ltd. and Actelion Clinical Research, Inc. (collectively

"Actelion," "plaintiffs," or "counterclaim defendants") alleging anticompetitive conduct in blocking the potential marketing of lower-cost generic versions of Actelion products Tracleer and Zavesca.

Roxane brings its claims to facilitate competition in the markets for Tracleer and Zavesca, to prevent further injury to Roxane, and to receive treble damages for the harms inflicted upon it by Actelion. Roxane seeks this relief under Sections 1 and 2 of the Sherman Act and under state law for harm resulting from Actelion's anticompetitive conduct.

ANSWER

Roxane answers Actelion's complaint as follows:

1. This action concerns the fundamental right of a business to choose for itself with whom to deal and to whom to supply its products. Apotex and Roxane are seeking to force Actelion to supply them with product, turning well-settled law, not to mention basic free-market principles, on their head. Moreover, Apotex's and Roxane's demands would also require Actelion to violate its regulatory obligations. Actelion brings this case under 28 U.S.C. §§ 2201 and 2202 seeking a declaration of rights.

Roxane admits that Actelion purports to bring a declaratory judgment action pursuant to the Declaratory Judgment Act as cited, but denies that Actelion has met the requirements for bringing a declaratory judgment action. The remaining allegations of Paragraph 1 state legal conclusions to which no response is required. To the extent the remaining allegations of Paragraph 1 are interpreted as requiring a response, Roxane denies them.

2. APL obtained approval from the Food and Drug Administration ("FDA") of its New Drug Application ("NDA") for a pharmaceutical product, Tracleer. Because of potentially serious side effects associated with Tracleer, the FDA's approval was subject to Actelion's implementation of and compliance with a Risk Evaluation and Mitigation Strategy ("REMS"). The REMS places significant limitations on the sale and distribution of Tracleer, described more fully below.

Roxane admits that Tracleer is subject to a REMS program, and that Actelion places restrictions on the sale and distribution of Tracleer. Roxane lacks knowledge or information

sufficient to form a belief about the truth of the remaining allegations of Paragraph 2 and therefore denies them.

3. Apotex and Roxane have demanded samples of Tracleer from Actelion so that they can develop competing generic products. Actelion has not supplied Tracleer to Apotex or Roxane. Apotex became increasingly threatening in its demands for samples, including threatening to seek the extraordinary relief of a mandatory injunction to force Actelion to sell samples to Apotex, and treble damages against Actelion unless Actelion acquiesces and supplies Tracleer to Apotex. Roxane, too, stated that it will pursue antitrust and related claims against Actelion unless its demands for Tracleer are met.

Roxane admits that Actelion has refused to sell Tracleer samples to Roxane, despite offers to pay Actelion their full market price. Several of the allegations of Paragraph 3 are not directed toward Roxane, so no response is required. To the extent those allegations are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of those allegations, and therefore denies them. Roxane denies the remaining allegations of Paragraph 3.

4. In short, the relief that Apotex and Roxane have threatened to seek against Actelion would be in direct contravention of not only the REMS for Tracleer, but also of the well settled legal and commercial principle that companies have the right to choose with whom they will do business and to whom they will sell their products. Indeed, as explained below, Congress has *twice* explicitly rejected the very thing Apotex and Roxane are demanding here—i.e., creating a legal obligation that forces a branded company such as Actelion to supply a drug product covered by a REMS to a potential generic competitor. Actelion therefore seeks a judgment by this Court determining and declaring that Actelion has no duty to deal with Apotex or Roxane and it is under no obligation to supply Tracleer to Apotex or Roxane.

Roxane admits that Actelion purports to bring a declaratory judgment action, but denies that Actelion has met the requirements for bringing a declaratory judgment action. The remaining allegations of Paragraph 4 are legal conclusions to which no answer is required. To the extent the remaining allegations of Paragraph 4 are interpreted as requiring a response, Roxane denies them.

PARTIES

5. Actelion Pharmaceuticals Ltd. ("APL") is a pharmaceutical company with its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland. APL focuses on the discovery, development, and commercialization of innovative treatments to serve critical, unmet medical needs.

Roxane admits that Actelion Pharmaceuticals Ltd. is a pharmaceutical company with its principal place of business at the address cited. Roxane lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 5 and therefore denies them.

6. Actelion Clinical Research, Inc. ("ACR") is a Delaware corporation with its principal place of business at 1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ 08002. ACR is an affiliate of APL and manages the Tracleer NDA and Tracleer REMS in the United States as agent for APL.

Roxane admits that Actelion Clinical Research, Inc. is a Delaware corporation with its principal place of business at the address cited. Roxane lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 6 and therefore denies them.

7. Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9. Upon information and belief, Apotex Inc. is in the business of making and selling generic drug products.

The allegations of Paragraph 7 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 7 are interpreted as requiring a response, Roxane admits them.

8. Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Upon information and belief, Apotex Corp. is in the business of making and selling generic drug products.

The allegations of Paragraph 8 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 8 are interpreted as requiring a response, Roxane admits them.

9. Roxane is a Nevada corporation with its principal place of business at 1809 Wilson Road, Columbus, Ohio, 43228. Upon information and belief, Roxane is in the business of making and selling generic drugs.

Roxane admits the allegations of Paragraph 9.

JURISDICTION AND VENUE

10. This case is brought under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, and raises issues under Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, Section 2 of the Sherman Antitrust Act, 15 U.S.C. §2, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355-1. This Court therefore has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

Roxane admits that Actelion purports to bring a declaratory judgment action pursuant to the Declaratory Judgment Act as cited, but denies that Actelion has met the requirements for bringing a declaratory judgment action. The remaining allegations of Paragraph 10 state legal conclusions to which no response is required. To the extent the remaining allegations of Paragraph 10 are interpreted as requiring a response, Roxane admits that this Court has subject matter jurisdiction over this dispute.

11. This Court has personal jurisdiction over Apotex Inc. under N.J. Court R. 4:4-4. Apotex Inc. has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Apotex Inc. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use, offer to sell, or sell pharmaceutical products throughout the State of New Jersey. In addition, Apotex Inc. has purposefully availed itself of the laws of this forum by instituting legal proceedings in this jurisdiction.

The allegations of Paragraph 11 are not directed toward Roxane, and state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 11 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 11 and therefore denies them.

12. This Court has personal jurisdiction over Apotex Corp. under N.J. Court R. 4:4-4. Apotex Corp. has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Apotex Corp. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use, offer to sell, or sell pharmaceutical products throughout the State of

New Jersey. In addition, Apotex Corp. has purposefully availed itself of the laws of this forum by instituting legal proceedings in this jurisdiction.

The allegations of Paragraph 12 are not directed toward Roxane, and state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 12 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 12 and therefore denies them.

13. This Court has personal jurisdiction over Roxane under N.J. Court R. 4:4-4. Roxane has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Roxane has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use, offer to sell, or sell pharmaceutical products throughout the State of New Jersey. Upon information and belief, Roxane is registered to do business in New Jersey and has a registered agent in New Jersey. In addition, Roxane has previously submitted to the jurisdiction of this Court.

The allegations of Paragraph 13 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 13 are interpreted as requiring a response, Roxane admits them.

14. Venue is appropriate in this district pursuant to 28 U.S.C. § 1391(c) because Apotex Inc., Apotex Corp., and Roxane transact business and can be found in this district. Moreover, management of the Tracleer NDA and Tracleer REMS is performed in this district by ACR from its principal place of business in Cherry Hill, New Jersey.

Roxane admits to transacting business in this district, and that venue for this dispute is appropriate in this district. Roxane lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 14 and therefore denies them.

FACTUAL BACKGROUND

15. Actelion develops and commercializes innovative treatments to serve critical, unmet medical needs. Actelion, through a U.S. affiliate, markets in the United States a treatment for pulmonary arterial hypertension ("PAH"), a relatively rare, serious progressive disorder characterized by abnormally high blood pressure in the arteries of the lungs, making the right side of the heart work harder than is normal. APL submitted to the FDA a New Drug Application ("NDA") for its PAH treatment. Following FDA approval, Actelion launched its medicine under the proprietary name Tracleer. ACR manages the NDA and acts as APL's agent in all NDA-related issues with the FDA.

Roxane admits that Actelion sells a drug product under the proprietary name Tracleer, and that Tracleer is used to treat pulmonary arterial hypertension. Roxane lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 15 and therefore denies them.

16. Tracleer is a patented drug covered by United States Patent No. 5,292,740 (the "'740 Patent"). APL is the exclusive licensee under the '740 Patent.

Roxane admits that Tracleer purports to be subject to a United States Patent as cited, but Roxane lacks knowledge or information sufficient to form a belief about the validity of such patent, and therefore denies its validity. Roxane lacks knowledge or information sufficient to form a belief about the validity of the remaining allegations of Paragraph 16 and therefore denies them.

17. As reflected on its label, Tracleer has the potential to cause very serious side effects. In particular, Tracleer can cause serious liver damage, including in rare cases liver failure, as well as serious birth defects if taken during pregnancy. As a result of these risks, in order to obtain FDA approval for Tracleer, the FDA required APL to adopt a Risk Evaluation and Mitigation Strategy ("REMS"), a strategy to manage a known or potential serious risk associated with a drug or biological product. ACR manages the REMS program for Tracleer and acts as APL's agent in all REMS-related issues with the FDA.

Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 17 and therefore denies them.

18. Tracleer's FDA-mandated and approved REMS program dictates that, among other things, Tracleer will only be dispensed through pharmacies, practitioners, and health care settings that are specially certified and bound by contract to follow a strict protocol to monitor and protect patient health. The protocol includes monthly follow-up with patients to ensure that liver function testing and pregnancy testing have been completed; that only a limited supply of Tracleer can be distributed at a time; that Tracleer can only be dispensed to patients who are enrolled in the REMS program; and that certain defined patient counseling is completed regularly. Actelion's distribution of Tracleer must, and does, comply in all respects with its FDA-mandated REMS program.

Roxane admits that the distribution of Tracleer is significantly restricted by means of agreements and contracts between Actelion and certain "specially certified" entities. Roxane

lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 18 and therefore denies them.

19. To fulfill its REMS obligations, Actelion works only with wholesale distributors which agree to comply with Tracleer's REMS. Pursuant to the REMS program, wholesalers can only sell Tracleer to those entities which are specially certified and bound by contract to follow the Tracleer REMS protocol. Wholesale distributors of Tracleer must, and do, comply with and effectively implement the REMS program.

Roxane admits that Actelion has entered into agreements and contracts with wholesale distributors of Tracleer which restrict the sales of Tracleer. Roxane lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 19 and therefore denies them.

20. Moreover, as a result of the potential side effects, Actelion has a legitimate interest in how Tracleer is used and administered to patients. Any harm caused as a result of the potential misuse of Tracleer during testing by a generic could have a significant impact on Actelion and Tracleer's reputation and standing in marketplace. This interest exists independent of the REMS.

Roxane denies the allegations of Paragraph 20.

21. On January 21, 2011, Actelion Pharmaceuticals US, Inc. ("APUS"), an affiliate of APL, received a letter from counsel for Apotex Inc. informing Actelion of Apotex's desire to file an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of Actelion's patented Tracleer drug product. Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness required in an NDA. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner) to the innovator drug product.

Roxane admits that generic drug applicants generally are required to demonstrate bioequivalence to a brand-name drug to obtain FDA approval to market a generic version of that drug. The remaining allegations of Paragraph 21 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 21 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 21, and therefore denies them.

22. In its January 21, 2011 letter, Apotex Inc. sought samples of Tracleer from APUS so that it could complete bioequivalency studies and submit an ANDA seeking FDA approval of a generic version of Actelion's Tracleer drug product. Although the request was directed to APUS, any samples would actually be supplied by APL.

The allegations of Paragraph 22 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 22 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 22, and therefore denies them.

23. When Actelion did not provide samples of Tracleer, Apotex Inc. sent additional letters repeating its demands for Tracleer samples and suggesting that Actelion is required by law to fulfill Apotex Inc.'s request.

The allegations of Paragraph 23 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 23 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 23, and therefore denies them.

24. More recently, Apotex Inc.'s counsel sent a letter on June 26, 2012 repeating Apotex Inc.'s demands. On July 2, 2012, counsel for Actelion responded, reminding Apotex of both the restrictions of Tracleer's REMS program and the well settled law that Actelion has the right to choose with whom it does business. Actelion declined to provide Apotex samples.

The allegations of Paragraph 24 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 24 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 24, and therefore denies them.

25. Counsel for Apotex Inc. responded on August 1, 2012, again demanding Tracleer samples and, this time, threatening litigation if its demands were not met. Enclosed with its letter was a draft complaint seeking, among other things, treble damages under the antitrust laws and an extraordinary mandatory injunction which, if granted, would force Actelion to provide samples to Apotex. Apotex's draft complaint alleged that Actelion is required to supply samples for the purpose of helping Apotex meet the bioequivalence testing requirements for its potential ANDA. Apotex asserted in the draft complaint that the patent-protected product Tracleer is an "essential facility."

The allegations of Paragraph 25 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 25 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 25, and therefore denies them.

26. On August 9, 2012, counsel for Actelion responded to Apotex Inc., reiterating Actelion's right to decide with whom it does business and its legal obligation to comply with the REMS program, which Apotex never addressed.

The allegations of Paragraph 26 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 26 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 26, and therefore denies them.

27. Apotex's counsel replied on August 17, 2012, stating that Apotex intended to make changes to its bioequivalence study protocol that the FDA recommended, including changes to comply with even the most basic training, patient education, and liver function testing procedures that Apotex initially omitted from its protocol. As far as Actelion is aware, Apotex has not yet made such changes. Apotex again threatened to file its antitrust complaint against Actelion if its demands were not met.

The allegations of Paragraph 27 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 27 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 27, and therefore denies them.

28. Actelion and Apotex attempted to resolve this dispute without the assistance of the Court, but have been unable to do so.

The allegations of Paragraph 28 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 28 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 28, and therefore denies them.

29. In early 2012, Roxane sent a letter to APUS demanding that Actelion sell it Tracleer tablets and indicating that Roxane was seeking samples for the purpose of filing an ANDA for a generic version of Tracleer.

Roxane admits that in early 2012, Roxane contacted Actelion to discuss the purchase of Tracleer tablets at their market price for the purpose of bioequivalence testing. Roxane denies the remaining allegations of Paragraph 29.

30. Actelion responded on February 10, 2012, declining to provide Roxane with Tracleer tablets and maintaining its right to choose with whom it does business.

Roxane admits that Actelion sent a letter to Roxane on February 10, 2012, declaring its intent not to provide Roxane with Tracleer tablets at their market price and refusing to do business with Roxane despite statutory prohibitions on using REMS to block or delay generics. Roxane denies the remaining allegations of Paragraph 30.

31. Counsel for Roxane again demanded Tracleer tablets by letter of August 1, 2012. The letter asserted that Actelion's denial of Roxane's demands and Actelion's acts to insure that its distributors follow the FDA-mandated REMS requirements were antitrust violations. Roxane threatened to "pursue all available options, including notifying the Federal Trade Commission and/or asserting antitrust and related claims against Actelion."

Roxane admits that counsel for Roxane sent a letter to Actelion on August 1, 2012, in which counsel for Roxane explained that Actelion's conduct violated the antitrust laws, which letter speaks for itself. Roxane denies the remaining allegations of Paragraph 31.

32. On August 9, 2012, counsel for Actelion responded, restating Actelion's right to make independent decisions regarding with whom it does business and how it structures its distribution system. The letter further reminded Roxane of Actelion's obligations to comply with strict distribution limitations under Tracleer's REMS, an issue Roxane never addressed.

Roxane admits that on August 9, 2012, counsel for Actelion responded to counsel for Roxane's letter of August 1, 2012, refusing to sell (or permit others to sell) samples to Roxane despite statutory prohibitions on using REMS to block or delay generics. Roxane denies the remaining allegations of Paragraph 32.

33. Actelion is under no duty or obligation to supply samples of Tracleer to Apotex or Roxane. There is no legal basis pursuant to which Apotex and Roxane can compel Actelion to sell Tracleer tablets. As an initial matter, their demands are inconsistent with the restrictions in the REMS for Tracleer. Because of Tracleer's potential for causing the deterioration of liver functioning and severe birth defects, the FDA, through the Tracleer REMS, requires Actelion to take specific steps to ensure the safety of patients. As described above, distribution of Tracleer is limited to pharmacies, practitioners, and health care settings that are specially certified and bound by contract to follow a strict protocol. Under the FDA-mandated REMS program, Actelion may not distribute Tracleer to Apotex, Roxane, or to any other entity that does not specifically qualify under Tracleer's REMS. *See* Food and Drug Amendments Act of 2007, 21 U.S.C. § 355-1 (the "REMS statute").

The allegations of Paragraph 33 state legal conclusions to which no answer is required. To the extent that the allegations of Paragraph 33 are interpreted as requiring a response, Roxane denies them.

34. Further, Actelion must ensure that any distribution through wholesalers is structured to comply with Tracleer's REMS. This requires that wholesalers follow the REMS program to the letter. Actelion's agreements with wholesalers requiring compliance with FDA-mandated restricted distribution are permissible under the antitrust laws and are justified to protect Actelion from liability relating to Tracleer's REMS. *See, e.g., Sports Ctr. Inc. v. Riddell, Inc.*, 673 F.2d 786, 791 (5th Cir. 1982).

Roxane admits that Actelion has agreements and contracts with wholesalers that restrict the sales of Tracleer. The remaining allegations of Paragraph 34 state legal conclusions to which no response is required. To the extent that the remaining allegations of Paragraph 34 are interpreted as requiring a response, Roxane denies them.

35. More fundamentally, even if sales of Tracleer were not restricted by the REMS to assure patient safety, it is well settled that Actelion, like any other company, has an independent right to choose with whom it deals. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko,* LLP, 540 U.S. 398, 408 (2004); *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (holding that nothing in the Sherman Act restricts a company's discretion as to parties with whom it will deal). As a corollary of this principle, Actelion also has the right *not to* deal with or assist a rival. *Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 375 (7th Cir. 1986). As a result, courts have consistently held that companies such as Actelion are under no duty to deal with a competitor.

The allegations of Paragraph 35 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 35 are interpreted as requiring a response, Roxane denies them.

36. When Congress enacted the REMS statute, it did not create an independent duty to supply drugs covered by a REMS program to potential generic manufacturers or abrogate the long-standing principle that a company can choose not to assist a rival. There is no provision in the REMS statute that the owner of a drug subject to a REMS program is required to provide samples of its drug upon the request of a potential competitor.

The allegations of Paragraph 36 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 36 are interpreted as requiring a response, Roxane denies them.

37. To the contrary, the suggestion of such a requirement was rejected by Congress when it enacted the REMS statute. Specifically, the House version of the REMS legislation contained language providing:

> **(6) BIOEQUIVALENCE TESTING - Notwithstanding any other provisions in this subsection, the holder of an approved application that is subject to distribution restrictions required under this subsection that limit the ability of a sponsor seeking approval of [an ANDA] to purchase on the open market a sufficient quantity of drug to conduct bioequivalence testing shall provide to such a sponsor a sufficient amount of drug to conduct bioequivalence testing if the sponsor seeking approval [of an ANDA] agrees to such restrictions on distribution as the Secretary finds necessary to assure safe use of the drug during bioequivalence testing; and (B) pays the holder of the approved application the fair market value of the drug purchased for bioequivalence testing.**

H.R. 2900, 110th Cong. § 901 (2007). This language was omitted from the final version of the Act, demonstrating that Congress did not impose on the drug innovator a duty to deal with a potential generic competitor. *See* 21 U.S.C. 355-1.

Roxane admits that the quoted language is in the legislative history, which speaks for itself. The remaining allegations of Paragraph 37 state legal conclusions to which no response is required. To the extent the remaining allegations of Paragraph 37 are interpreted as requiring a response, Roxane denies them.

38. Even more recently, similar language was again rejected from the Food and Drug Administration Safety and Innovation Act. Language in the Senate amendment proposed:

> **(k) DRUG DEVELOPMENT AND TESTING.— (1) In General.— Notwithstanding any other provision of law, if a drug is a covered drug, no elements to ensure safe use shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for the purpose of conducting testing necessary to support [an ANDA], if the Secretary has issued a written notice described in paragraph (2), and the eligible drug developer has agreed to comply with the terms of the notice.**

S. 3187, 112th Cong. § 1331 (May 24, 2012). This proposed language was not included in the final version of the bill, enacted on July 9, 2012.

Roxane admits that the quoted language is in the legislative history, which speaks for itself. Roxane denies the remaining allegations of Paragraph 38.

39. The right to choose with whom one does business is subject to only a few narrow exceptions. *See Trinko*, 540 U.S. at 408. No exception is applicable here.

The allegations of Paragraph 39 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 39 are interpreted as requiring a response, Roxane denies them.

40. One exception might arise where the parties have a history of dealing that is terminated for no legitimate business purpose. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985). The Supreme Court has held that even this exception is "at or near the outer boundary of [Sherman Act] § 2 liability." *Trinko*, 540 U.S. at 409.

The allegations of Paragraph 40 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 40 are interpreted as requiring a response, Roxane admits that Actelion has cited decisions, which decisions speak for themselves. Roxane denies the remaining allegations of Paragraph 40.

41. Actelion does not have a history of providing samples of Tracleer to Apotex or Roxane. In fact, it has never done so. Actelion's decision not to provide Tracleer samples stands on its own. Actelion has no affirmative obligation to assist Apotex or Roxane with

their efforts to develop generic drugs, particularly where the generics' testing may create risk for Actelion and the Tracleer brand.

Roxane admits that Actelion refuses to provide samples of Tracleer to Roxane or to permit Roxane to purchase from other distributors. The remaining allegations of Paragraph 41 are not directed toward Roxane, or state legal conclusions to which no response is required. To the extent that the remaining allegations of Paragraph 41 are interpreted as requiring a response, Roxane denies them.

42. Another potential exception to the right to choose with whom to deal, though of questionable validity, is the so-called "essential facilities" doctrine. That doctrine requires that a monopolist provide access to a facility if an alternative to the facility is utterly infeasible; it does not impose any duty to deal merely because a lack of access to a facility is inconvenient or more expensive. *Eatoni Ergonomics, Inc. v. Research in Motion Corp.,* No. 11-cv-5328, 2012 WL 2348443, at *9-10 (2d Cir. June 21, 2012). The validity of the essential facilities doctrine has been called into question by the Supreme Court. *See Trinko*, 540 U.S. at 410 ("[The] 'essential facilities' doctrine [was] crafted by some lower courts. . . . We have never recognized such a doctrine.").

The allegations of Paragraph 42 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 42 are interpreted as requiring a response, Roxane admits that the essential facilities doctrine imposes a legal duty to provide competitors access to essential facilities. Roxane denies the remaining allegations of Paragraph 42.

43. To the extent the essential facilities doctrine is still viable after *Trinko*, it is inapplicable here, where Apotex and Roxane are demanding samples of a patented product. Apotex and Roxane cannot use the essential facilities doctrine to subvert Actelion's patent rights by forcing it to supply Tracleer tablets. *See Eatoni*, 2012 WL 2348443, at *10 ("We agree with the district court that § 2 does not obligate [a company] to share its patented [] technology, from which [a company] derives the lawful power to exclude others' use.") (emphasis added); *Applera Corp. v. ML Research, Inc.*, 349 F. Supp. 2d 338, 348 (D. Conn. 2004) ("To find a patent an 'essential facility' to which [a company] must provide access would subvert the plain meaning and purpose of the Patent Act.").

The allegations of Paragraph 43 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 43 are interpreted as requiring a response, Roxane denies them.

44. Moreover, to qualify as an essential facility, access to alternatives must not be feasible. *Eatoni*, 2012 WL 2348443, at *9. But here, there are alternatives to obtaining Tracleer samples from Actelion if Apotex or Roxane intends to develop treatments for PAH. If Apotex or Roxane develops a treatment for PAH, that company can file an NDA, just as Actelion's parent company did for Tracleer, which does not require a demonstration of bioequivalence with any existing treatment. This option renders samples of Tracleer unnecessary.

The allegations of Paragraph 44 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 44 are interpreted as requiring a response, Roxane denies the allegations of Paragraph 44.

45. In addition, the essential facilities doctrine does not apply where there are legitimate regulatory and business justifications for declining access, as there are here with the Tracleer REMS program. *See Illinois ex rel. Burris v. Panhandle E. Pipe Line Co.*, 935 F.2d 1469 (7th Cir. 1991) (affirming district court's finding that defendant was motivated by regulatory concerns in denying access to "essential facility"); *So. Pac. Comm. Co. v. Am. Tel. & Tel. Co.*, 740 F.2d 980, 1009 (D.C. Cir. 1984) (affirming judgment for defendant where denials of access to "essential facilities" were based on defendant being an enterprise regulated under a "public interest" standard); *see also MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1137 (7th Cir. 1982) ("Ordinarily, antitrust liability should not be imposed when a firm acts in compliance with its regulatory obligations.").

The allegations of Paragraph 45 state legal conclusions to which no response is required. To the extent that the allegations of Paragraph 45 are interpreted as requiring a response, Roxane denies the allegations of Paragraph 45.

COUNT I
(Declaratory Relief)

46. Actelion incorporates by reference paragraphs 1 through 45 as if set forth fully above.

Roxane incorporates its answers to Paragraphs 1 through 45 as if set forth fully in response to Paragraph 46.

47. Apotex and Roxane have each repeatedly demanded from Actelion samples of Actelion's patent-protected product Tracleer for the purpose of bioequivalence testing to support the submission of ANDAs. Actelion has resisted their demands and has continued to assert its time-honored rights to choose the parties with which it deals. Moreover, Actelion has a legal obligation to comply with the restricted distribution scheme of its

REMS program, which does not allow it to provide samples of Tracleer to Apotex or Roxane.

Roxane admits that it has attempted to purchase samples of Actelion's Tracleer product at their market price, and that Actelion has refused to sell, or to permit others to sell, Tracleer tablets to Roxane. The remaining allegations of Paragraph 47 state legal conclusions to which no response is required. To the extent that the remaining allegations of Paragraph 47 are interpreted as requiring a response, Roxane denies them.

48. Because Actelion has maintained its rights, Apotex has now threatened antitrust litigation, seeking treble damages and the extraordinary remedy of a mandatory injunction.

The allegations of Paragraph 48 are not directed toward Roxane, so no response is required. To the extent the allegations of Paragraph 48 are interpreted as requiring a response, Roxane lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 48, and therefore denies them.

49. Roxane has similarly made threats to pursue antitrust litigation against Actelion.

Roxane admits that Roxane's counsel sent a letter to Actelion on August 1, 2012, in which Actelion declared its intent to consider all options available to remedy Actelion's antitrust violations, including, *inter alia*, coming to a mutually beneficial negotiated solution or asserting antitrust claims against Actelion. Roxane denies the remaining allegations of Paragraph 49.

50. Accordingly, there is currently an actual controversy between Actelion and Apotex and between Actelion and Roxane concerning Actelion's right to decline Apotex's and Roxane's demands for samples of Tracleer.

Roxane admits that there is an actual controversy between Actelion and Roxane concerning Actelion's refusal to sell (or to permit others to sell) Tracleer tablets to Roxane despite Roxane's offer to pay their market price. The remaining allegations in Paragraph 50 are legal conclusions, or are not directed toward Roxane, so no response is required. To the extent

the remaining allegations in Paragraph 50 are interpreted as requiring a response, Roxane denies them.

51. Pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, Actelion is entitled to a declaration of rights whereby it is declared that Actelion has no duty or obligation to provide Tracleer tablets to Apotex or Roxane.

Roxane admits that Actelion purports to bring a declaratory judgment action pursuant to the Declaratory Judgment Act as cited, but denies that Actelion has met the requirements for bringing a declaratory judgment action. The remaining allegations of Paragraph 51 are legal conclusions to which no response is required. To the extent the remaining allegations of Paragraph 51 are interpreted as requiring a response, Roxane denies them.

AFFIRMATIVE DEFENSES

Without assuming any burdens that it would not otherwise bear, Roxane asserts the following affirmative defenses:

First Affirmative Defense

1. Plaintiffs' claims are barred, in whole or in part, for failure to state a claim upon which relief can be granted.

Second Affirmative Defense

2. Plaintiffs' claims are barred, in whole or in part, because plaintiffs lack standing to assert their claims.

Third Affirmative Defense

3. Plaintiffs' claims are barred, in whole or in part, because plaintiffs have not suffered injury proximately caused by any conduct of Roxane and/or have not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent.

Fourth Affirmative Defense

4. Plaintiffs have not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit.

Fifth Affirmative Defense

5. Plaintiffs' claims are barred, in whole or in part, because they have failed to properly plead a claim under the Declaratory Judgment Act.

Sixth Affirmative Defense

6. Any and all of Roxane's actions alleged by plaintiffs were lawful, justified, and pro-competitive.

Seventh Affirmative Defense

7. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver, estoppel, unclean hands, and/or laches.

Eighth Affirmative Defense

8. Plaintiffs' claims are barred, in whole or in part, because plaintiffs' alleged injuries were not legally or proximately caused by any acts or omissions of Roxane and/or were caused, if at all, by the conduct of plaintiffs and/or third parties and/or by the operation of a statutory and/or regulatory scheme.

Ninth Affirmative Defense

9. Plaintiffs have failed to state a legal basis for their claims.

Tenth Affirmative Defense

10. Plaintiffs' claims are barred, in whole or in part, because the acts or omissions of Roxane are protected under FDA and other law.

Eleventh Affirmative Defense

11. Plaintiffs' claims are barred by United States FDA laws.

Twelfth Affirmative Defense

12. Roxane adopts by reference any additional, applicable defense pleaded by the other defendants in this matter.

Roxane reserves the right to amend this Answer or to assert other defenses as this action proceeds. Based on all the foregoing as well as other grounds, Roxane denies that plaintiffs are entitled to any relief whatsoever.

* * * * * * * *

COUNTERCLAIMS OF ROXANE AGAINST ACTELION

Counterclaim Plaintiff Roxane Laboratories, Inc. ("Roxane") brings this action against counterclaim defendants Actelion Pharmaceuticals Ltd. and Actelion Clinical Research, Inc. (collectively "Actelion" or "counterclaim defendants") alleging anti-competitive conduct in blocking the potential marketing of lower-cost generic versions of two branded drugs manufactured and sold by Actelion—conduct that has cost Roxane (and the patients who use these drugs) hundreds of millions of dollars. Roxane brings these claims to facilitate competition in the markets for bosentan (brand name Tracleer) and miglustat (brand name Zavesca), to prevent further injury to Roxane, and to receive treble damages for the harms inflicted upon it by Actelion. Roxane seeks this relief under Sections 1 and 2 of the Sherman Act and under state law for harm resulting from Actelion's anticompetitive conduct in the markets for bosentan and miglustat. Roxane alleges as follows on information and belief:

INTRODUCTION

1. This case seeks remedies to the illegal and anticompetitive conduct of Actelion which has prevented lower-cost generic competition from Roxane with respect to Actelion's two key products—Tracleer and Zavesca. With combined worldwide sales of nearly $1.4 billion in the first nine months of 2012 alone (which amounts to approximately 90% of Actelion's total sales during this period), the prospect of Roxane developing generic versions of Tracleer and Zavesca was a major threat to Actelion.

2. Faced with this threat to its monopolies, Actelion engaged in a scheme to prevent Roxane from obtaining the FDA-mandated drug samples necessary to develop Roxane's generic products, by prohibiting distributors to sell to Roxane and by refusing to sell to Roxane itself. Through its actions, Actelion has unlawfully prevented Roxane from developing generic versions of these drugs.

3. To date, Actelion has been able to block Roxane from developing lower-priced generic products to compete with Actelion's own products, which will unlawfully cost both Roxane as well as consumers hundreds of millions of dollars in sales and savings. Actelion's anticompetitive scheme to thwart generic competition denies patients the opportunity to purchase lower-cost generic versions of Tracleer and Zavesca, forcing customers to pay hundreds of millions of dollars more for these drugs than if Roxane were not unlawfully prevented from developing lower cost generic alternatives.

Nature of the Action

4. This is a civil antitrust action under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and state law, seeking treble damages arising out of Actelion's unlawful exclusion of Roxane from the markets for bosentan and miglustat. Bosentan is sold by Actelion under the brand name Tracleer. It is indicated for treatment of pulmonary arterial hypertension ("PAH"), a rare, chronic, life-threatening disorder that severely compromises the functions of the lungs and heart. Tracleer sales totaled over $1.2 billion worldwide in the first nine months of 2012. Miglustat is sold by Actelion under the brand name Zavesca. It is the first and only oral medication approved for the oral treatment of adult patients with mild to moderate type 1 Gaucher disease, and it may only be used in those patients for whom enzyme replacement therapy is unsuitable. Zavesca sales totaled over $67 million worldwide in the first nine months of 2012.

5. Currently, there are no generic alternatives for either Tracleer or Zavesca, and the capsules may cost critically ill patients thousands of dollars a month and tens of thousands of dollars per year.

6. Seeking to file an ANDA for FDA approval of a lower cost generic version of Tracleer and Zavesca, Roxane approached Actelion to purchase samples of both drugs at market price. Such samples are necessary to conduct the FDA-mandated bioequivalence studies before

seeking approval for prospective generic versions of these two branded drugs. Roxane approached Actelion directly, because after attempting to acquire samples from traditional wholesale distribution outlets, Roxane discovered that Tracleer and Zavesca are not available through normal distribution channels. To date, Actelion has refused Roxane's repeated requests for the purchase of such samples at market price and refused to permit distributors to sell directly to Roxane.

7. For most drug products, the generic applicant is able to obtain a sufficient amount of samples of the listed drug to conduct FDA-required bioequivalence testing (as well as retained samples) using normal distribution channels; for example, through drug product wholesalers. However, some drugs with heightened risk profiles may be covered by FDA's Risk Evaluation and Mitigation Strategy ("REMS"). Other drugs may be subject to a "restricted distribution" program, as adopted and implemented by the manufacturer.

8. A branded drug manufacturer like Actelion can prevent generic companies from acquiring the necessary samples to conduct bioequivalence studies of a REMS-restricted distribution drug product by implementing certain distribution restrictions that significantly limit drug product availability. In so doing, Actelion can prevent a prospective generic applicant from obtaining a sufficient quantity of the drug product to conduct required bioequivalence testing and for retained samples. Similar results can be achieved without a formal REMS program, through implementation of a manufacturer-imposed restricted distribution program.

9. Tracleer and Zavesca may cause birth defects if taken during pregnancy, so both drugs are either currently under a REMS program or otherwise subject to a restricted distribution program, as designed, implemented, and enforced by Actelion. Actelion limits the distribution of these drugs to wholesalers who enter into restrictive distribution agreements with Actelion. Hence, Roxane cannot purchase the required samples from wholesalers.

10. Actelion, however, refuses to allow Roxane to purchase samples either from Actelion or the wholesalers to whom Actelion distributes these drugs, citing their REMS or restricted distribution programs. Such conduct is nothing more than a scheme to block or delay

generic competition and is clearly unlawful under FDA's REMS anti-gaming provision, which expressly prohibits manufacturers such as Actelion from using REMS "to block or delay approval" of an ANDA application. *See* § 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act ("FDCA").

11. Actelion is unlawfully using REMS and restricted distribution agreements to stop Roxane from developing generic versions of Tracleer and Zavesca. In short, Actelion is using REMS and distribution restrictions as a pretext to block or delay generic competition in violation of FDA law, the antitrust laws, and state law.

PARTIES

12. Roxane Laboratories, Inc. is a corporation organized and existing under the laws of Nevada, with its principal place of business in Ohio.

13. On information and belief, Actelion Pharmaceuticals Ltd. ("APL") is a pharmaceutical company with its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland. APL focuses on the discovery, development, and commercialization of innovative treatments to serve unmet medical needs.

14. On information and belief, Actelion Clinical Research, Inc. ("ACR") is a Delaware corporation with its principal place of business at 1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ 08002. ACR is an affiliate of APL and manages the Tracleer NDA and Tracleer REMS in the United States as agent for APL.

JURISDICTION AND VENUE

15. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages, costs of suit, and reasonable attorney's fees for the injuries sustained by Roxane from Actelion's unlawful anticompetitive conduct in the markets for miglustat and bosentan.

16. This court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1367.

17. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. § 1391, because Actelion and its subsidiaries transact business within this District. Specifically, venue is proper as to Actelion and its affiliates because a substantial part of the events or omissions giving rise to these counterclaims occurred in this district. In addition, venue is proper to APL pursuant to 28 U.S.C. § 1391(c)(3), because APL is not resident in any judicial district, and therefore may be sued in any district; venue is proper as to ACR pursuant to 28 U.S.C. § 1391(b)(1), because ACR has its principal place of business within this district, and is subject to personal jurisdiction in this district.

STATUTORY AND INDUSTRY BACKGROUND

18. The Federal Food, Drug and Cosmetic Act ("FDCA") governs the approval of pharmaceuticals in the United States. Originally, its provisions applied equally to all drugs—branded and generic alike. A manufacturer seeking to market a new drug had to prove that it was safe and effective and that it was accurately and adequately labeled. Meeting these requirements involved lengthy and expensive clinical testing.

19. By the early 1980's, Congress recognized that millions of Americans were struggling to afford essential medications, and that state and federal authorities were likewise spending untold billions on expensive name-brand drugs. In order to alleviate the burden on consumers and governments, Congress decided to create an abbreviated process for the approval of generic versions of branded drugs.

20. The resulting "Hatch-Waxman Act," Pub. L. No. 98-417, 98 Stat. 1585 (Sept, 24, 1984) for the first time drew clear statutory distinctions between branded and generic drugs. After Hatch-Waxman, a manufacturer seeking approval for a new drug must still obtain FDA permission to conduct clinical trials to establish a drug's safety and efficacy. The company must

then file a New Drug Application (NDA) containing full reports of this testing so that FDA can make a substantive determination as to whether the drug is safe and effective for its intended use.

21. An applicant seeking approval of a generic equivalent, on the other hand, need not submit a full NDA based on independent clinical trials. Instead, generic applicants submit an Abbreviated New Drug Application (ANDA), the purpose of which is to show that the generic product is identical in all material respects to the previously-approved NDA product (known as the "reference listed drug," or RLD). In addition to showing that the labeling and warnings on the generic drug match those of the reference listed drug, an ANDA applicant also must conduct testing to demonstrate that the therapeutic ingredient in its drug is the "bioequivalent" of the name-brand drug. If an ANDA meets these criteria, the FDA relies on the manufacturer's studies to validate the safety and efficacy of the generic drug; the ANDA applicant need not repeat the lengthy and costly clinical trials process.

22. In order to perform the necessary bioequivalence testing between a proposed generic drug product and the RLD, the generic manufacturer needs to obtain samples of the RLD. FDA's regulations also require that the responsible party conducting bioequivalence testing to retain reserve samples of batches of the proposed generic and RLD used to conduct the tests, in sufficient quantity for FDA to perform each test required in the application or supplemental application five times.

23. For most drugs, a generic manufacturer can obtain adequate amounts of the RLD for bioequivalence testing and retained samples through normal distribution channels, such as through a wholesaler, simply by purchasing a sufficient quantity of the drug at market price.

24. As numerous courts and commentators have recognized, the Hatch-Waxman amendments, and in particular the ANDA process, had one overarching purpose—to "get generic drugs into the hands of patients at reasonable prices—fast." *Andrx. Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (3d Cir. 2012) ("The goal of the Hatch–Waxman Act is to increase the availability of low cost generic drugs."); *Glaxo, Inc. v.*

Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997) ("[T]he purposes of the legislation are 'to make available more low cost generic drugs,'" and "provide regulatory relief, increase competition, economy in government, and best of all, [allow] the American people [to] save money, and yet receive the best medicine that pharmaceutical science can provide.") (quoting *inter alia* Stmnt. On Signing S. 1583 Into Law, 20 Weekly Comp. Pres. Doc. 1359, 1360 (Sept. 24, 1984)).

25. The Hatch-Waxman Act also included changes that were extremely valuable for brand name drug manufacturers. Specifically, brand manufacturers were now entitled to five years of exclusivity for new drugs (regardless of patent protection), *see* 21 U.S.C. § 355(c)(3)(E)(ii), and brand name manufacturers could also obtain five additional years of patent protection for their drugs upon request, *see* 35 U.S.C. § 156. This was the central compromise behind the legislation: longer exclusivity and patent protection for brand name drugs, in exchange for faster and cheaper generic entry once the exclusivity periods and patent protection expired (or a patent was successfully challenged or designed around).

26. The FDA has been experimenting with different ways to manage risks related to pharmaceutical drugs since at least the 1960s. These efforts began with full-disclosure requirements requiring healthcare professionals to provide full complete information about the drug product's indication, side effects, dosing, etc. to healthcare professionals. The Controlled Substances Act (CSA) of 1970 placed additional regulations on manufacturers, prescribers, dispensers, and product labeling, providing for, *inter alia*, boxed warning messages on packaging and "Dear Healthcare Provider" letters. In the 1990s, the FDA first began working with manufacturers to develop risk management programs for drugs with potentially dangerous side effects.

27. In March 2005 FDA issued a final guidance document entitled "Guidance for Industry: Development and Use of Risk Management Plans." The guidance for "RiskMAPs" gave manufacturers specific direction about how to address product risk-related goals using "tools" to meet the goal of minimizing product risk while preserving benefits. These tools varied

from restricted distribution systems to distribution of educational materials to mitigate risks. Products considered risky by the FDA were approved only if an appropriate RiskMAP was instituted by the manufacturer. As of February 2007, there were 30 drugs with some type of RiskMAP, most of which involved targeted education and outreach.

28. In September 2007, President George W. Bush signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). The FDAAA gave the FDA the authority to require Risk Evaluation and Mitigation Strategies (REMS) for new drug products *and* already approved products, if it determines that a REMS program is necessary to "ensure the benefits of the drug outweigh the risks of the drug." In addition to requirements such as a medication guide and package insert, the components of a REMS program (known as elements to assure safe use) can include potential restrictions on distribution of the drug, such as special certifications for practitioners, pharmacies, or healthcare settings that can dispense the drug, patient monitoring, and enrollment of eligible patients in a registry.

29. Congress included a specific provision in the FDAAA mandating that REMS programs must not be wielded by branded drug makers as a tool to keep generic competitors out of the market. Specifically, FDC Act § 505-1(f)(8) states: "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 to prevent application of such element under [FDC Act § 505-1(i)(1)(B)] to a drug that is the subject of an [ANDA]."

30. While generic drugs are therapeutically equivalent to their brand counterparts, even the first generic is typically introduced into the market at a price significantly lower than the brand. Upon the entry of additional AB-rated generic drugs, the prices fall even more. As a result, consumers and other payors can enjoy significant savings by using generic versions of branded drugs. According to a September 2010 study by the Congressional Budget Office, the average retail price of a generic drug is 74% lower than the average retail price of its brand-name counterpart.

31. Because of the lower prices available for generic drugs, almost all states encourage generic competition by allowing pharmacists to dispense an AB-rated generic whenever a prescription for a brand equivalent is presented. Similarly, most third party payors (such as health insurance plans) have policies encouraging generic substitution.

32. As a result of the lower generic prices and ease of substitution, most consumers routinely switch from the branded to the generic drug upon its introduction. Accordingly, AB-rated generic drugs typically capture a large share of the brand name drug's sales.

33. Competition from generic drugs generates massive savings for consumers. A recent IMS Health study showed that, between 2000 and 2009, the use of generic prescription drugs in place of their brand-name counterparts saved the nation's health care system more than $824 billion dollars. In 2009 alone, the use of FDA-approved generics saved $139.6 billion—a 15% growth over the prior year's savings—or about $382 million every day. Another study from September 2011 estimated the aggregate consumer savings from generic substitution to be in excess of $1 trillion dollars over the past decade. In an era of rapidly increasing health care costs, it is critical that consumers—not to mention other payors like the Medicare program—continue to enjoy and increase these savings.

34. While the goal of ensuring that the benefits of a potentially harmful drug outweigh the risks is a laudable one, experience has shown that REMS have in fact been used by branded manufacturers as a tool to improperly restrict generic competition. Branded drug manufacturers like Actelion, which design, submit, and implement their own REMS programs, are using REMS as a pretext to prevent generic companies from obtaining drug product samples necessary to conduct bioequivalence testing. These branded companies have recognized that they can attempt to game the system by entering into agreements with distributors that prohibit distribution of the RLD to generic drug makers for bioequivalence testing, and by refusing to sell the drug directly to a potential generic competitor, all under the guise of adhering to REMS or restricted distribution requirements they designed themselves.

35. In a December 23, 2009 response to draft guidance on REMS issued by the FDA, the Generic Pharmaceutical Association noted that "REMS potential for abuse is on the fast track of becoming another powerful lifecycle management tool meant to turn the balance of Hatch-Waxman on its head . . . ."

36. FDA has also stated that this practice is frustrating the purpose of the Hatch-Waxman amendments. In a February 12, 2007 letter to a generic drug maker regarding the branded company's refusal to provide samples of a branded product subject to a REMS program, the FDA stated:

> The agency is aware that [the brand] has expressed concern that providing [the RLD] to a generic drug manufacturer (or its agent) for use in bioequivalence studies would interfere with [the brand's] ability to track dispensing of the drug and undermine the [REMS] program. It is FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the [REMS] program to prevent manufacturers of generic drugs from obtaining [RLD] for use in bioequivalence testing necessary to obtain approval of an abbreviated new drug application for [generic RLD].

FDA went on to say that it would not attempt to enforce any REMS violations penalties against the brand for providing samples of the RLD to the generic, because to permit the REMS program to block development of a generic would "frustrate" the "intention of Congress in enacting the Generic Drug Approval Provisions in Section 505(j) . . . ."

37. Historically, most REMS programs included only a medication guide and/or a communication plan for educating practitioners about risks. As brand manufacturers have determined to use REMS as a method of restricting competition, the number of REMS that include the distribution-restrictive elements to assure safe use have increased exponentially.

38. Despite the plain language of the statute and the FDA's stated position, the practice of using REMS to block the procurement of samples for bioequivalence testing continues, as branded drug manufacturers have determined that they can use elements of a REMS program as an excuse to restrict competition.

39. Approval of generic Tracleer and Zavesca would give consumers the choice between those branded products and lower-priced generic versions. Most customers would choose to purchase lower-priced generic drugs instead of higher-priced branded Tracleer and Zavesca. Most payors—including federal health care programs—would also welcome the savings produced by generic competition for these products.

40. Roxane could thus capture a significant portion of Actelion's sales over time, generating substantial sales (even at the reduced price) that would provide considerable savings to consumers and health plans.

41. The availability of generic versions of Tracleer and Zavesca would quickly and significantly reduce Actelion's sales and lead to a significant reduction in the average price purchasers would pay for these drugs. Over time, consumers would likely save hundreds of millions of dollars a year by purchasing generic versions of Tracleer and Zavesca from Roxane, which in turn would receive substantial revenue from these generic sales.

42. Through its anticompetitive conduct, Actelion has retained those revenues and potential consumer savings for itself. Actelion's unlawful and exclusionary conduct has enabled Actelion to sell Tracleer and Zavesca at artificially inflated, supracompetitive prices.

Acts Giving Rise to Roxane's Claims

History of Bosentan and Miglustat

43. Actelion was founded in 1997. Martine Clozel, a co-founder of Actelion, originally worked as a researcher for F. Hoffmann-La Roche Ltd. During that time, Clozel initiated the research project on endothelin and endothelin receptor antagonists which led to the discovery and clinical development of bosentan, among other molecules. According to Actelion, "The compound bosentan would later become Actelion's first product on the market, Tracleer®, and lift the company into profitability in record time."

44. In November 2001, the FDA approved Tracleer for the treatment of pulmonary arterial hypertension ("PAH"). Tracleer was the first oral treatment for PAH. Actelion obtained approval subject to distribution limitations implemented through its own restricted distribution program.

45. Tracleer is Actelion's "lead" product, reaping sales in the billions of dollars over the years.

Actelion's Tracleer NDA No. 21-290

46. FDA lists Actelion as the holder of NDA No. 21-290 for bosentan tablets, which Actelion markets as Tracleer.

47. FDA approved the Tracleer NDA No. 21-290 in November 2001. Actelion launched Tracleer in the United States the following month, in December 2001.

48. Actelion is the only company that has FDA approval to market a pharmaceutical product containing bosentan as the active ingredient in the United States.

49. On information and belief, Actelion markets and sells 100% of all FDA-approved pharmaceutical products containing bosentan as the active ingredient in the United States.

50. On information and belief, in the first nine months of 2012 alone, Actelion's product sales world-wide were nearly $1.4 billion, 42% of which came from the United States. Tracleer was responsible for over $1.2 billion in world-wide revenues for Actelion during that time period.

51. Actelion calls its REMS program for bosentan the Tracleer Access Program ("T.A.P."). Under it, Actelion distributes Tracleer by entering into unlawful agreements with each of its "specially certified" wholesalers, under which such participants agree with Actelion not to supply Tracleer to any entity that does not have Actelion's approval.

52. Tracleer is contained in the FDA's Orange Book, with its listed patent being U.S. Patent No. 5,292,740 (the "´740 patent"). Although the ´740 patent was originally scheduled to expire on June 9, 2012, Actelion successfully obtained a 1,259 day extension pursuant to 35

U.S.C. § 156—the same statutory provision that was central to the Hatch-Waxman compromise between brand name and generic pharmaceutical manufacturers. As a result, the listed patent for Tracleer expires on or before November 20, 2015.

53. On information and belief, the impending expiration of the ´740 patent offers Actelion a powerful incentive to engage in the anticompetitive conduct alleged herein in order to prevent successful generic entry on or near November 20, 2015 (or before if the patent were held invalid or not infringed).

54. Unless restrained by this court, Actelion will succeed in profiting from both sides of the central Hatch-Waxman Act compromise: taking full advantage of the patent extension provisions for Tracleer, but then also preventing generic entry.

Actelion's Zavesca NDA No. 21-438

55. FDA lists Actelion as the holder of NDA No. 21-438 for miglustat capsules, which Actelion markets as Zavesca.

56. FDA approved the Zavesca NDA No. 21-438 in August 2003.

57. According to Actelion, "Zavesca (miglustat) is currently the only approved oral treatment for mild to moderate forms of type 1 Gaucher's disease, a rare and debilitating metabolic disorder, and used in patients for whom enzyme replacement therapy is unsuitable."

58. Actelion is the only company that has FDA approval to market a pharmaceutical product containing miglustat as the active ingredient in the United States.

59. On information and belief, Actelion markets and sells 100% of all FDA-approved pharmaceutical products containing miglustat as the active ingredient in the United States.

60. On information and belief, in the first nine months of 2012 alone, Actelion's product sales world-wide were nearly $1.4 billion, 42% of which came from the United States. Zavesca was responsible for nearly $67 million in world-wide revenues for Actelion during that time period. According to Actelion, this "represents an increase of 22% in local currencies

driven predominantly by strong patient demand in Niemann Pick Type-C indication (outside the US) as well as a positive US pricing impact."

61. As a "CuraScript Exclusive Product," Zavesca is subject to a restricted distribution program. Although not a formal REMS program, Actelion similarly restricts the distribution of Zavesca such that Roxane cannot purchase it for market price from CuraScript.

62. Zavesca is contained in the FDA's Orange Book, with its listed patents being U.S. Patent Nos. 5,472,969 (the "´969 patent") and 5,525,616 (the "´616 patent"). The ´969 patent expires on May 13, 2013, and the ´616 patent expires on June 11, 2013. As a result, the listed patents for Zavesca expire on or before June 11, 2013.

63. On information and belief, the impending expiration of the ´969 and ´616 patents offers Actelion a powerful incentive to engage in the anticompetitive conduct alleged herein in order to prevent successful generic entry on or near June 11, 2013.

Roxane's Attempts to Develop Generic Bosentan and Miglustat

64. Roxane is a pharmaceutical company engaged in the business of developing, manufacturing and marketing lower-priced generic versions of brand-name drugs, and specifically began developing generic versions of bosentan and miglustat. Roxane intended to file ANDAs with the FDA, seeking approval to market the generic bosentan and miglustat products it was developing as AB-rated equivalents to Tracleer and Zavesca.

65. Before submitting its ANDA, the generic manufacturer typically must perform bioequivalence studies and validation testing to be included in the ANDA for FDA approval.

66. In order to prepare its bosentan product and miglustat products and file its ANDAs, Roxane needed to secure samples of bosentan and miglustat for use in bioequivalence studies.

67. In 2011, Roxane attempted to obtain Tracleer samples through normal distribution channels but was unable to do so. In January 2012, Roxane asked to purchase Tracleer capsules

from Actelion for the purposes of developing a generic product. Roxane indicated it was making the request at the instruction of the FDA, who stated that companies must obtain the brand product from the manufacturer for the purposes of developing a generic product.

68. On February 10, 2012, Actelion refused to sell product to Roxane, stating that it "has the right to choose with whom it does business" and "has concluded that it will not be fulfilling Roxanne's request."

69. On August 1, 2012, counsel for Roxane urged Actelion "to reconsider [its] position regarding Roxane's efforts to purchase research quantities of Tracleer for development purposes." Roxane renewed its request to purchase Tracleer tablets directly from Actelion, stating that "Roxane has been unable to purchase this product, as it normally does in the ordinary course of business, from pharmaceutical wholesalers due to Actelion's restrictions. Accordingly, Roxane requested to purchase supply from Actelion directly."

70. Meanwhile, Roxane conducted a pilot bioequivalence study between its potential generic bosentan drug product and a Canadian version of Tracleer. The bioequivalence study was carefully and specifically designed to satisfy FDA safety guidance. For example, to eliminate the risk of women who could potentially become pregnant while participating in the study, the study protocols were modified to include male subjects only.

71. Despite the presence of FDA-approved safety protocols, this Canadian pilot study was insufficient to prove bioequivalence for the purpose of preparing an ANDA, because FDA regulations make clear that bioequivalence must be proven with respect to an FDA-approved "listed drug," 21 C.F.R. § 314.94(a)(3), and a foreign-purchased version of a drug is not the FDA-approved "listed drug." Thus, Roxane put its studies on hold while further attempts were made to obtain the FDA-approved version of Tracleer from Actelion directly, as well as through traditional distribution channels.

72. In response to Roxane's continuing efforts to purchase Tracleer samples at their market price, Actelion replied by continuing to refuse to sell Roxane samples, and asking a

number of baseless questions, which were clearly designed to delay and continue to deprive Roxane of samples and foreclose potential competition.

73. For example, in an August 9, 2012 letter to Roxane's counsel, Actelion's counsel stressed Actelion's desire to "protect its intellectual property rights" as a reason not to provide Tracleer samples to Roxane—despite the widely-known Hatch-Waxman Act research exemption, which explicitly states that "[i]t shall not be an act of infringement" to conduct studies "reasonably related to the development and submission" of an ANDA. 35 U.S.C. § 271(e)(1).

74. Actelion's conduct with respect to miglustat was comparable. Roxane had likewise attempted to obtain Zavesca samples through normal distribution channels but was unable to do so. On April 19, 2010, Roxane requested to purchase Zavesca capsules from Actelion for the purposes of developing a generic product. Roxane stated that the purchased product would be used for developmental purposes to support an ANDA filing. Roxane also offered to pay fair market value for the capsules. Actelion, however, refused to sell any capsules to Roxane.

75. On June 6, 2011, counsel for Actelion renewed Roxane's request to purchase Zavesca samples. Once again, Actelion stonewalled. Actelion first suggested that Roxane purchase Zavesca samples in Europe or "elsewhere," despite the presence of clear FDA regulations prohibiting the use of foreign samples in bioequivalence studies in preparation for an ANDA. Roxane responded that "the FDA will not permit generics to use foreign-purchased product for an ANDA submission." To support this contention, Roxane attached a letter from the FDA confirming FDA's position that "to obtain marketing approval in the United States," a generic manufacturer was required to "use the US approved reference listed drug" in bioequivalence studies.

76. Roxane further stated that it "[did] not need to buy from Actelion if you will permit your US supplier to sell to us." But Actelion refused to sell Zavesca to Roxane at market price, either directly or through its supplier CuraScript. On November 9, 2011, Actelion

definitively notified Roxane that "it is Actelion's position that it has the right to choose with whom it does business, and under what terms" and that "Actelion is under no obligation to provide samples to Roxane, or otherwise change the manner in which it distributes Zavesca."

77. Actelion's actions directly caused significant delays in Roxane's filing of its ANDAs for bosentan and miglustat.

78. Roxane has been injured by Actelion's interference, which has delayed the filing of ANDAs on bosentan and miglustat by Roxane.

79. But for Actelion's conduct, Roxane would have been able to introduce a lower-priced competing bosentan product at least one year earlier than it will now be able. Similarly, Actelion's conduct has already delayed Roxane's development of a lower-priced, competing miglustat product by at least 2 1/2 years.

80. At all relevant times, Roxane has intended to, and currently intends to enter the markets for bosentan and miglustat drug products. Roxane has extensive experience in the generic drug market, possesses the knowledge and experience necessary to complete approvable ANDAs for generic bosentan and miglustat products, and has the financial capability to develop and market these products. Roxane has taken actual and substantial affirmative steps towards entry in these markets, including but not limited to conducting pilot bioequivalence studies using foreign samples, and attempting to obtain domestic samples from Actelion for bioequivalence testing that meets FDA requirements. Roxane's inability to obtain domestic bioequivalence samples stands as the final, major obstacle to successful entry, and but for Actelion's conduct, Roxane would already have obtained these samples.

Anticompetitive Effects

81. Because Roxane cannot obtain bosentan or miglustat inside or outside Actelion's REMS or restricted distribution programs, Actelion's agreements clearly have an anticompetitive impact on the markets for bosentan and miglustat. The Actelion REMS and restricted

distribution agreements preclude access to the necessary bioequivalence samples, prevent any ANDA filings, and therefore thwart entry into the market for bosentan and miglustat. Nor are the restrictions on distribution to preclude Roxane reasonably necessary to achieve legitimate ends given the FDA's approval of Roxane's testing protocols. Actelion's restrictions, as applied to Roxane, are a mere pretext to eliminate competition.

82. Competition in the bosentan and miglustat markets is restricted due to the need for FDA approval before a competitor may market a substitute product rated as therapeutically equivalent to Tracleer or to Zavesca. In addition, prior to submitting an application to FDA for approval, a drug company incurs significant costs and requires significant knowledge and time in order to formulate and develop a drug for FDA approval.

83. Competition in the bosentan and miglustat markets is further restricted because an ANDA applicant must include a certification as to the patents listed in the Orange Book in order to obtain FDA approval prior to patent expiration, which can further delay FDA approval. Specifically, if an ANDA applicant seeks approval of its ANDA prior to expiration of the Orange Book-listed patents, the ANDA applicant must submit paragraph IV certifications to those patents. If Actelion sues the ANDA applicant within 45 days of receiving notice of a paragraph IV certification to any of the patents, the ANDA is automatically subject to a 30-month stay of FDA approval, absent court action. Alternatively, an applicant can submit a certification seeking approval for a product to be launched upon patent expiry.

84. Actelion wields monopoly power over both bosentan-based and miglustat-based products and any possible substitutes for these products. Actelion has 100 percent market share over the currently marketed drugs and there are no reasonable substitutes. On information and belief, Tracleer and Zavesca together account for over 90% of Actelion's annual revenue.

85. Actelion offers its products at a retail price to customers who are willing to abide by certain safety protocols, yet it is unwilling to sell those same products at retail prices to Roxane. Actelion has further required that all of its customers agree not to resell its retail products to "unapproved" buyers, including Roxane.

86. On information and belief, Actelion has permitted others to do exactly what Roxane seeks to do here, on multiple occasions. Specifically, Actelion has frequently allowed access to Tracleer and Zavesca samples—directly or indirectly—to other companies and organizations, for the purpose of conducting careful and safe clinical studies. Roxane seeks only to be treated the same way Actelion has treated the sponsors of these other studies.

87. On information and belief, over the past twenty years, Actelion has allowed access—directly or indirectly—to Tracleer samples for at least 47 publicly-disclosed clinical studies conducted by others. Some of these studies were conducted by research hospitals, or the National Institute of Health. Notably, some of these studies were conducted by large, brand-name pharmaceutical companies, like Novartis. Indeed, one Novartis study is currently ongoing today.

88. On information and belief, over the past twenty years, Actelion has allowed access—directly or indirectly—to Zavesca samples for at least eight publicly-disclosed clinical studies conducted by others. Some of these studies were conducted by research hospitals. Notably, five of these studies were conducted by large, brand-name pharmaceutical companies, like G.D. Searle (now a part of Pfizer), and Glaxo Wellcome (now GlaxoSmithKline).

89. On information and belief, Actelion has a long history of allowing access—directly or indirectly—to Tracleer and Zavesca samples for clinical testing purposes to research organizations, and brand-name pharmaceutical companies. There is only one plausible explanation for Actelion's willingness to allow access to such samples to these entities, on one hand, and its steadfast refusal to allow access to such samples to potential generic competitors, on the other hand: a desire to "block or delay" generic competition, in violation of FDC Act § 505-1(f)(8) and the antitrust laws.

90. On information and belief, the organizations who conducted the clinical trials referenced above did not obtain Tracleer samples through Actelion's Tracleer Access Program, nor did they obtain Zavesca through Actelion and CuraScript's restricted distribution program. Thus, Actelion's purported justification for its refusal to deal—a need to restrict distribution of

Tracleer and Zavesca samples through these restrictive programs—rings hollow. Actelion's purported "justification" is nothing more than an anticompetitive scheme calculated to delay generic competition as long as possible.

91. Tracleer and Zavesca samples constitute a resource essential to participation in these markets that Roxane has no way to duplicate.

RELEVANT MARKETS

92. With respect to Roxane's claims regarding bosentan, the relevant product market in this case is the market for FDA-approved bosentan drug products.

93. With respect to Roxane's claims regarding miglustat, the relevant product market in this case is the market for FDA-approved miglustat drug products.

94. The relevant geographic market in this case is the United States.

95. Actelion has monopoly power and market power in the market for FDA-approved bosentan drug products because it is the only company with FDA approval to market a bosentan drug product in the United States. There is no reasonably interchangeable drug product available to prescribing physicians for the indications for which Tracleer is prescribed. According to Actelion, "Tracleer is the "first and only approved dual endothelin receptor antagonist." Actelion has sufficient market power to keep prices of FDA-approved bosentan drug products artificially high and quantities artificially low.

96. Actelion has monopoly power and market power in the market for FDA-approved miglustat drug products because it is the only company with FDA approval to market a miglustat drug product in the United States. There is no reasonably interchangeable drug product available to prescribing physicians for the indications for which Zavesca is prescribed. According to Actelion, "Zavesca is the "first and only oral medication approved for the oral treatment of adult patients with mild to moderate type 1 Gaucher disease, and it may only be used in those patients for whom enzyme replacement therapy is unsuitable." Actelion has sufficient market power to

keep prices of FDA-approved miglustat drug products artificially high and quantities artificially low.

97. Actelion has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved bosentan drug products and in the market for FDA-approved miglustat drug products by causing output to be artificially low, raising competitors' costs and/or keeping the market price for FDA-approved bosentan and miglustat drug products above a competitive level.

98. Actelion has also raised the cost of entry into the market by requiring potential competitors to incur the costs and delays resulting from Actelion's conduct, including but not limited to preventing potential competitors from obtaining samples and active pharmaceutical ingredient ("API") supplies.

Count I (Sherman Act Section 2 -- Tracleer)

Monopolization, Attempted Monopolization and Conspiracy to Monopolize

99. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-98.

100. There is a relevant market for Tracleer and its generic equivalents (collectively "bosentan").

101. Actelion possesses monopoly power in the relevant market for bosentan. That market is characterized by significant entry barriers.

102. This counterclaim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Actelion has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize and conspiring to monopolize the market for FDA-approved bosentan drug products.

103. Through the foregoing acts, Actelion, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will

continue to use its power in the market for FDA-approved bosentan drug products to monopolize, attempt to monopolize, and conspire to monopolize the market for FDA-approved bosentan drug products.

104. Actelion knowingly and intentionally engaged in an anticompetitive scheme designed to unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of an AB-rated generic version of Tracleer, and thus to willfully to maintain its monopoly power.

105. Specifically, because Actelion prohibits access to bioequivalence samples using its REMS program as a pretext, even in the presence of FDA-approved safety protocols and offers of compensation at retail prices, Actelion's conduct demonstrates predatory intent and has the effect of excluding potential competitors while preserving Actelion's dominant position.

106. Actelion intentionally and wrongfully maintained its monopoly power with respect to Tracleer by entering into unlawful agreements with wholesale distributors and its "specially certified" pharmacies, under which such participants agree with Actelion not to supply Tracleer to any entity that does not have Actelion's approval.

107. "Even though exclusivity arrangements are often analyzed under § 1, such exclusionary conduct may also be an element in a § 2 claim." *LePage's Inc. v. 3M*, 324 F.3d 141, 157 (3d Cir. 2003) (en banc).

108. By means of such agreements, Actelion has acted pursuant to a conspiracy and for the specific purpose of monopolizing the market for FDA-approved bosentan drug products.

109. In addition, Actelion intentionally and wrongfully maintained its monopoly power with respect to Tracleer by refusing to deal with Roxane and other entities that are not "specially certified."

110. By means of its refusal to deal, Actelion has acted pursuant to a conspiracy and for the specific purpose of monopolizing the market for FDA-approved bosentan drug products.

111. Actelion's conduct has no procompetitive, legitimate business justification. Actelion's conduct can be explained only by anticompetitive motives, and a desire to foreclose competition in the relevant market. Actelion's purported justifications are pretextual.

112. To the extent there are legitimate business justifications for Actelion's exclusionary conduct, Actelion's conduct is more anticompetitive than necessary to serve those justifications.

113. Actelion currently enjoys a monopoly in the market for FDA-approved bosentan drug products, and there is a dangerous probability Actelion will succeed in maintaining its monopoly by means of its unlawful conduct.

114. By its scheme, Actelion intentionally and wrongfully maintained its monopoly power with respect to bosentan in violation of Section 2 of the Sherman Act. As a result of Actelion's unlawful maintenance of monopoly power, Roxane has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

115. The foregoing acts and practices have harmed consumers and competition.

116. Actelion's anticompetitive and exclusionary conduct has directly and proximately caused injury to Roxane's business and property, as set forth above. Roxane's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

117. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

118. Actelion's refusal to sell Tracleer to Roxane "*even if compensated at retail price* reveal[s] a distinctly anticompetitive bent." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004) (emphasis in original). Actelion has "turned down a proposal to sell at its own retail price, suggesting a calculation that its future monopoly retail price would be higher." *Id.*

119. Roxane is entitled to a judgment that Actelion has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Actelion's continued violations.

Count II (Sherman Act Section 2 -- Zavesca)

Monopolization, Attempted Monopolization and Conspiracy to Monopolize

120. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-119.

121. There is a relevant market for Zavesca and its generic equivalents (collectively "miglustat").

122. Actelion possesses monopoly power in the relevant market for miglustat. That market is characterized by significant entry barriers.

123. This counterclaim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Actelion has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize and conspiring to monopolize the market for FDA-approved miglustat drug products.

124. Through the foregoing acts, Actelion, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use its power in the market for FDA-approved miglustat drug products to monopolize, attempt to monopolize, and conspire to monopolize the market for FDA-approved miglustat drug products.

125. Actelion knowingly and intentionally engaged in an anticompetitive scheme designed to unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of an AB-rated generic version of Zavesca, and thus to willfully to maintain its monopoly power.

126. Specifically, because Actelion prohibits access to bioequivalence samples using Zavesca's restricted distribution program as a pretext, even in the presence of FDA-approved safety protocols and offers of compensation at retail prices, Actelion's conduct demonstrates predatory intent and has the effect of excluding potential competitors while preserving Actelion's dominant position.

127. Actelion intentionally and wrongfully maintained its monopoly power with respect to Zavesca by entering into unlawful agreements with CuraScript and other participants, under which CuraScript and other participants agree with Actelion not to supply Zavesca to any entity without Actelion's approval.

128. "Even though exclusivity arrangements are often analyzed under § 1, such exclusionary conduct may also be an element in a § 2 claim." *LePage's Inc. v. 3M*, 324 F.3d 141, 157 (3d Cir. 2003) (en banc).

129. By means of these agreements, Actelion has acted pursuant to a conspiracy and for the specific purpose of monopolizing the market for FDA-approved miglustat drug products.

130. In addition, Actelion intentionally and wrongfully maintained its monopoly power with respect to Zavesca by refusing to deal with Roxane and other entities that are excluded from its restricted distribution program.

131. By means of its refusal to deal, Actelion has acted pursuant to a conspiracy and for the specific purpose of monopolizing the market for FDA-approved miglustat drug products.

132. Actelion's conduct has no procompetitive, legitimate business justification. Actelion's conduct can be explained only by anticompetitive motives, and a desire to foreclose competition in the relevant market. Actelion's purported justifications are pretextual.

133. To the extent there are legitimate business justifications for Actelion's exclusionary conduct, Actelion's conduct is more anticompetitive than necessary to serve those justifications.

134. Actelion currently enjoys a monopoly in the market for FDA-approved miglustat drug products, and there is a dangerous probability Actelion will succeed in maintaining its monopoly by means of its unlawful conduct.

135. By its scheme, Actelion intentionally and wrongfully maintained its monopoly power with respect to miglustat in violation of Section 2 of the Sherman Act. As a result of Actelion's unlawful maintenance of monopoly power, Roxane has suffered and will continue to

suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

136. The foregoing acts and practices have harmed consumers and competition.

137. Actelion's anticompetitive and exclusionary conduct has directly and proximately caused injury to Roxane's business and property, as set forth above. Roxane's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

138. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

139. Actelion's refusal to sell Zavesca to Roxane "*even if compensated at retail price* reveal[s] a distinctly anticompetitive bent." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004) (emphasis in original). Actelion has "turned down a proposal to sell at its own retail price, suggesting a calculation that its future monopoly retail price would be higher." *Id.*

140. Roxane is entitled to a judgment that Actelion has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Actelion's continued violations.

Count III (Sherman Act Section 2 -- Tracleer)

Monopolization, Attempted Monopolization and Conspiracy to Monopolize by Denial of an Essential Facility or Resource Necessary to Compete

141. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-140.

142. This counterclaim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Actelion has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize, and conspiring to

monopolize the market for FDA-approved bosentan drug products by denying its competitors access to an essential facility or resource required to compete in the relevant market.

143. There is a relevant market for Tracleer and its generic equivalents (collectively "bosentan").

144. Actelion possesses monopoly power in the market for bosentan. That market is characterized by significant entry barriers.

145. "A monopolist's denial to competitors of access to its 'essential' goods, services or resources has been held to violate § 2." *LePage's Inc. v. 3M*, 324 F.3d 141, 153 (3d Cir. 2003) (en banc) (citing *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973)).

146. Actelion, a monopolist, maintains exclusive control over an essential facility or resource required for competition in the market for bosentan drugs: Tracleer samples.

147. Roxane cannot practically or reasonably duplicate the essential facility or resource of Tracleer samples for the purpose of conducting bioequivalence studies that will meet FDA requirements. Nor can Tracleer samples useable for FDA-approved bioequivalence studies be obtained from another source.

148. Despite Roxane's offers to purchase Tracleer samples at their market price, Actelion has denied, and continues to deny the use of the essential facility or resource of Tracleer samples to Roxane, a potential competitor in the market for bosentan.

149. Providing Roxane with Tracleer samples would be feasible. Actelion could simply sell Tracleer to Roxane at or near the market price it provides to other customers. No ongoing supervision by the court would be required to enforce such an order.

150. Actelion has no legitimate, procompetitive justification for sacrificing profits by refusing to sell Tracleer to Roxane at its market price. Actelion's purported justifications are pretextual.

151. Actelion's conduct has an exclusionary and anticompetitive purpose and effect, and can only be explained by a desire to unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of a competing generic version of Tracleer.

152. To the extent there are legitimate business justifications for Actelion's exclusionary conduct, Actelion's conduct is more anticompetitive than necessary to serve those justifications.

153. By its denial of access to an essential facility or resource necessary to compete in the relevant market, Actelion has intentionally and wrongfully maintained its monopoly power with respect to bosentan in violation of Section 2 of the Sherman Act.

154. As a result of Actelion's unlawful denial of access to an essential facility or resource, Roxane has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

155. The foregoing acts and practices have harmed consumers and competition, by preventing competition between brand-name and generic bosentan drug products.

156. Actelion's anticompetitive and exclusionary conduct has directly and proximately caused injury to Roxane's business and property, as set forth above. Roxane's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

157. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

158. Roxane is entitled to a judgment that Actelion has violated Section 2 of the Sherman Act; to the damages it has suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Actelion's continued violations.

Count IV (Sherman Act Section 2 -- Zavesca)

Monopolization, Attempted Monopolization and Conspiracy to Monopolize by Denial of an Essential Facility or Resource Necessary to Compete

159. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-158.

160. This counterclaim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Actelion has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize, and conspiring to monopolize the market for FDA-approved miglustat drug products by denying its competitors access to an essential facility or resource required to compete in the relevant market.

161. There is a relevant market for Zavesca and its generic equivalents (collectively "miglustat").

162. Actelion possesses monopoly power in the market for miglustat. That market is characterized by significant entry barriers.

163. "A monopolist's denial to competitors of access to its 'essential' goods, services or resources has been held to violate § 2." *LePage's Inc. v. 3M*, 324 F.3d 141, 153 (3d Cir. 2003) (en banc) (citing *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973)).

164. Actelion, a monopolist, maintains exclusive control over an essential facility or resource required for competition in the market for miglustat drugs: Zavesca samples.

165. Roxane cannot practically or reasonably duplicate the essential facility or resource of Zavesca samples for the purpose of conducting bioequivalence studies that will meet FDA requirements. Nor can Zavesca samples useable for FDA-approved bioequivalence studies be obtained from another source.

166. Despite Roxane's offers to purchase Zavesca samples at their market price, Actelion has denied, and continues to deny the use of the essential facility or resource of Zavesca samples to Roxane, a potential competitor in the market for miglustat.

167. Providing Roxane with Zavesca samples would be feasible. Actelion could simply sell Tracleer to Roxane at or near the market price it provides to other customers. No ongoing supervision by the court would be required to enforce such an order.

168. Actelion has no legitimate, procompetitive justification for sacrificing profits by refusing to sell Zavesca to Roxane at its market price. Actelion's purported justifications are pretextual.

169. Actelion's conduct has an exclusionary and anticompetitive purpose and effect, and can only be explained by a desire to unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of a competing generic version of Zavesca.

170. To the extent there are legitimate business justifications for Actelion's exclusionary conduct, Actelion's conduct is more anticompetitive than necessary to serve those justifications.

171. By its denial of access to an essential facility or resource necessary to compete in the relevant market, Actelion has intentionally and wrongfully maintained its monopoly power with respect to miglustat in violation of Section 2 of the Sherman Act.

172. As a result of Actelion's unlawful denial of access to an essential facility or resource, Roxane has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

173. The foregoing acts and practices have harmed consumers and competition, by preventing competition between brand-name and generic miglustat drug products.

174. Actelion's anticompetitive and exclusionary conduct has directly and proximately caused injury to Roxane's business and property, as set forth above. Roxane's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

175. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

176. Roxane is entitled to a judgment that Actelion has violated Section 2 of the Sherman Act; to the damages it has suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Actelion's continued violations.

Count V (Sherman Act Section 1 — Tracleer)

Contract, Combination or Conspiracy in Restraint of Trade

177. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-176.

178. This counterclaim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Actelion has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the market for FDA-approved bosentan drug products.

179. "The foreclosure of markets through exclusive dealing contracts is of concern under the antitrust laws." *LePage's Inc. v. 3M*, 324 F.3d 141, 158 (3d Cir. 2003) (en banc).

180. Through the foregoing acts, Actelion, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the market for FDA-approved bosentan drug products.

181. Specifically, Actelion has entered into unlawful agreements with wholesale distributors to limit distribution of Tracleer to only those entities Actelion permits. Actelion has also entered into unlawful agreements with each of its "specially certified" pharmacies, under which such participants agree not to supply bosentan to any entity without Actelion's approval. On information and belief, Actelion uses these and similar agreements to exercise complete control over the distribution of Tracleer.

182. By restricting downstream distribution of the drugs to only entities it approves, Actelion is able to effectively foreclose all potential competitors from access to an essential input in the generic drug development process, and thus unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of a competing generic version of Tracleer, using its REMS program as a pretext.

183. Each of these agreements constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant market, and harmed Roxane thereby.

184. There is no legitimate, procompetitive business justification for Actelion's agreements with "specially certified" distributors that outweighs the anticompetitive effect of these agreements. Actelion's purported justifications are pretextual. Even if there was some business justification, the agreements are broader than necessary to achieve such a purpose.

185. The foregoing acts and practices have harmed consumers and competition.

186. As a result of Actelion's conduct, Roxane has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

187. Actelion's anticompetitive and exclusionary conduct has directly and proximately caused injury to Roxane's business and property, as set forth above. Roxane's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

188. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

189. Roxane is entitled to a judgment that Actelion has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Actelion's continued violations.

Count VI (Sherman Act Section 1 -- Zavesca)

Contract, Combination or Conspiracy in Restraint of Trade

190. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-189.

191. This counterclaim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Actelion has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the market for FDA-approved miglustat drug products.

192. "The foreclosure of markets through exclusive dealing contracts is of concern under the antitrust laws." *LePage's Inc. v. 3M*, 324 F.3d 141, 158 (3d Cir. 2003) (en banc).

193. Through the foregoing acts, Actelion, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the market for FDA-approved miglustat drug products.

194. Specifically, Actelion has entered into unlawful agreements with CuraScript and other participants, under which CuraScript and other participants agree with Actelion not to supply miglustat to any entity without Actelion's approval.

195. By restricting downstream distribution of the drugs to only entities it approves, Actelion is able to effectively foreclose all potential competitors from access to an essential input in the generic drug development process, and thus unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of a competing generic version of Zavesca, using its restricted distribution program as a pretext.

196. Each of these agreements constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant market, and harmed Roxane thereby.

197. There is no legitimate, procompetitive business justification for Actelion's agreements with CuraScript and other participants that outweighs the anticompetitive effect of these agreements. Actelion's purported justifications are pretextual. Even if there was some business justification, the agreements are broader than necessary to achieve such a purpose.

198. The foregoing acts and practices have harmed consumers and competition.

199. As a result of Actelion's conduct, Roxane has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

200. Actelion's anticompetitive and exclusionary conduct has directly and proximately caused injury to Roxane's business and property, as set forth above. Roxane's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

201. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

202. Roxane is entitled to a judgment that Actelion has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Actelion's continued violations.

Count VII (The New Jersey Antitrust Act, Sections 56:9-3 and 56:9-4)

203. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-202.

204. This counterclaim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 *et seq*, and seeks a judgment that Actelion's conduct as alleged herein violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-3 and § 56:9-4.

Section 56:9-4, Monopolization

205. Actelion's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

206. Specifically, Actelion's agreements with distributors and pharmacies to restrict distribution of Tracleer and Zavesca, as well as its refusal to sell Tracleer and Zavesca samples

to Roxane at their market price, are calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-4, Monopolization by Denial of an Essential Facility

207. In addition, Actelion's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize by denial of an essential facility or resource necessary to compete, in violation of N.J. Stat. Ann. § 56:9-4.

208. Specifically, Actelion's control over, and denial of access to competitors, of the essential, non-duplicable resource of Tracleer and Zavesca samples, when granting such access would be feasible, is calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-3, Agreement in Restraint of Trade

209. Actelion's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

210. Specifically, Actelion's agreements and contracts with wholesale distributors and "specially certified" pharmacies prohibiting sales of Tracleer to Actelion's competitors are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

211. Similarly, Actelion's agreements and contracts with CuraScript and other restricted distribution partners, limiting sales of Zavesca to entities approved by Actelion are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

* * *

212. The foregoing acts and practices, and the continuing course of Actelion's anticompetitive conduct, have harmed consumers and competition.

213. Actelion's anticompetitive and exclusionary conduct has directly and proximately caused injury to Roxane's business and property, as set forth above. Roxane's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

214. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

215. Roxane is entitled to a judgment that Actelion has violated Sections 56:9-3 and 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Actelion's continued violations.

Count VIII (Tortious Interference)

216. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-215.

217. This claim arises under New Jersey law and seeks a judgment that Actelion has tortuously interfered with Roxane's prospective business relationships and/or economic advantage with suppliers.

218. Actelion's conduct as alleged herein gives rise to common law liability for intentional interference with contractual relations and intentional interference with prospective economic advantage and/or prospective contractual or business relations.

219. At all relevant times, Roxane had valid contractual relationships or legitimate expectations of contractual or economic relationships with third parties.

220. The foregoing relationships would have provided economic and other benefits to Roxane but for Actelion's tortuous and anticompetitive conduct. Actelion's conduct interfered with Roxane's "interest in reasonable expectations of economic advantage." *Harris v. Perl*, 197 A.2d 359, 363 (N.J. 1964).

221. At all relevant times, Actelion knew of Roxane's contractual or prospective contractual and economic relationships with third parties.

222. Actelion willfully engaged in the foregoing acts and practices with the intent to induce breach or disruption of Roxane's existing and prospective contractual and economic relationships with third parties.

223. Actelion's deliberate and primary purpose of engaging in some of the foregoing acts and practices was to disrupt Roxane's prospective contractual and economic relationships with third parties.

224. But for Actelion's conduct, suppliers would have supplied Roxane with Tracleer and Zavesca samples, which would have ultimately provided Roxane an economic benefit.

225. Actelion intentionally interfered with the prospective business relationship and/or economic advantage between Roxane and suppliers with malice, intentionally and without justification or excuse.

226. As a result of Actelion's conduct, Roxane has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

227. Actelion's interference has directly and proximately caused injury to Roxane's business and property, as set forth above.

228. Actelion's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Roxane will suffer immediate and irreparable injury for which Roxane is without an adequate remedy at law.

229. Roxane is entitled to a judgment that Actelion has violated New Jersey common law and to the damages it suffered as a result of that violation.

Count IX (Mandatory Injunctive Relief)

230. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-229.

231. Roxane has a reasonable probability of success on the merits.

232. Roxane's right to relief in the form of access to sufficient samples of Tracleer and Zavesca to enable Roxane to perform bioequivalence testing in support of an ANDA is clear.

233. As a result of Actelion's alleged unlawful conduct, as alleged herein, Roxane will continue to suffer immediate and irreparable harm that cannot be fully remedied by money damages.

234. Roxane does not have an adequate remedy at law.

235. Granting immediate injunctive relief to Roxane will not result in greater harm to Actelion.

236. Granting immediate injunctive relief to Roxane will be in the public interest, as it will finally allow the pursuit of lower-cost, generic competitors to an important drug used to treat a serious disease, resulting in competition in the relevant markets.

237. Roxane is entitled to a mandatory immediate injunction pursuant to 15 U.S.C. § 26 and Fed. R. Civ. P. 65, requiring Actelion to permit generic drug manufacturers to purchase samples of Tracleer and Zavesca on the same or similar terms available to others.

Count X (Declaratory Relief)

238. Roxane realleges and incorporates by reference the allegations of Paragraphs 1-237.

239. Roxane seeks samples of Tracleer and Zavesca in order to perform bioequivalence studies, as required to submit an ANDA and ultimately obtain FDA approval to bring competing generic bosentan and miglustat drug products to market.

240. Roxane has requested that Actelion provide sufficient samples of Tracleer and Zavesca to allow Roxane to conduct bioequivalence testing, and Roxane has made clear that it is willing to pay Actelion the full market price in exchange for these samples.

241. Nevertheless, Actelion has continuously refused to provide the requested samples to Roxane, and claims a legal right not only to refuse to deal with Roxane, but also to restrict all distribution of Tracleer and Zavesca through traditional wholesale distribution channels, ensuring Actelion's ability to prevent potential competitors from obtaining access to a critical input in the generic development process.

242. Actelion has filed suit against Roxane, seeking a declaration that its anticompetitive conduct is permitted under the antitrust laws.

243. Thus, a dispute currently exists between Actelion and Roxane with respect to Actelion's right to restrict distribution of Tracleer and Zavesca to certain approved entities.

244. Roxane is therefore entitled, pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, to a declaration of rights and obligations whereby Actelion is precluded from refusing to deal with Roxane, precluded from denying access to the essential resource of Tracleer and Zavesca samples to Roxane, and precluded from enforcing agreements to restrict Tracleer and Zavesca distribution as alleged herein.

REQUEST FOR RELIEF

WHEREFORE, Roxane respectfully requests that this Court enter a Judgment and Order in its favor and against Actelion as follows:

I. enjoining and restraining Actelion from continuing its Sherman Act and state law violations;

II. enjoining and restraining Actelion from limiting distribution of Tracleer and Zavesca samples to Roxane through use of its REMS and/or restricted distribution programs or otherwise;

III. awarding Roxane three times its actual damages suffered as a result of Actelion's Sherman Act violations plus interest, including costs and attorneys' fees;

IV. awarding Roxane three times its actual damages suffered as a result of Actelion's New Jersey Antitrust Act violations plus interest, including costs and attorneys' fees;

V. awarding Roxane its damages suffered as a result of Actelion's New Jersey common law violations plus interest;

VI. granting Roxane a declaration that Actelion's anticompetitive conduct is unlawful; and

VII. awarding Roxane any further and additional relief as the Court deems just and proper.

JURY DEMAND

Roxane demands trial by jury as to all issues so triable.

Respectfully submitted,

Dated: November 27, 2012

By: /s/ Beth S. Rose

Beth S. Rose
Charles J. Falletta
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102
Telephone: (973) 643-7000
brose@sillscummis.com
cfalletta@sillscummis.com

Of Counsel:
Karen N. Walker (admitted *pro hac vice*)
Eunnice Eun (admitted *pro hac vice*)
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
Telephone: (202) 879-5000

Attorneys for Defendant
Roxane Laboratories, Inc.

LOCAL CIV. R. 11.2 CERTIFICATION

Pursuant to Local Civ. Rule 11.2, I hereby certify to the best of my knowledge, information and belief that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

I hereby certify under penalty of perjury that the foregoing is true and correct.

/s/ Beth S. Rose
BETH S. ROSE

Executed on November 27, 2012

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of November, 2012, the foregoing Answer, Jury Demand, and Counterclaim was served upon all counsel of record via the Court's electronic filing system.

/s/ Beth S. Rose
BETH S. ROSE

Dated: November 27, 2012