BAZELON, LESS & FELDMAN, P.C.
A Pennsylvania Professional Corporation
A. Richard Feldman
Michael A. Shapiro
8000 Sagemore Drive, Suite 8302
Marlton, NJ 08053
Tel: (856) 988-1319
Fax: (856) 988-0194

Counsel for Defendants Apotex Inc. and Apotex Corp.

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

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC.,	ECF Filing
Plaintiffs/Counterclaim-Defendants,	Civil Action No. 1:12-cv-05743-NLH-AMD
v.	**ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIM OF DEFENDANTS APOTEX INC. AND APOTEX CORP.**
APOTEX INC., APOTEX CORP., and ROXANNE LABORATORIES, INC.,	
Defendants/Counterclaim-Plaintiffs.	**JURY TRIAL DEMANDED**

Apotex Inc. (150 Signet Drive, Toronto, Ontario M9L1T9 Canada) and Apotex Corp. (2400 North Commerce Parkway, Suite 400, Weston, Florida 33326) (collectively, "Apotex"), by and through their undersigned counsel, respectfully respond to Actelion Pharmaceuticals, Ltd.'s (Gewerbestrasse 16, CH-4123 Allschwil, Switzerland) and Actelion Clinical Research, Inc.'s (1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ 08002) (collectively, "Actelion" or "Plaintiffs"), Complaint for Declaratory Judgment with the following Answer, Affirmative Defenses, and Counterclaim.

NATURE OF THE ACTION

1. Apotex denies the allegations concerning Apotex in the second sentence of Paragraph 1. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations concerning Roxane Laboratories, Inc. ("Roxane") in the second sentence of Paragraph 1, and on that basis, denies them. The remaining allegations in Paragraph 1 state conclusions of law and argument to which no response is required. To the extent that a response to the remaining allegations in Paragraph 1 is required, they are denied.

2. Upon information and belief, Apotex admits the allegations in the first sentence of Paragraph 2. Apotex admits that Tracleer is subject to a Risk Evaluation and Mitigation Strategy ("REMS") and denies the remaining allegations in the second sentence of Paragraph 2. Apotex denies the allegations in the third sentence of Paragraph 2.

3. Apotex admits that it attempted to purchase samples of Tracleer from Actelion at market prices so that it can develop a competing generic drug, and that Actelion refused to sell such samples to Apotex. While Apotex admits that it informed Actelion that it would file a civil action seeking injunctive relief, declaratory relief and money damages, Apotex denies the characterization in the second sentence of Paragraph 3 that it became "increasingly threatening" in its efforts to purchase samples of Tracleer. Instead, Apotex entered into good faith negotiations with Actelion in an attempt to resolve the dispute without resorting to litigation. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations concerning Roxane in Paragraph 3, and on that basis, denies them.

4. Paragraph 4 states conclusions of law and argument to which no response is required. In addition, the second sentence of paragraph 4 purports to characterize certain acts of Congress that speak for themselves. To the extent that the first sentence of Paragraph 4 alleges

facts that are inconsistent with, contrary to, not supported by, or outside those acts of Congress, those allegations are denied. In addition, to the extent that the second sentence of Paragraph 4 infers that the absence of a statute requiring a brand-name drug manufacturer to sell samples of a drug subject to a REMS to a generic drug manufacturer supports Actelion's declaratory judgment action, that inference is denied. Apotex notes that section 505-1(f)(8) of the Food, Drug, and Cosmetic Act (21 U.S.C. § 355-1), which addresses REMS, provides that "[n]o holder of an approved application shall use any element to assure safe use required by the Secretary [of the Food and Drug Administration] under this subsection to block or delay approval of an application under section 355(b)(2) or (j)." Section 355(j) applies to the submission of an "abbreviated new drug application" (or "ANDA") by a generic drug manufacturer like Apotex.

PARTIES

5. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 5, and on that basis, denies them.

6. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 6, and on that basis, denies them.

7. Apotex admits the allegations in Paragraph 7.

8. Apotex admits the allegations in the first sentence of Paragraph 8. Apotex admits the allegation in the second sentence of Paragraph 8 that Apotex Corp. is in the business of selling generic drug products. Apotex denies the remaining allegations in the second sentence of Paragraph 8.

9. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 9, and on that basis, denies them.

JURISDICTION AND VENUE

10. Paragraph 10 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 10 is required, those allegations are denied.

11. Paragraph 11 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 11 is required, those allegations are denied.

12. Paragraph 12 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 12 is required, those allegations are denied.

13. Paragraph 13 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 13 is required, those allegations are denied.

14. Paragraph 14 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 14 is required, those allegations are denied.

FACTUAL BACKGROUND

15. Upon information and belief, Apotex admits that Actelion submitted to the U.S. Food and Drug Administration ("FDA") a New Drug Application ("NDA") for a pulmonary arterial hypertension ("PAH") drug, that FDA approved the NDA, and that Actelion markets the drug under the proprietary name Tracleer. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations in Paragraph 15, and on that basis, denies them.

16. Apotex admits that Tracleer purports to be a drug covered by U.S. Patent No. 5,292,740, but denies the remaining allegations in the first sentence of Paragraph 16. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in the second sentence of Paragraph 16, and on that basis, denies them.

17. Upon information and belief, Apotex admits that Tracleer may cause side effects and that Tracleer is subject to a REMS. Apotex denies the remaining allegations in the third sentence of Paragraph 17. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in the second and fourth sentences of Paragraph 17, and on that basis, denies them.

18. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 18, and on that basis, denies them.

19. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 19, and on that basis, denies them.

20. Apotex denies the allegations in Paragraph 20.

21. Apotex admits the allegation in the first sentence of Paragraph 21 that Apotex Inc. sent a letter to Actelion Pharmaceuticals U.S., Inc. ("Actelion U.S.") on January 21, 2011 and clarifies that the letter was not sent by Apotex Inc.'s outside counsel, but instead by its Vice-President for Global Intellectual Property, who is a lawyer. The remaining allegations in the first sentence of Paragraph 21 purport to summarize the January 21, 2011 letter, a document that speaks for itself. To the extent that the first sentence of Paragraph 21 alleges facts that are inconsistent with, contrary to, not supported by, or outside the document, those allegations are denied. Apotex lacks knowledge or information sufficient to form a belief about the truth or

falsity of the allegations in the second sentence of Paragraph 21, and on that basis, denies them. Apotex admits the allegations in the third sentence of Paragraph 21.

22. The allegations in the first sentence of Paragraph 22 purport to summarize the January 21, 2011 letter, a document that speaks for itself. To the extent that the first sentence of Paragraph 22 alleges facts that are inconsistent with, contrary to, not supported by, or outside the document, those allegations are denied. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in the second sentence of Paragraph 22, and on that basis, denies them.

23. Apotex admits that Apotex Inc. sent additional letters to Actelion U.S. when a response was not received to the January 21, 2011 letter. The remaining allegations in Paragraph 23 purport to summarize those letters, which are documents that speak for themselves. To the extent that Paragraph 23 alleges facts that are inconsistent with, contrary to, not supported by, or outside the documents, those allegations are denied.

24. Apotex admits that its counsel sent a letter to Actelion U.S. on June 26, 2012, repeating its request to purchase samples of Tracleer for bioequivalence testing, and that Actelion's counsel responded with a letter on July 2, 2012 that refused to sell Apotex such samples. The remaining allegations in Paragraph 24 purport to characterize those letters, which are documents that speak for themselves. To the extent that Paragraph 24 alleges facts that are inconsistent with, contrary to, not supported by, or outside the documents, those allegations are denied.

25. Apotex admits that its counsel sent a letter to Actelion's counsel on August 1, 2012, and that enclosed with the letter was a draft complaint. The remaining allegations in Paragraph 25 purport to summarize the August 1, 2012 letter and the draft complaint, which are

documents that speak for themselves. To the extent that Paragraph 25 alleges facts that are inconsistent with, contrary to, not supported by, or outside the documents, those allegations are denied.

26. Apotex admits that Actelion's counsel sent a letter to Apotex's counsel on August 9, 2012. The remaining allegations in Paragraph 26 purport to summarize the August 9, 2012 letter, a document that speaks for itself. To the extent that Paragraph 26 alleges facts that are inconsistent with, contrary to, not supported by, or outside the document, those allegations are denied.

27. Apotex admits the allegation in the first sentence of paragraph 27 that its counsel sent a letter to Actelion's counsel on August 17, 2012. The remaining allegation in the first sentence of Paragraph 27 and the allegations in the third sentence purport to summarize the August 17, 2012 letter, a document that speaks for itself. To the extent that those sentences allege facts that are inconsistent with, contrary to, not supported by, or outside the document, those allegations are denied. Apotex denies the allegations in the second sentence of Paragraph 27.

28. Apotex admits the allegations in Paragraph 28.

29. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 29, and on that basis, denies them.

30. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 30, and on that basis, denies them.

31. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations in Paragraph 31, and on that basis, denies them.

32. Apotex lacks information or knowledge sufficient to form a belief about the truth or falsity of the allegations in Paragraph 32, and on that basis, denies them.

ACTELION'S LEGAL CONTENTIONS

33. Paragraph 33 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 33 is required, those allegations are denied.

34. Paragraph 34 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 34 is required, those allegations are denied.

35. Paragraph 35 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 35 is required, those allegations are denied.

36. Paragraph 36 states conclusions of law and argument to which no response is required. To the extent that a response to those allegations is required, they are denied. Paragraph 36 also purports to summarize the "REMS statute" (the Food and Drug Administration Amendments Act of 2007, 21 U.S.C. § 355-1), which speaks for itself. To the extent that Paragraph 36 alleges facts that are inconsistent with, contrary to, not supported by, or outside the statute, those allegations are denied. In addition, to the extent that Paragraph 36 infers that the alleged absence of a provision in the "REMS statute" requiring a brand-name drug manufacturer to sell samples of a drug subject to a REMS to a generic drug manufacturer supports Actelion's declaratory judgment action, that inference is denied.

37. Paragraph 37 states conclusions of law and argument to which no response is required. To the extent that a response to those allegations is required, they are denied.

Paragraph 37 also purports to summarize the "House [of Representatives] version of the REMS legislation" and the final "REMS statute," which speak for themselves. To the extent that Paragraph 37 alleges facts that are inconsistent with, contrary to, not supported by, or outside the House bill or the final REMS statute, those allegations are denied. In addition, to the extent that Paragraph 37 infers that the alleged absence of a provision in the REMS statute requiring a brand-name drug manufacturer to sell samples of a drug subject to a REMS to a generic drug manufacturer supports Actelion's declaratory judgment action, that inference is denied.

38. Paragraph 38 states conclusions of law and argument to which no response is required. To the extent that a response to those allegations is required, they are denied. Paragraph 38 also purports to summarize certain amendments to the Food and Drug Administration Safety and Innovation Act that the Senate proposed on May 24, 2012 and the final bill that was enacted on July 9, 2012, which speak for themselves. To the extent that Paragraph 38 alleges facts that are inconsistent with, contrary to, not supported by, or outside the Senate amendments or the final bill, those allegations are denied. In addition, to the extent that Paragraph 38 infers that the alleged absence of a provision in the final bill requiring a brand drug manufacturer to sell samples of a drug subject to a REMS to a generic drug manufacturer supports Actelion's declaratory judgment action, that inference is denied.

39. Paragraph 39 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 39 is required, those allegations are denied.

40. Paragraph 40 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 40 is required, those allegations are denied.

41. Apotex admits the allegations concerning Apotex in the first two sentences of Paragraph 41. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations concerning Roxane in the first two sentences of paragraph 41, and on that basis, denies them. The third and fourth sentences of Paragraph 41 state conclusions of law and argument to which to response is required. To the extent that a response to the allegations in those sentences is required, they are denied.

42. Paragraph 42 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 42 is required, those allegations are denied.

43. Paragraph 43 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 43 is required, those allegations are denied.

44. Paragraph 44 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 44 is required, those allegations are denied.

45. Paragraph 45 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 45 is required, those allegations are denied.

COUNT 1

(Declaratory Relief)

46. Apotex incorporates by reference its responses to Paragraphs 1 through 45 above as if set forth in full.

47. Apotex admits the allegations in the first two sentences of Paragraph 47 that it has attempted to purchase samples of Tracleer from Actelion for the purpose of bioequivalence testing to support the submission of an ANDA, and that Actelion has rejected those attempts. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations concerning Roxane in the first two sentences of Paragraph 47, and on that basis, denies them. The remaining allegations in Paragraph 47 state conclusions of law and argument to which no response is required. To the extent that a response to those allegations is required, they are denied.

48. Apotex admits that it informed Actelion of its intentions to file a civil action seeking injunctive relief, declaratory relief, and money damages if Actelion continued to illegally maintain its monopoly over bosentan – the active ingredient in Tracleer – by refusing to allow generic competitors the opportunity to purchase samples of Tracleer needed for bioequivalence testing necessary to prepare and submit an ANDA. Apotex denies that it "threatened" to file such a lawsuit because Actelion "maintained its rights."

49. Apotex lacks information or knowledge sufficient to form a belief about the truth or falsity of the allegations in Paragraph 49, and on that basis, denies them.

50. Paragraph 50 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 50 is required, those allegations are denied.

51. Paragraph 51 states conclusions of law and argument to which no response is required. To the extent that a response to the allegations in Paragraph 51 is required, those allegations are denied.

GENERAL DENIAL

Except as expressly admitted, Apotex denies each and every allegation contained in Plaintiffs' Complaint and denies that Plaintiffs are entitled to any relief sought in the Complaint or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Apotex hereby asserts the following affirmative defenses without assuming the burden of proof for issues where the burden would not ordinarily be upon the responding party.

First Affirmative Defense

Plaintiffs have failed to state a claim for which relief can be granted.

Second Affirmative Defense

As a result of their own acts and omissions, Plaintiffs are estopped, in whole or in part, from maintaining the claims asserted in, or obtaining the relief sought by, the Complaint.

Third Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the doctrine of laches.

Fourth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the FDA and antitrust laws.

Fifth Affirmative Defense

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

Apotex adopts by reference any additional, applicable defenses pleaded by any other defendant in this case and reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, all defenses under the FDA and antitrust laws, and any other defenses, in law

or in equity, that may now exist or in the future be available based on discovery and further factual investigation in this case.

***

WHEREFORE, Apotex respectfully requests that the Court enter judgment in its favor and against Plaintiffs on their Complaint for declaratory judgment.

COUNTERCLAIM FOR DAMAGES, INJUNCTIVE RELIEF, AND DECLARATORY RELIEF

NATURE OF THE ACTION

1. Actelion is the manufacturer of Tracleer, a brand-name drug containing the active ingredient bosentan. Tracleer is the only drug product of its kind (*i.e.*, with the active ingredient bosentan) approved for marketing by FDA. Actelion therefore controls 100% of the commercial market for bosentan, the first oral treatment approved by FDA for pulmonary arterial hypertension ("PAH"), a chronic and potentially life-threatening disease that severely compromises the functions of the lungs and the heart.

2. As part of the approval process for an abbreviated new drug application ("ANDA") under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the FDA requires an applicant to conduct tests in order to demonstrate that its generic drug product is bioequivalent to the brand-name drug. Drug manufacturers seeking to develop a generic bosentan product must therefore obtain samples of Tracleer, the brand-name drug, to perform bioequivalence testing.

3. Actelion has abused its monopoly power by denying Apotex the ability to purchase Tracleer samples for bioequivalence testing and to submit an ANDA to FDA for a generic bosentan product. As a result, Actelion has thwarted the market entry of any competing products, unlawfully maintaining its monopoly on bosentan in violation of Section 2 of the Sherman Act and New Jersey state law.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action, pursuant to 28 U.S.C. §§ 1331 and 1337, in that this action involves federal questions arising under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26. In addition, this Court has supplemental jurisdiction over the New Jersey state law claims in this action pursuant to 28 U.S.C. §§ 1367, in that those claims are substantially related to the federal antitrust claims and therefore are part of the same case or controversy.

5. Venue is proper in this Court as to Counterclaim-Defendant Actelion Pharmaceuticals, Ltd. ("APL"), pursuant to the provisions of 28 U.S.C. § 1391(b)(2), in that a substantial part of the events or omissions giving rise to this counterclaim – specifically, APL subsidiary Actelion Clinical Research, Inc.'s ("ACR") management of the Tracleer NDA and REMS – occurred in this district. In addition, venue is proper as to APL, pursuant to the provisions of 28 U.S.C. § 1391(c)(3), in that APL is not resident in any judicial district and therefore may be sued in any district.

6. Venue is proper in this Court as to Counterclaim-Defendant ACR, pursuant to the provisions of 28 U.S.C. § 1391(b)(2), in that a substantial part of the events or omissions giving rise to this counterclaim – specifically, ACR's management of the Tracleer NDA and REMS – occurred in this district. In addition, venue is proper as to ACR, pursuant to the provisions of 28 U.S.C. § 1391(b)(1), in that ACR, which has its principal place of business within this judicial district, is subject to personal jurisdiction in this district.

THE PARTIES

7. Counterclaim-Plaintiff Apotex Inc. is a Canadian pharmaceutical company. Founded in 1974, Apotex Inc. is the largest privately-owned Canadian producer of generic drugs.

It produces more than 300 generic drugs and exports its products to more than 115 countries, including the United States.

8. Counterclaim-Plaintiff Apotex Corp. is a Delaware corporation that maintains its place of business in Florida. Apotex Corp. is an affiliate of Apotex Inc.

9. Counterclaim-Defendant APL is a multinational pharmaceutical company based in Allschwil/Basel, Switzerland. APL was founded in 1997, and its annual sales average almost $2 billion. APL has subsidiaries in more than 20 countries and has approximately 2,500 employees.

10. Counterclaim-Defendant ACR is a Delaware corporation that maintains its principal place of business in New Jersey. ACR is an affiliate of APL, and Actelion alleges in its Complaint that ACR manages the Tracleer NDA and REMS in the United States as an agent of APL.

STATUTORY AND REGULATORY BACKGROUND

FDA Approval for Brand-Name Drugs

11. Before marketing a new drug in the United States, a manufacturer must submit a new drug application ("NDA") to FDA, and FDA must approve it. Once approved, new drugs generally are referred to as brand-name drugs because they are marketed under a trade name or trademark for the drug product rather than under the chemical name of the drug product's active ingredient.

12. Among other things, an NDA must contain technical data on the composition of the drug product, including its active ingredient, the means for its manufacture and a statement of its proposed uses. FDA approves a new drug only if it determines, based on evidence submitted by the manufacturer, that the drug is safe and effective for its proposed use(s).

The Hatch-Waxman Amendments and Generic Drugs

13. Congress enacted the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments ("Hatch-Waxman") to the FFDCA, to increase the availability of low-cost generic drugs by expediting the FDA approval process. In recognition of the competing interests of brand-name manufacturers, Hatch-Waxman also provided brand-name manufacturers with a valuable benefit. Under Hatch-Waxman, brand-name drug manufacturers became entitled to five years of exclusivity for new drugs and were given the ability to apply to extend the patent protection for their drugs by an additional five years. *See* 21 U.S.C. § 355(c)(3)(E)(ii); 35 U.S.C. § 156.

14. A generic drug is a version of a brand-name drug that contains the same active ingredient as the brand-name drug but typically sells at a lower cost than the brand-name drug.

15. Generic drugs are frequently prescribed in an effort to control healthcare costs and represent an increasing portion of the medicines used in the United States. The introduction of a generic drug as an alternative to a brand-name drug typically results in a dramatic reduction in the brand-name drug's market share, particularly within the first six months.

16. The Generic Pharmaceutical Association estimates that from 2001 through 2010, the nation's health care system saved $931 billion from the use of generic drugs.

17. Before marketing a generic drug in the United States, a manufacturer must submit an ANDA to FDA, and FDA must approve it. An ANDA applicant must show that its generic drug is as safe and effective as the approved brand-name drug, known as the "reference listed drug" or "RLD," in part by demonstrating that the generic drug is bioequivalent to the RLD. 21 U.S.C. § 355(j)(2)(A). The two drug products are considered bioequivalent if the rate and extent of absorption of the generic drug does not differ significantly from the rate and extent of

absorption of the brand-name drug. FDA has established regulations and scientific guidance on how an applicant can demonstrate bioequivalence.

18. Under Hatch-Waxman, brand companies are required to submit patents claiming an approved drug to FDA for inclusion in the agency's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

19. A generic drug manufacturer is free to perform bioequivalence testing and other research and drug development activities without fear of infringing the patents claiming the RLD that are listed in the Orange Book. The Patent Code expressly states that such research activities shall not constitute an act of infringement. 35 U.S.C. § 271(e)(1).

20. A generic applicant must identify as part of its ANDA any patents listed in the Orange Book for the RLD and must certify as to each such patent (I) that no patent information has been filed with FDA; (II) that the claimed patent has expired; (III) the date on which the filed patent will expire; or (IV) that the filed patent is invalid, unenforceable, or will not be infringed by the generic drug for which approval is sought (the latter of which is known as a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

21. As an incentive for generic applicants to challenge invalid, unenforceable, or non-infringed brand-company patents, Hatch-Waxman awards 180 days of marketing exclusivity to the generic applicant that is first to file with, or as an amendment to, its ANDA a Paragraph IV certification with respect to any patent that the brand company asserts covers the RLD. 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity recipient is known as the "first filer."

Risk Evaluation and Mitigation Strategies

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

23. FDA approved NDA No. 21-290 in November 2001, and Actelion began marketing Tracleer in December 2001.

24. Under the Food and Drug Administration Amendments Act of 2007, FDA has the authority to require Risk Evaluation and Mitigation Strategies ("REMS") from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A REMS can include a medication guide, a patient package insert and potential restrictions on the distribution of the drug (*e.g.*, by requiring practitioners, pharmacies or healthcare settings to obtain special certifications in order to dispense the drug).

25. In enacting the REMS framework, Congress anticipated that brand-name drug manufacturers like Actelion would use REMS programs as a basis for withholding samples of brand-name drugs from generic drug manufacturers like Apotex. Accordingly, Congress enacted section 505-1(f)(8) of the FDCA (21 U.S.C. § 355-1(f)(8)) which prohibits a brand-name drug manufacturer from using a REMS "to block or delay approval of" an ANDA.

FACTUAL BACKGROUND

Bosentan

26. Tracleer is the brand-name drug containing the active ingredient bosentan.

27. Bosentan is a dual endothelin receptor antagonist. It works by blocking endothelin-1 (ET-1), a protein which causes blood vessels to narrow.

28. Tracleer was approved by the FDA in 2001 for the treatment of PAH and was the first oral treatment approved by FDA for such treatment. Currently, there is no generic alternative for Tracleer.

29. The patent for Tracleer (U.S. Patent No. 5,292,740, hereinafter "the '740 Patent") was issued on March 8, 1994. Although the '740 Patent was originally set to expire on June 9,

2012, the patent holder obtained an extension under Hatch-Waxman. With that extension, the patent protection for the '740 Patent will expire on November 20, 2015.

30. Upon information and belief, after the Food and Drug Administration Amendments Act of 2007 was enacted (giving FDA the authority to require REMS from manufacturers), Tracleer became subject to a REMS that was based on the Tracleer Access Program that was adopted in 2001, at the time Tracleer was approved by FDA.

31. Tracleer is extremely expensive, with an average monthly wholesale price of approximately $3,000. However, because of Actelion's monopoly power in this market, it has been able to maintain this premium pricing for Tracleer since its inception.

32. Tracleer has been a blockbuster drug for Actelion. Sales of Tracleer have accounted for a large majority of the company's revenues. In the first nine months of 2012, Actelion's combined worldwide sales of Tracleer were approximately $1.2 billion. Analysts following Actelion's stock have warned that loss of its monopoly over bosentan without a follow-up product to take its place could be financially ruinous for the company. Actelion therefore has a pronounced incentive to maintain its monopoly over bosentan.

Apotex Researches, Develops and Identifies Generic Version of Bosentan

33. As part of its normal research into promising candidates for generic drugs, Apotex identified the opportunity and need for a generic equivalent to Actelion's RLD Tracleer.

34. Apotex then developed a generic drug that it believes is bioequivalent to Tracleer.

35. Before marketing the drug in the United States, Apotex must submit, and obtain approval by the FDA of, an ANDA.

36. Before submitting an ANDA, Apotex must perform sufficient testing to demonstrate the bioequivalence between its generic product and Actelion's Tracleer.

37. To demonstrate bioequivalence, Apotex must obtain a sufficient quantity of Tracleer to perform its bioequivalence testing.

38. Tracleer is therefore an essential facility, access to which is wholly controlled by Actelion.

Apotex Repeatedly Attempts to Purchase Tracleer for Bioequivalence Testing

39. Apotex attempted to purchase samples of Tracleer through normal wholesale distribution channels but was unable to do so. Upon information and belief, Actelion has entered into agreements with the wholesalers and distributors of Tracleer that prevent such wholesalers and distributors from supplying Tracleer samples to Apotex and other generic manufacturers.

40. On January 21, 2011, Apotex sent Actelion a letter seeking to purchase Tracleer samples for bioequivalence testing.

41. In this letter, Apotex noted the quantity and amounts of Tracleer that it sought to purchase and explained the following with respect to its request:

a. The samples sought "would be used to develop a generic equivalent of Tracleer Tablets to be submitted as an ANDA to US FDA. The samples received would be used to analyzing [sic] the reference listed drug Tracleer and also conducting [sic] bioequivalence studies to compare the Apotex Bosentan generic product and Tracleer Tablets. Apotex intends to develop this product for submission to the USFDA as ANDA."

b. The samples were "not for commercial sale and will not be sold in the U.S. to any patient."

c. Apotex was "willing to pay the price per bottle at market value," and "[a]ll reasonably necessary controls will be put into place to control the access and handling of the bottles."

42. Although Apotex noted that it would "appreciate a response in the next few weeks," Actelion never responded to the letter.

43. On April 12, 2011, having received no response to its previous request, Apotex sent another letter to Actelion, repeating its request to purchase samples of Tracleer for bioequivalence testing.

44. This second letter repeated Apotex's commitment to exercise all reasonably necessary controls over the samples and noted again, "*[t]he samples are not for commercial sale and will not be sold in the U.S. to any patient.*" (Emphasis in the original.)

45. The letter again explained that Apotex was seeking the samples of Tracleer in order to conduct bioequivalence testing for inclusion in an ANDA and repeated Apotex's willingness to pay market price for the samples.

46. This second letter noted that Apotex had "not yet heard back from Actelion," and that the letter was designed "to reiterate Apotex's request for samples as again set forth below."

47. Although this letter also asked for a response "in the next few weeks," Actelion never responded to this letter, either.

Apotex Attempts to Use the Canadian Equivalent of Tracleer for Bioequivalence Testing

48. On April 21, 2011, Apotex submitted a letter to the FDA's Office of Generic Drugs ("OGD") describing its attempts to purchase Tracleer from Actelion (as well as a second RLD from a different manufacturer). Apotex further informed OGD that it had procured samples of the Canadian version of Tracleer, which was also manufactured by Actelion, and

argued that the Canadian version of Tracleer was an appropriate substitute for the U.S. RLD for the purpose of bioequivalence testing. Finally, Apotex informed OGD that, because of its inability to procure samples of the RLD in the United States, Apotex intended to conduct a bioequivalence study using the Canadian version of Tracleer and submit the results of this testing in support of an ANDA for a generic alternative to Tracleer. Apotex asked for the FDA's "feedback on the issue at the earliest to ensure that we can plan appropriately to submit the ANDAs on time."

49. On May 10, 2011, Apotex submitted a bioequivalence study protocol to OGD, setting forth the manner in which the bioequivalence study would be performed. Consistent with Apotex's stated intent, the bioequivalence protocol proposed using Tracleer from Canada or Europe for the study.

50. On February 21, 2012, the OGD Division of Clinical Review sent Apotex its comments on Apotex's proposed bioequivalence study protocol for bosentan tablets. Although the agency agreed with the suggestion in Apotex's proposed protocol that the study only involve male subjects to minimize the risk of fetal exposure to bosentan, it recommended certain changes to the protocol in order to ensure that the controls constituted an adequate substitute to those in the REMS governing Tracleer.

51. In its response, the OGD noted that the review by the Division of Clinical Review was conducted exclusively for safety, and that comments on the design of the bioequivalence study were referred to the OGD's Division of Bioequivalence II.

52. On May 21, 2012, the OGD Division of Bioequivalence II provided its comments on the proposed bioequivalence study protocol submitted by Apotex on May 10, 2011. The FDA

stated that the proposed protocol was acceptable, provided that Apotex adopted a number of recommendations.

53. In August 2012, Apotex submitted to OGD a revised protocol incorporating OGD's recommendations. Apotex incorporated all of OGD's recommendations save one, the recommendation that the studies "should be performed using the approved US product as the reference product. It is not acceptable to use an approved Canadian drug product as described in your protocols." Because of Actelion's refusal to sell Apotex the requested samples of Tracleer, Apotex has been unable to procure "the approved US product" to use in its bioequivalence study, as directed by OGD.

Counsel for Apotex Attempts to Acquire Tracleer Samples for Bioequivalence Testing

54. Given the FDA's insistence that Apotex acquire and use samples of the U.S. RLD Tracleer for the bioequivalence study, Apotex tried, for a third time, to obtain these samples from Actelion.

55. On June 26, 2012, counsel for Apotex sent a letter to Actelion reprising Apotex's previous request to purchase sufficient quantities of Tracleer to conduct a bioequivalence study.

56. Counsel for Apotex noted that Actelion had never responded to Apotex's prior attempts to purchase Tracleer for bioequivalence testing, and that Apotex was willing to pay market price for the samples and to implement all reasonably necessary controls for the access and handling of Tracleer under the REMS. Counsel further noted the impropriety of Actelion denying access to its "RLD to thwart efforts by generic manufacturers to bring competing products to market," and that it had been 17 months since Apotex had first requested that Actelion sell Apotex samples of Tracleer for bioequivalence testing. Counsel stated that this delay was causing Apotex economic harm by delaying Apotex's submission of an ANDA for a

competing generic bosentan product. Finally, counsel noted that, while Apotex preferred to avoid litigation, it was "unwilling to further delay its efforts to bring an important generic drug to market because of stonewalling on the part of Actelion."

57. Counsel for Actelion responded by letter dated July 2, 2012. In this letter, Actelion flatly refused to sell Apotex samples of Tracleer for bioequivalence testing, claiming that Actelion "has the right to choose with whom it does business and to whom it will sell its products."

58. Although Actelion's letter cited the existence of the Tracleer REMS, which it argued "does not provide for the sale of Tracleer tablets to Apotex," counsel for Actelion made clear that Actelion's claimed right not to sell Tracleer samples to Apotex "exists independently of the REMS program for Tracleer, and [that Actelion] has concluded that it will not be fulfilling Apotex's request for Tracleer tablets."

59. Actelion's persistent refusal to sell samples of Tracleer to Apotex has caused significant and continuing delay in Apotex's ability to file an ANDA for a generic bosentan product. But for Actelion's refusal to sell such samples, Apotex would have filed an ANDA for a generic bosentan product by late 2011 and would have been in a position to obtain approval of that ANDA, at a minimum, before the protection for the '740 Patent expires in November 2015.

COUNT I

(Violation of Section 2 of The Sherman Act – Unlawful Monopolization)

60. Apotex realleges and incorporates by reference paragraphs 1 through 59 as if set forth in full.

61. The relevant market for Tracleer is the market for bosentan in the United States. This market is characterized by significant entry barriers.

62. Actelion possesses monopoly power in the relevant market for Tracleer. Actelion controls 100% of the commercial market for bosentan, the first oral treatment approved by FDA for PAH.

63. By refusing to sell samples of Tracleer at market prices to Apotex so that Apotex can perform the bioequivalence testing necessary to submit an ANDA for generic bosentan, Actelion has unlawfully and willfully maintained its monopoly power in the relevant market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

64. Actelion's refusal to sell samples of Tracleer at market prices to Apotex for bioequivalence testing was intended to, and did, thwart the entry to market of any competing products, thereby extending its monopoly power in the relevant market.

65. Actelion does not have a legitimate, pro-competitive business purpose for refusing to sell samples of Tracleer at market prices to Apotex.

66. Actelion's refusal to sell Apotex samples of Tracleer at market prices, in furtherance of its unlawful monopoly, has had the effect of delaying the entry of a generic competitor for many months, during which time:

a. Competition in the manufacture, sale and distribution of bosentan is restrained, suppressed and eliminated;

b. Actelion has sold and will continue to sell Tracleer at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and

c. Deprived of the benefits of free and open competition in the purchase of bosentan, patients who purchase Tracleer have been and will continue to be forced to pay artificially high, monopolist's prices for bosentan.

67. As a result of Actelion's unlawful conduct, Apotex has been injured in its business and property, in that Actelion's refusal to sell Apotex samples of Tracleer has prevented and delayed Apotex from bringing a competing generic bosentan product to market, causing Apotex damages in an amount to be determined at trial.

COUNT II

(Violation of Section 2 of The Sherman Act – Essential Facilities)

68. Apotex realleges and incorporates by reference paragraphs 1 through 67 as if set forth in full.

69. The relevant market for Tracleer is the market for bosentan in the United States. This market is characterized by significant entry barriers.

70. It is impossible for a generic manufacturer like Apotex to bring a competing bosentan product to market without access to Tracleer for bioequivalence testing. Tracleer, the distribution of which is controlled by Actelion, is thus an essential facility for the production of generic bosentan, and Actelion is a monopolist with control over this essential facility.

71. By refusing to sell samples of Tracleer at market prices to Apotex so that Apotex can perform the bioequivalence testing necessary to submit an ANDA for generic bosentan, Actelion has controlled an essential facility necessary for the production of bosentan, thereby effectively maintaining its monopoly power in the relevant market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

72. Actelion's refusal to sell samples of Tracleer at market prices to Apotex for bioequivalence testing was intended to, and did, extend its monopoly in the relevant market.

73. Apotex cannot practically or reasonably duplicate samples of Tracleer for the purpose of conducting a bioequivalence study that satisfies FDA's requirements. Indeed, FDA has rejected Apotex's proposal to use samples of the Canadian version of Tracleer to conduct its bioequivalence study. In addition, Apotex cannot obtain samples of the FDA-approved version of Tracleer from other sources, such as Actelion's wholesalers and distributors.

74. It would be feasible for Actelion to sell Apotex samples of Tracleer. Apotex simply would sell Apotex the samples at full market prices, which Apotex has offered to pay. In attempting to purchase samples of Tracleer, Apotex has assured Actelion that the samples would not be sold to any patient in the United States, and that all reasonably necessary controls for the access and handling of the samples under the REMS would be implemented.

75. Actelion does not have a legitimate, pro-competitive business purpose for refusing to sell Apotex samples of Tracleer at market prices.

76. Actelion's refusal to sell Apotex samples of Tracleer at market prices, in furtherance of its unlawful monopoly, has had the effect of delaying the entry of a generic competitor for many months, during which time:

a. Competition in the manufacture, sale and distribution of bosentan is restrained, suppressed and eliminated;

b. Actelion has sold and will continue to sell Tracleer at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and

c. Deprived of the benefits of free and open competition in the purchase of bosentan, patients who purchase Tracleer have been and will continue to be forced to pay artificially high, monopolist's prices for bosentan.

77. As a result of Actelion's unlawful conduct, Apotex has been injured in its business and property, in that Actelion's refusal to sell Apotex samples of Tracleer has prevented and delayed Apotex from bringing a competing generic bosentan product to market, causing Apotex damages in an amount to be determined at trial.

COUNT III

(Violation of The New Jersey Antitrust Act – Unlawful Monopolization)

78. Apotex realleges and incorporates by reference paragraphs 1 through 77 as if set forth in full.

79. The relevant market for purposes of The New Jersey Antitrust Act is the market for bosentan in New Jersey. This market is characterized by significant entry barriers.

80. Actelion possesses monopoly power in the relevant market, controlling 100% of the commercial market for bosentan in New Jersey.

81. By refusing to sell samples of Tracleer at market prices to Apotex so that Apotex can perform the bioequivalence testing necessary to submit an ANDA for generic bosentan, Actelion has unlawfully and willfully maintained its monopoly power in the relevant market, in violation of The New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4.

82. Actelion's refusal to sell samples of Tracleer at market prices to Apotex, in furtherance of its unlawful monopoly, has had the effect of delaying the entry of a generic competitor for many months, during which time:

a. Competition in the manufacture, sale and distribution of bosentan in New Jersey is restrained, suppressed and eliminated;

b. Actelion has sold and will continue to sell Tracleer in New Jersey at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and

c. Deprived of the benefits of free and open competition in the purchase of bosentan, patients who purchase Tracleer in New Jersey have been and will continue to be forced to pay artificially high, monopolist's prices for bosentan.

83. As a result of Actelion's unlawful conduct, Apotex has been injured in its business and property, in that Actelion's refusal to sell Apotex samples of Tracleer has prevented and delayed Apotex from bringing a competing generic bosentan product to market, causing Apotex damages in an amount to be determined at trial.

COUNT IV

(Violation of The New Jersey Antitrust Act – Essential Facilities)

84. Apotex realleges and incorporates by reference paragraphs 1 through 83 as if set forth in full.

85. The relevant market for purposes of The New Jersey Antitrust Act is the market for bosentan in New Jersey. This market is characterized by significant entry barriers.

86. Actelion possesses monopoly power in the relevant market, controlling 100% of the commercial market for bosentan in New Jersey.

87. By refusing to sell Apotex samples of Tracleer at market prices so that Apotex can perform the bioequivalence testing necessary to submit an ANDA for generic bosentan, Actelion has controlled an essential facility necessary for the production of bosentan, thereby

effectively maintaining its monopoly power in the relevant market, in violation of The New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4.

88. Actelion's refusal to sell Apotex samples of Tracleer at market prices, in furtherance of its unlawful monopoly, has had the effect of delaying the entry of a generic competitor for many months, during which time:

a. Competition in the manufacture, sale and distribution of bosentan in New Jersey is restrained, suppressed and eliminated;

b. Actelion has sold and will continue to sell Tracleer in New Jersey at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and

c. Deprived of the benefits of free and open competition in the purchase of Tracleer, patients who purchase Tracleer in New Jersey have been and will continue to be forced to pay artificially high, monopolist's prices for bosentan.

89. As a result of Actelion's unlawful conduct, Apotex has been injured in its business and property, in that Actelion's refusal to sell Apotex samples of Tracleer has prevented and delayed Apotex from bringing a generic bosentan product to market, causing Apotex damages in an amount to be determined at trial.

COUNT V

(Tortious Interference with an Economic Advantage)

90. Apotex realleges and incorporates by reference paragraphs 1 through 89 as if set forth in full.

91. Apotex has a reasonable expectation of economic advantage from a prospective economic relationship with individuals suffering from PAH, to whom it would sell a generic bosentan product.

92. Actelion is aware of Apotex's intention to submit an ANDA for a generic bosentan product and has been so aware since at least January 2011. Accordingly, Actelion is aware of Apotex's reasonable expectation of economic advantage from sales of a generic bosentan product.

93. By refusing to sell Apotex samples of Tracleer at market prices so that Apotex can perform the bioequivalence testing necessary to submit an ANDA for generic bosentan, Actelion has intentionally and maliciously interfered with Apotex's reasonable expectation of economic advantage from sales of a generic bosentan product. Actelion does not have a legitimate, pro-competitive business purpose for refusing to sell Apotex samples of Tracleer at market prices.

94. In the absence of Actelion's refusal to sell Apotex samples of Tracleer, there is a reasonable probability that Apotex would be able to sell a generic bosentan product to individuals suffering from PAH and would realize an economic benefit from such sales.

95. Actelion's tortious interference has directly and proximately caused injury to Apotex's business and property, including but not limited to lost profits and lost business opportunities.

COUNT VI

(Mandatory Injunctive Relief)

96. Apotex realleges and incorporates by reference paragraphs 1 through 95 as if set forth in full.

97. Apotex has a reasonable probability of success on the merits.

98. Apotex's right to relief, in the form of access to sufficient samples of Tracleer to enable it to perform bioequivalence testing in support of an ANDA, is clear.

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

100. Apotex does not have an adequate remedy at law.

101. Granting immediate injunctive relief to Apotex will not result in greater harm to Actelion.

102. Granting immediate injunctive relief to Apotex 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 potentially fatal disease, resulting in competition in the relevant product and geographic markets.

103. Apotex is entitled to a mandatory and immediate injunction pursuant to 15 U.S.C. § 26 and Fed. R. Civ. P. 65, requiring Actelion to sell Apotex sufficient quantities of Tracleer tablets at market prices so that Apotex can perform the bioequivalence testing necessary to support an ANDA for a generic bosentan product.

COUNT VII

(Declaratory Relief)

104. Apotex realleges and incorporates by reference paragraphs 1 through 103 above as if set forth in full.

105. Apotex seeks to submit an ANDA to manufacture generic bosentan. The OGD has stated that this ANDA must demonstrate bioequivalence based on bioequivalence studies performed using the RLD (*i.e.*, FDA-approved) Tracleer.

106. Apotex has requested that Actelion sell Apotex sufficient samples of Tracleer to perform this bioequivalence testing, and has indicated that it will pay Actelion market price for these samples and will take all reasonably necessary and appropriate precautions in handling the drug.

107. Nevertheless, Actelion has refused to sell samples of Tracleer to Apotex and has claimed that it has no obligation to sell Tracleer to Apotex.

108. Thus, a dispute currently exists between Actelion and Apotex with respect to Actelion's obligation to sell Apotex samples of Tracleer for bioequivalence testing.

109. Apotex is therefore entitled, pursuant to the Declaratory Judgments Act, 28 US.C. §§ 2201 and 2202, to a declaration of rights and obligations whereby Actelion is obliged to sell Apotex sufficient quantities of Tracleer at market prices so that Apotex can perform the bioequivalence testing necessary to support an ANDA for a generic bosentan product.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests judgment in its favor and against Actelion as follows:

a. Granting preliminary and permanent mandatory injunctive relief pursuant to 15 U.S.C. § 26, Fed. R. Civ. P. 65, and N.J. Stat. Ann. § 56:9-10 compelling Actelion to sell Apotex sufficient quantities of Tracleer at market prices so that Apotex can perform bioequivalence testing;

b. Compensatory damages for Apotex's lost sales of generic bosentan, and profits on those sales, that are caused by Apotex's delay in submitting an ANDA;

c. Treble damages pursuant to 15 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;

d. An award of attorneys' fees and costs pursuant to 28 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;

e. A declaration that Actelion is required to sell Apotex sufficient samples of Tracleer so that Apotex can perform bioequivalence testing; and

f. Such other and further relief as the Court deems just and proper.

JURY DEMAND

Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. demand a trial by jury on all issues so triable.

Dated: November 27, 2012

Respectfully submitted,

s/A. Richard Feldman
A. Richard Feldman
Michael A. Shapiro
BAZELON, LESS & FELDMAN, P.C.
A Pennsylvania Professional Corporation
8000 Sagemore Drive, Suite 8302
Marlton, NJ 08053
Tel: (856) 988-1319
Fax: (856) 988-0194
Email: afeldman@bazless.com
mshapiro@bazless.com

Aitan D. Goelman (*pro hac vice*)
Alexandra W. Miller (*pro hac vice*)
Paul B. Hynes, Jr. (*pro hac vice*)
Zuckerman Spaeder LLP
1800 M Street, NW
Washington, DC 20036
Tel: (202) 778-1800

Fax: (202) 822-8106
Email: agoelman@zuckerman.com
smiller@zuckerman.com
phynes@zuckerman.com

LOCAL RULE 11.2 CERTIFICATION

I, A. Richard Feldman, hereby certify that the matters in controversy in the foregoing Answer, Affirmative Defenses, and Counterclaim of Apotex Inc. and Apotex Corp. are not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

s/A. Richard Feldman
A. Richard Feldman