UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GOVERNMENT EMPLOYEES HEALTH ASSOCIATION on behalf of itself and all others similarly situated, 310 NE Mulberry Street Lees Summit, Missouri 64086-5861 County of Residence: Jackson County Plaintiff, v. ACTELION PHARMACEUTICALS LTD. Gewerbestrasse 16, CH-4123 Allschwil, Switzerland and ACTELION PHARMACEUTICALS US, INC. 5000 Shoreline Court, Suite 200, South San Francisco, California 94080 County of Residence: San Mateo County and ACTELION CLINICAL RESEARCH, INC. 1820 Chapel Avenue West, Suite 300, Cherry Hill, New Jersey 08002 County of Residence: Camden County Defendants.	CIVIL ACTION NO. _____ CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Plaintiff, the Government Employees Health Association, brings this action on behalf of itself, and all others similarly situated, against Actelion Pharmaceuticals Ltd., Actelion Clinical Research, Inc., and Actelion Pharmaceuticals US, Inc. (collectively, "Defendants" or "Actelion"). These allegations are based on publicly available materials and knowledge, information, and belief.

I. INTRODUCTION

1. This case arises from Actelion's illegal scheme to maintain its monopoly over the prescription drug bosentan. Bosentan is a dual endothelin receptor antagonist that Actelion sells as a treatment for pulmonary artery hypertension ("PAH") under the brand name "Tracleer." PAH is a relatively rare, but chronic, and potentially fatal disorder in which elevated blood pressure in the arteries of the lungs causes the heart to work harder than normal. It affects between 10,000 and 20,000 people in the U.S. — most of them women. PAH is a progressive condition. Without treatment, only about 70% of patients survive a year after diagnosis. PAH is also an extremely expensive condition to treat. In 2016, America's Health Insurance Plans, an industry organization of health insurers, estimated that average drug spending for PAH patients was between $103,464 and $196,560 per year.

2. While Tracleer is a highly profitable drug (billions in sales for Actelion) and Actelion's regulatory and patent exclusivity over the use of bosentan to treat PAH expired by November 20, 2008 and November 20, 2015, respectively, no generic manufacturer has brought a generic bosentan to market. Why? Not for lack of interest. At least four manufacturers started the process of bringing a generic bosentan to market, but Actelion unlawfully blockaded the regulatory process for generic manufacturers to proceed and, thereby, illegally maintained its monopoly over bosentan.

3. Specifically, Actelion blocked would-be generic bosentan manufacturers from obtaining samples of Tracleer. To obtain FDA approval of a generic drug application, a generic manufacturer must run comparison tests to establish that the brand and the generic are bioequivalent — that is, that the generic is absorbed in the body at the same rate and to the same extent as the brand. Doing so requires samples of the brand product. Without these samples, generic manufacturers cannot complete the regulatory process and cannot bring a competing generic to market.

4. Actelion prevented would-be generic bosentan competitors from purchasing samples of Tracleer by forbidding its distributors from selling Tracleer to those generic manufacturers and refusing to sell Tracleer directly to the manufacturers as well. By doing both, Actelion blocked every path generic manufacturers had to obtain samples of Tracleer.

5. Actelion admits that it included restrictive language in contracts with all of its Tracleer distributors that prevents those distributors from selling Tracleer to generic manufacturers. This admission is confirmed by the experience of all four would-be generic manufacturers who unsuccessfully attempted to purchase Tracleer samples from the distributors.

6. Unable to get samples of Tracleer from distributors as they usually would, at least four generic manufacturers requested samples directly from Actelion, offering to pay the market price for the samples. Actelion refused, offering subterfuge for its reason. Tracleer carries risks of serious liver damage and birth defects if taken during pregnancy. Therefore, the FDA approved Actelion's New Drug Application ("NDA") for Tracleer subject to two restrictions: (1) a "black box" warning on Tracleer's packaging, and (2) Actelion's implementation of a Risk Evaluation and Mitigation Strategy ("REMS") for Tracleer. Actelion cited its REMS as the reason it would not sell to would-be generic competitors.

7. In particular, Actelion cited the safety protocols imposed by FDA as the reason it refused to sell Tracleer samples to generic manufacturers (and the reason it prevented its distributors from selling them as well). Congress has specified however, that REMS may *not* be used to delay generic competition. The FDA has also expressly indicated that REMs do *not* prevent distributors from selling samples to generics nor empower the NDA holder to veto such sales. Indeed, the FDA has repeatedly confirmed that allowing the generics to buy samples *does not* run afoul of the FDA's required safety protocols, both generally and with respect to Tracleer specifically.

8. Actelion's invocation of its REMS protocols was inconsistent. Actelion freely permitted other *non-competitor* research entities to buy Tracleer for testing purposes, but it denied samples to generics under the guise of those safety protocols. Ultimately, Actelion admitted its true purpose: squelching generic competition.

9. Actelion wanted to keep its competitors out of the market in order to prevent competition and prolong its monopoly well past its period of legitimate exclusivity. This is the only logical explanation for Actelion foregoing potential sales, but it is illegal. The FTC, the FDA, courts, and commentators all agree that the antitrust laws do not tolerate such exclusionary conduct.

10. Actelion's anticompetitive scheme has been 100% effective. To date, no generic Tracleer is available in the U.S. nearly three years after the expiration of the Tracleer patent.

11. Actelion's scheme has forced Plaintiff and other purchasers to pay higher prices for bosentan for far longer than they otherwise would have. Absent Actelion's years-long blockade, one or more generics would have been available at or around the expiration of Tracleer's patent protection in November 2015.

12. Plaintiff brings this action as a purchaser of Tracleer, on its own behalf and on behalf of all similarly situated purchasers. Defendants' unlawful conduct has prevented generic manufacturers from entering the market with competing generic bosentan products and has cost purchasers hundreds of millions of dollars in overcharge damages.

13. Plaintiff and the proposed class seek to recover damages, including treble damages, under the state antitrust and consumer protection laws enumerated below or, in the alternative, under Section 2 of the Sherman Act[1] and Sections 4 and 16 of the Clayton Act.[2] Plaintiff and members of the class also seek a permanent injunction under Section 16 of the Clayton Act, 15 U.S.C. § 26, prohibiting Actelion from denying samples of Tracleer to prospective Abbreviated New Drug Applications ("ANDA") filers. Unless enjoined, Actelion will continue its unlawful conduct and Plaintiff and the proposed class will continue to bear the financial brunt of Actelion's antitrust violations.

II. JURISDICTION AND VENUE

14. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs; there are more than one hundred members of the class; and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

15. In the alternative, the Court has jurisdiction over this action pursuant to Section 2 of the Sherman Act and Sections 4 and 16 of the Clayton Act and requests injunctive and equitable relief and seeks to recover overcharge and treble damages for injuries sustained by Plaintiff and

[1] 15 U.S.C. § 2.

[2] 15 U.S.C. §§ 15(a), 26.

the class resulting from Defendants' unlawful foreclosure of the United States market for bosentan. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

16. Defendants transact business within this District and/or have agents in and/or that can be found in this District. Venue is appropriate in this District under Section 12 of the Clayton Act[3] and under 28 U.S.C. § 1391(b) and (c).

17. The Court has personal jurisdiction over each of Defendants. Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District.

III. THE PARTIES

18. Plaintiff, the Government Employees Health Association ("GEHA") is a not-for-profit corporation providing health and dental plans to federal employees and retirees and their families through the Federal Employees Health Benefits Plan and the Federal Employees Dental and Vision Insurance Program. GEHA is the second-largest national health plan and the second-largest national dental plan serving federal employees, federal retirees and their families, providing benefits to nearly 1.5 million covered lives with federal employee members residing in all 50 states as well as the District of Columbia and Puerto Rico. GEHA is organized under the laws of Missouri and its principal place of business is located at 310 NE Mulberry Street, Lees Summit, Missouri 64086-5861.

19. Defendant Actelion Pharmaceuticals Ltd. is a Swiss corporation having its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

[3] 15 U.S.C. § 22.

20. Defendant Actelion Pharmaceuticals US, Inc. is a Delaware corporation having its principal place of business at 5000 Shoreline Court, Suite 200, South San Francisco, California 94080. Actelion Pharmaceuticals US, Inc. is a subsidiary of Defendant Actelion Pharmaceuticals Ltd.

21. Defendant Actelion Clinical Research, Inc. is a Delaware corporation having its principal place of business at 1820 Chapel Avenue West, Suite 300, Cherry Hill, New Jersey 08002. Actelion Clinical Research, Inc. is a subsidiary of Defendant Actelion Pharmaceuticals Ltd. According to Actelion, Actelion Clinical Research, Inc. manages the Tracleer NDA and the Tracleer REMS in the United States as an agent for Actelion Pharmaceuticals Ltd.

22. Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. were acquired by Johnson & Johnson for an estimated $30 billion on June 16, 2017 and are now part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

23. All three defendant entities are referred to individually and collectively herein as "Actelion."

24. Defendants' wrongful actions described in this complaint are part of, and were taken in furtherance of the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment and with their actual, apparent, or ostensible authority.

IV. ECONOMIC BACKGROUND

25. The marketplace for the sale of prescription pharmaceutical products in the United States is unusual. In most industries, the person who pays for a product is also the person who chooses the product. When the same person has both the payment obligation and the choice of

products, the price of the product plays a predominant role in the person's choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

26. The pharmaceutical marketplace, in contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the payment obligation and the product selection. The patient (or his or her insurer) has the obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

27. In 1984, Congress sought to ameliorate the "disconnect," by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed further below. Now, when a pharmacist receives a prescription for a branded drug and an AB-rated[4] generic version of that drug is available, state laws permit (and in many cases require) the pharmacist to dispense the generic instead of the brand. In this way, price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is lessened. When an AB-rated generic equivalent is introduced and not prevented from competing, brand manufacturers can no longer exploit the "disconnect," their monopoly power dissipates, and some of the normal competitive pressures are restored.

[4] AB-rated generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their brand name counterparts. Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic.

28. Because AB-rated generic versions of brand-name drugs contain the same active ingredients and are determined by the FDA to be just as safe and effective as their branded counterparts, the only material differences between generic drugs and their branded counterparts are their prices and manufacturers. Because AB-rated generic versions of branded products are commodities that cannot otherwise be differentiated, the primary basis for generic competition is price.

29. Typically, generics are at least 25% less expensive than their branded counterparts when there is a single generic competitor. They are 50% to 80% (or more) less expensive when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a bioequivalent generic drug usually results in significant cost savings to all drug purchasers.

30. The combination of these factors — the regulatory interchangeability of bioequivalent generics for the brand, state substitution laws, margin incentives of pharmacies, and the like — results in the typical phenomenon that once a brand drug "goes generic," the product swiftly moves from a monopoly priced to a commodity priced item.

31. Generic competition enables all members of the proposed class to purchase generic versions of the drug at substantially lower prices and to purchase the brand drug at a reduced price.

32. The Hatch-Waxman Act has significantly advanced the rate of generic drug launches while also ushering in an era of historically high profits for brand drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total annual prescription drug revenue had soared to $300 billion.

33. The Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. As a result, brand drug manufacturers view competition from generics as a grave threat to their bottom lines.

34. When a brand drug faces generic drug competition, purchasers are able to (a) purchase generic versions of the drug at much lower prices; and/or (b) purchase the brand drug at a reduced price. Until the generic version of a brand drug enters the market, however, there is no bioequivalent generic to substitute for, and compete with, the branded drug, so the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand drug manufacturers, well aware of the rapid erosion of brand drug sales by generics, have a strong incentive to delay the start of generic drug competition. Brand manufacturers often seek to extend their monopolies by any means possible, sometimes even resorting to illegal ones.

V. REGULATORY BACKGROUND

A. A New Drug Application must show that the brand drug is safe and effective.

35. Under the Federal Food, Drug, and Cosmetics Act ("FDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Amendments"), drug companies who wish to sell a *new* drug product must file a New Drug Application ("NDA") with the FDA. An NDA submission must include specific data concerning the safety and effectiveness of the drug, including information from at least two clinical trials.

36. An NDA applicant must submit to the FDA information about each patent that purportedly covers the drug product or methods-of-using the drug product described in the NDA and for which "a claim of patent infringement could reasonably be asserted if a person not licensed

by the owner engaged in the manufacture, use, or sale of the drug."[5] The FDA then publishes this information in a digest titled *Approved Drug Products with Therapeutic Equivalence Ratings* (known as "the Orange Book").

37. The FDA performs only a ministerial act in listing patents in the Orange Book. The FDA does not have the resources or authority to verify the manufacturer's representations for accuracy or trustworthiness. Thus, the FDA relies completely on the manufacturer's truthfulness about the information it supplies for the Orange Book, including whether the listed patent is valid and may reasonably be asserted against a generic applicant.

38. Once a brand manufacturer lists a patent in the Orange Book, that listing puts potential generic competitors on notice that the brand considers the patent to cover its drug. The listing triggers important regulatory consequences.

B. An Abbreviated New Drug Application must show that the generic is pharmaceutically equivalent and bioequivalent to the brand.

39. One of the primary ways that the FDA facilitates a competitive marketplace is through the efficient approval of generic drugs. Generics cost less than brand drugs. Although generic drugs account for 80% of prescriptions filled in the United States, they comprise only about 27% of overall prescription drug costs.

40. Congress passed the Hatch-Waxman Amendments to the FDAC to balance the need to provide brand companies with incentives to develop new medicines against the countervailing need to speed the entry of cheaper, equally effective generic versions of these medications. According to the FDA, "[i]n passing the 1984 Hatch-Waxman Amendments to the Federal Food,

[5] 21 U.S.C. § 355(b)(1), (c)(2).

Drug, and Cosmetic Act, Congress created a system that balances encouraging and rewarding medical innovation with facilitating robust and timely market competition."[6]

41. The Hatch-Waxman Amendments were designed to ensure the timely introduction of generic drugs in the market. To speed the introduction of low-cost generic drugs to market, the amendments enable generic manufacturers to file ANDAs with the FDA. Rather than requiring generic manufacturers to conduct expensive clinical trials to re-prove the drugs' safety and efficacy, Congress chose to allow generic manufacturers to rely on the data that the brands have already submitted to prove the drugs' safety and efficacy.

42. Instead of conducting their own clinical trials, generic manufacturers must show that their generic versions are both pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the already-approved brand drug. The premise — codified by Congress and implemented by the FDA for the past thirty years — is that two drug products containing the same active pharmaceutical ingredient, in the same dose, delivered the same way, and at the same speed, are equally safe and effective.

43. Specifically, an ANDA applicant must show that the drug product described in the ANDA contains the same active ingredient, same conditions of use, same route of administration, same dosage form, same strength, and same (with certain permissible differences) labeling, and must show that the same amount of the drug gets into the blood stream over the same time period as the brand drug.

---

[6] *Reference Listed Drug (RLD) Access Inquiries*, FDA (Aug. 13, 2018), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm ("*RLD Access Inquiries*").

1. Congress gave the FDA broad discretion to evaluate bioequivalence.

44. The FDCA states that a generic drug is "bioequivalent" to the brand drug (referred to as the "reference listed drug" or "RLD") if "the rate and extent of absorption of the [generic] drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses."[7]

45. Bioequivalence testing determines whether differences in formulation (*e.g.*, differences in inactive ingredients) between a proposed generic drug and the reference-listed drug have an impact on the rate and extent to which the active ingredient becomes available at the site of action. The statute, regulations, and case law give the FDA considerable flexibility in determining how the bioequivalence requirement may be met. The testing methods may include *in vivo* data (data from a study on live subjects), *in vitro* data (data from laboratory studies), or both. The selection of the method used to meet an *in vivo* or *in vitro* testing requirement depends upon the purpose of the study, the analytical methods available, and the nature of the drug product. Applicants are required to conduct bioavailability and bioequivalence testing using the most accurate, sensitive, and reproducible approach available. The method used must be capable of measuring bioavailability or establishing bioequivalence, as appropriate, for the product being tested.

46. For systemically acting drug products (like most ordinary pills), the rate and extent of systemic absorption of the drug is usually the most sensitive, accurate, and reliable indicator of the rate and extent to which the active ingredient becomes available at the site of drug action. The determination of the bioequivalence of a drug product whose primary mechanism of action

[7] 21 U.S.C. § 355(j)(8)(B)(i); *see also* 21 C.F.R. § 320.23(b).

depends on systemic absorption generally rests on a comparison of the drug and/or metabolite concentrations in an accessible biological fluid, such as blood or urine, after administration of a single dose or multiple doses of the drug product to healthy volunteers.

2. Samples are essential for generic companies to establish bioequivalence.

47. A company seeking to show that its proposed generic drug is bioequivalent to the branded counterpart must have access to samples of that counterpart. As a general matter, without samples, it is virtually impossible to complete and file an ANDA application for a systemically acting product.

48. FDA regulations require ANDA applications to include "[e]vidence demonstrating that the drug product that is the subject of the [ANDA] is bioequivalent to the reference listed drug . . ." including "[a] complete study report . . . for the bioequivalence study upon which the applicant relies for approval."[8]

49. The regulations giving guidelines on the design of bioequivalence and bioavailability studies all refer to a comparison of the drug product to be tested and "the appropriate reference material," *i.e.*, the approved drug product.[9]

50. The FDA has explained why samples are so important:

> **Why are samples of the RLD important to a prospective ANDA applicant?**
>
> To obtain approval for a generic drug, the generic company needs to show, among other things, that its version of the product is bioequivalent to the RLD [*i.e.*, the brand drug, or reference listed drug]. This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain samples of the RLD used in testing after a study is complete. To conduct these kinds of bioequivalence studies, the generic

[8] 21 C.F.R. § 320.21(b)(1).

[9] 21 C.F.R. § 320.25–320.27.

company needs to obtain samples (generally between 1,500 and 5,000 units) of the RLD.[10]

51. Only samples of the reference listed drug approved by the FDA and marketed in the United States ("U.S. samples") may be used for bioequivalence testing purposes.

52. In the ordinary course, an ANDA applicant obtains samples by buying them, at the market price, from a drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from brand and generic manufacturers for the purposes of re-selling them to pharmacies or other wholesalers.

53. Generic companies are authorized — as research institutions or otherwise — to buy prescription drugs from distributors for testing purposes.

3. Other features of the generic drug approval pathway.

54. *Patent information/certification.* An ANDA must include one of the following four certifications with respect to the patents covering the branded drug it seeks to produce:

i. That such information has not been filed (a "Paragraph I certification");

ii. That such patent has expired (a "Paragraph II certification");

iii. The date on which such patent will expire (a "Paragraph III certification"); or

iv. That such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (a "paragraph IV certification").[11]

55. *Conducting bioequivalence testing does not constitute infringement.* The Hatch-Waxman Amendments also made clear that conducting bioequivalence testing with another manufacturer's patented drug product does not infringe that product's patents.

[10] *RLD Access Inquiries.*

[11] 21 C.F.R. 355(j)(2)(A)(vii)(I)-(IV).

56. *505(b)(2) applications are not ANDAs.* Under certain circumstances, a manufacturer may use a different abbreviated approval pathway in order to receive approval to sell a drug, namely, a 505(b)(2) application.

57. A 505(b)(2) application, like a typical NDA, must contain full reports of investigations of safety and effectiveness of the drug product it describes. Unlike a typical NDA, however, the application confirms that "one or more of the investigations relied upon by the applicant for approval 'were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.'"[12]

58. A 505(b)(2) application is usually used for changes to a previously approved drug product, such as a change in dosage form, strength, and/or route of administration from a previously approved product.

59. A 505(b)(2) application cannot be used to obtain approval for a duplicate of an approved product and/or a product that is eligible for approval through the ANDA pathway. The FDA has stated that it will generally "refuse to file a 505(b)(2) application for a drug that is a duplicate of a listed drug and eligible for approval under section 505(j) of the FD&C Act."[13]

60. A 505(b)(2) application will not necessarily be rated therapeutically equivalent to the listed drug it references upon approval (and so would not be automatically substituted for the

[12] Draft Guidance on Applications Covered by Section 505(b)(2) from the FDA's Center for Drug Evaluation and Research at 2, 11 (October 1999), https://www.fda.gov/downloads/Drugs/Guidances/ucm079345.pdf (quoting 21 U.S.C. § 355(b)(2)).

[13] Draft Guidance on Determining Whether to Submit an ANDA or a 505(b)(2) Application from the FDA's Center for Drug Evaluation and Research at (October 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM579751.pdf.

brand at the pharmacy). Even so, a manufacturer submitting a 505(b)(2) application will, in most cases, need to conduct bioequivalence testing comparing the proposed drug and the reference listed drug.

C. The FDA sometimes imposes REMS.

61. Since at least the 1960s, the FDA has been experimenting with different ways to manage risks related to pharmaceutical products. These efforts began with disclosure requirements, mandating that manufacturers provide complete information about a drug's indications, side effects, dosing, among other information, to healthcare professionals. The Controlled Substances Act of 1970[14] added regulations governing manufacturers, prescribers, dispensers, and labelers, and allowing the FDA to require, *inter alia*, boxed warning messages on packaging and "Dear Healthcare Provider" letters from drug makers.

62. In the 1990s, the FDA began working together with drug manufacturers to develop risk management programs for drugs with potentially dangerous side effects.

63. In the mid-2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs"), a voluntary system by which drug sponsors implemented risk minimizing plans to address known safety risks.

64. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA").[15] Section 505-1(a)(1) of the FDAAA authorizes the FDA to require that sponsors of drug applications submit a proposed REMS if the agency determines that such is needed to ensure that a drug's benefits outweigh its safety risks. A REMS can include a medication guide, patient

[14] 21 U.S.C. 801 *et seq*. (2002).

[15] Pub. L. No. 110-85, 121 Stat. 823.

package inserts, and/or restrictions on the distribution of the drug (*e.g.*, by requiring practitioners, pharmacies, or healthcare settings to obtain special certifications before dispensing the drug).

65. In determining whether a REMS for a particular drug will be required, the FDA considers factors including (1) the population size likely to use the drug; (2) the seriousness of the disease; (3) the drug's expected benefit; (4) the expected duration of treatment; (5) the seriousness of adverse effects; and (6) the drug's novelty. The FDA can require a REMS before a drug enters the market, based on known risks, or after a drug has been approved based on new evidence of risk.

66. Every REMS must include a timetable for submission of periodic reports to the FDA regarding the program. Other requirements vary depending on the risk profile of the particular drug and the need to inform doctors or patients of safety concerns. REMS programs differ in their level of restriction. The "least restrictive" program includes medication guides for patients and communication plans for healthcare practitioners.

67. Some REMS programs have "Elements To Assure Safe Use (ETASU)." These may require, *e.g.*, that prescribers have particular training, that entities that dispense the drug be "specially certified," and that, if the drug is dispensed to patients, certain requirements are met.

68. The statute's stated purpose is to "provid[e] safe access for patients to drugs with known serious risks that would otherwise be unavailable," including mandating access to trainings or certifications to "any willing provider"[16] in some areas. ETASUs, in other words, are *not* intended to make drugs less available. Rather, they are intended only to give the FDA the authority to condition drug approval on the implementation of a program with defined elements necessary to address the known serious risks of particular products.

[16] 21 U.S.C. § 355 1(f)(3)(A) and (B).

69. These ETASU requirements can, in practical effect, restrict a drug's distribution and how it may be sold to consumers. For example, not all prescribers or distributors may want to take on the responsibility of complying with ongoing certification or reporting requirements. The statute, however, does *not* contemplate that ETASU may require that the drug be distributed by *only* a handful of entities, that the drug be distributed or sold *only* to patients, nor that the brand company be able to dictate to whom distributors may re-sell its drug. Rather, it lists steps for training, certification, or monitoring of health care providers, pharmacies, health care settings, or patients.

70. ETASU measures are "designed to be compatible with established distribution, procurement, and dispensing systems for drugs."[17] The FDA has sought to ensure that ETASU requirements do not burden patients who "have difficulty accessing health care (such as patients in rural or medically underserved areas)" or those with "serious or life-threatening diseases or conditions."[18]

71. Since their enactment in 2007, REMS — and in particular, ETASU requirements — have been increasingly common in the FDA approval process. Roughly 40% of new drugs have REMS programs.

72. Nothing in the REMS statute, the ETASU provision, or elsewhere in the applicable statute prohibits the sales of REMS-controlled drugs to qualified generic companies that will use those drugs in controlled, FDA-required bioequivalence testing.

[17] 21 U.S.C. § 355 1(f)(2)(C)ii.

[18] 21 U.S.C. § 355 1(f)(2)(C)i.

73. Nothing in the REMS statute, the ETASU provision, or elsewhere in the applicable statute gives an NDA holder the right to interfere with a competitors' ability to purchase necessary samples.

D. Brand manufacturers can unlawfully abuse REMS to delay or block generic competition.

74. Competition from generics decimates a brand drug companies' profits because the presence of generics in the market dramatically lowers prices for drug purchasers and captures most of the brand's market share. Brand manufacturers like Actelion are thus highly motivated to keep generics off the market thereby extending their monopolies for as long as possible. Sometimes brand manufacturers resort to illegal means.

75. As the FDA has explained: "One of the primary ways that FDA facilitates a competitive marketplace is through the efficient approval of generic drugs, which are often lower cost than brand drugs. Unfortunately, the process established by Congress may not always function as intended. At times, certain 'gaming' tactics have been used to delay generic competition."[19]

76. An increasingly common "gaming" tactic that brand manufacturers use to delay or defeat generic competition is denying would-be generic competitors access to the sample quantities of the brand drug they need to conduct bioequivalence testing. As a leading FDA official testified in 2016, brand companies sometimes use REMS programs designed to ensure safety "as an excuse to not give the drug to the generics so they can compare it to their drug." She noted that such behavior causes "barriers and delays in getting generics on the market."[20]

---

[19] *RLD Access Inquiries*.

[20] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

77. The FDA has also looked at the issue of why prospective generic applicants encounter roadblocks to obtaining samples of the RLD:

> Often, generic companies are able to obtain RLD samples through normal drug distribution channels, *i.e.*, via wholesalers. Sometimes, however, samples of the RLD are not available through normal distribution channels. A drug may not be available through standard distribution channels because the RLD sponsor limits the distribution of the drug (for example, by selling it through a central or small group of pharmacies) on its own initiative for a variety of business reasons. In other cases, a REMS with elements to assure safe use (ETASU) might impact the way the product is distributed. For example, only a limited number of pharmacies might be willing and/or able to meet the specific pharmacy certification requirements in a REMS. Once such limitations are in place, we understand that some RLD sponsors (1) refuse to sell the product directly to the generic company (or impose terms on the sale that generic companies find burdensome or impossible to comply with), or (2) place limitations on the ability of pharmacies or wholesalers to sell samples to the generic companies for development purposes.[21]

78. Thus, while generic applicants must have access to sufficient quantities of the brand drug to conduct the bioequivalence testing required for submitting an ANDA, some brand companies resort to the REMS's restricted distribution provisions as a pretext for refusing to sell (or prohibiting their distributors from selling) samples of their drugs to would-be generic competitors.

79. Indeed, Congress anticipated that brand drug manufacturers might improperly try to maintain monopoly profits in this way. When it enacted the FDAAA, it thus included § 505-1(f)(8), explicitly prohibiting brand drug manufacturers from using a REMS "to block or delay approval of" an ANDA, in the statute.

80. The FDA has noted that when brand companies use REMS or other limited distribution programs "as a basis for blocking potential generic applicants from accessing the

[21] *RLD Access Inquiries*.

samples [of the RLD]," the generic drug development process "slows down[] or [is] "entirely impede[d] . . . leading to delays in bringing affordable generic alternatives to patients in need."[22]

81. Such conduct undermines the competition between brands and generics that is at the heart of the Hatch-Waxman Act. A brand drug maker's strategic refusal to sell samples to generics also flouts the statute's direct prohibition on using a REMS program to block or delay ANDAs by preventing would-be generic competitors from accessing samples of drugs.

82. When brand manufacturers play this "game," generic companies have no recourse. A generic manufacturer cannot buy the drug from its normal suppliers, because the brand company is refusing to allow the distributor to sell to the generic (often citing the REMS ETASU restrictions). It cannot use foreign (*i.e.*, non-U.S.) samples as substitutes because the FDA does not consider a foreign sample to be the same drug product for bioequivalence testing purposes. It cannot file a 505(b)(2) application because (1) the FDA says that is not the right vehicle for seeking approval of a substitutable generic drug *and* (2) it would still require testing samples. Even if a generic knows the exact "recipe" of a brand formulation, it cannot manufacture its own version for testing purposes because only the brand's product constitutes the "reference listed drug" under the Hatch-Waxman Act. Absent access to the brand samples, the generic company cannot demonstrate bioequivalence, cannot file an ANDA, and cannot bring its lower-priced generic product to market.

E. Congress and the FDA have tried to prevent brand companies from using REMS to block or delay generics.

83. By all accounts, this problem is growing. One study of 40 drugs subject to restricted access REMS programs found that generics' resulting inability to enter the market increases U.S. healthcare costs by more than $5 billion a year.

[22] *Id*.

84. In recent years, members of Congress from both sides of the aisle have spoken out against the practice of using REMS to block generic firms' access to drug samples. Senator Charles Grassley (R-IA) strongly criticized brand firms that "misus[e] their . . . REMS[] to withhold access to drug samples for bioequivalence testing and generic drug development in violation of FDA regulations and the Hatch-Waxman Act."[23] Likewise, Senator Patrick Leahy (D-VT) lamented that "[t]his simple delay tactic uses regulatory safeguards as a weapon to block competition," noting that brands need not even refuse to deal with a generic to effectively stifle competition; instead they "simply engage in never-ending negotiations that have the effect of delaying entry."[24]

85. Courts, too, have noted that brand drug companies sometimes find ways to manipulate REMS programs to preclude a generic from filing an ANDA, and that doing so may violate the antitrust laws.

86. REMS abuse has become rampant. In an effort to facilitate access to samples of branded drugs, the FDA began issuing "safety determination" letters to brand companies that confirmed, in writing, that the FDA would not consider providing the branded drug, or RDL, for these purposes to be a violation of the REMS. In 2014, the FDA stated,

> In the interest of facilitating prospective generic applicants' access to RLD supplies to conduct the testing necessary to support ANDA approval, FDA has, on request, reviewed the [generic's] BE study protocols proposed by prospective ANDA applicants to assess whether they provide safety protections comparable to those in the applicable REMS ETASU. When the Agency has determined that comparable protections existed, FDA has issued letters to the RLD sponsors stating so and indicating that FDA would not consider it to

[23] 130 CONG. REC. 24427 (1984) (statement of Sen. Grassley).

[24] 130 CONG. REC. 24427 (1984) (statement of Sen. Leahy).

be a violation of the REMS for the RLD sponsor to provide drug product to the prospective ANDA applicant.[25]

87. The FDA's safety determination letters inform the brand manufacturer that:

- The FDA has received a request from a prospective generic applicant seeking help in obtaining samples of the brand product for purposes of testing the proposed generic against the brand/reference listed drug;
- The brand drug has a REMS in place;
- The generics proposed study protocols include safety precautions comparable to those set forth in the brands REMS;
- The FDA *will not consider it a violation of REMS* for the brand to provide the prospective generic applicant a quantity of the brand product sufficient to support its ANDA;
- The FDCA prohibits NDA holders from using elements of REMS to block or delay approval of a generic product;
- The NDA holder should supply the generic with a sufficient quantity to enable it to conduct the testing necessary;
- Holders of NDAs covered by a REMS are prohibited by law from using any ETASU to block or delay approval of an ANDA.[26]

88. Despite the FDA's efforts to help generics by issuing such letters, it has made very clear that there is no requirement that a generic company seek or obtain such a letter from the FDA: "Requesting or obtaining such a letter from FDA is not a legal requirement."[27]

---

[25] Draft Guidance on How To Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD from FDA's Center for Drug Evaluation and Research at 2 (December 2014), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatory information/guidances/ucm425662.pdf.

[26] FDA's Sample Safety Determination Letter, https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM602358.pdf.

[27] Draft Guidance on How To Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD, at 2.

89. In 2016, a Senate committee concluded that the FDA has "attempted to stymie [brands'] obstruction" by providing letters to generic companies indicating that the agency "see[s] no safety risk," but its "actions have been largely ineffective."[28]

90. In 2017, the FDA took the further step of committing to responding to inquiries from generics seeking help accessing samples within 60 days of receipt.

91. On May 17, 2018, the FDA announced that it would begin regularly publishing a list of brand-name drugs that have been the target of complaints that their NDA-holders are denying access to samples of RLDs when generic companies seek to buy them. The initial list confirmed that the FDA had sent at least twenty-one safety determinations letters to at least six brand companies. Its larger list specified 57 different drugs, with annual combined sales of $13.9 billion, to which sample access had reportedly been denied. The names of the prospective generic applicant companies who sought and received these letters are not publicly available.

92. The FDA's list reported complaints concerning five different Actelion products as to which inquiries about impeded access had been received: Opsumit (8 complaints), Tracleer (14 complaints), Veletri (1 complaint), and Zavesca (1 complaint). Like Tracleer, Opsumit is a PAH medicine subject to a REMS with an ETASU that restricts distribution.

93. To date, the FDA has issued five Safety Determination Letters to Actelion concerning requests for sample quantities of Tracleer. The first of the five Safety Determination Letters to Actelion about Tracleer samples was dated July 31, 2013; two were dated September 1, 2015; another was dated October 16, 2015, and one was dated January 29, 2016. These letters inform Actelion that it may provide samples of Tracleer to five different generic manufacturers

[28] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System: Hearing Before S. Special Comm. on Aging*, 114th Cong. 115 (2016).

without violating the Tracleer REMS. In each of its five Safety Determination Letters to Actelion regarding Tracleer samples, the FDA advised that it had reviewed the specific protocols that the particular generic company proposed to use in its clinical trials of Tracleer and its generic product, and that the proposed protocols were adequate to protect the safety of test subjects.

VI. FACTS

A. 1990–2001: Tracleer (bosentan) is developed, approved, and launched.

1. Scientists at Hoffman-LaRoche discover and patent bosentan.

94. In the 1990s, researchers at Hoffman-LaRoche Inc. ("Roche") discovered and developed the endothelin receptor antagonist bosentan.

95. In 1992, seven Roche-based co-inventors of the bosentan molecule submitted U.S. Patent Application No. 896,015.

96. On March 8, 1994, the United States Patent and Trademark Office ("PTO") issued the resulting patent, U.S. Patent No. 5,292,740 ("the '740 patent"). It was assigned to Roche. In approximately 1997, Actelion became the U.S. exclusive licensee of the patent. The '740 patent was listed as covering Tracleer in the FDA's Orange Book from 2001 until the patent expired on November 20, 2015.

97. The '740 patent discloses that the claimed compounds (ostensibly including bosentan) can be used to treat disorders "associated with endothelin activities," including hypertension and pulmonary high blood pressure.

98. The '740 patent would and did expire on November 20, 2015.

2. Actelion Pharmaceuticals, a Roche spin off, obtains an exclusive license for the bosentan patent.

99. In 1997, a small group of scientists and managers, including two of the '740 patent's inventors, left Roche to found Actelion Pharmaceuticals Ltd.

100. From 1997 on, Actelion Pharmaceutical Ltd. was the exclusive licensee to the '740 patent. Roche gave Actelion (and only Actelion) the right to develop, make, and sell products covered by the '740 patent — including products containing the compound bosentan. In doing so, Roche gave up its own ability to commercialize the '740 patent.

3. The FDA reviews and approves Actelion's Tracleer.

101. On November 17, 2000, Actelion filed an NDA seeking FDA approval to sell tablets containing bosentan, bearing the tradename Tracleer.

102. Actelion asked the FDA to approve the drug to treat PAH. Pulmonary hypertension refers to abnormally high blood pressure in the blood vessels connecting the lungs and the heart. PAH — a subset of pulmonary hypertension — occurs when the small arteries in the lungs narrow or become scarred. This restricts blood flow, increases blood pressure, and reduces the amount of oxygen in the blood. Over time, PAH causes damage to the heart as well as the lungs.

103. Risk factors for PAH include a family history, obesity, sleep apnea, gender, pregnancy, altitude, various diseases (including heart disease, lung disease, liver disease, HIV, COPD, and lupus), and methamphetamine or cocaine use. The most common window of diagnosis is between 20 and 60 years of age. Idiopathic PAH is twice as common in women as in men. Women of childbearing age are thought to be more susceptible.

104. At the time Actelion filed its NDA, there were no approved oral products to treat PAH.

105. Actelion's NDA included two double-blind randomized clinical studies intended to support the oral formulation's efficacy. Actelion also submitted an open label (*i.e.*, not double blind) safety study.

106. The FDA's review of Actelion's studies identified serious hepatotoxicity (liver problems) and teratogenicity (the potential to cause birth defects), as well as other potential side effects.

107. The FDA observed that about 10-11% of patients who took bosentan during the clinical trials experiences increased liver-produced enzymes in the blood at least three times the upper limit of normal; one patient had an elevated liver-enzyme level that was 73 times higher than his baseline value. The FDA noted that there was no indication that bosentan was tied to any death, that there were no reports of liver failure or need for liver transplant, and that there was no indication that the increase in liver enzymes was not reversible by discontinuing the drug (and, in fact, liver effects appeared reversible). The FDA concluded that, because of the toxic effects on the liver, it is recommended that a patient registry with education for physicians who treat patients with PAH be implemented prior to the marketing of Tracleer.

108. The FDA concluded that bosentan was teratogenic (*i.e.*, capable of causing congenital anomalies or birth defects) and fetotoxic (*i.e.*, capable of poisoning or causing degenerative effect in a developing fetus or embryo) in rats. Observed defects in fetuses included craniofacial abnormalities and blood vessel variations. These effects were not observed in rabbits.

109. The FDA's pharmacology review ultimately recommended that Tracleer be approved — despite toxicity concerns — "because of the seriousness of the proposed indication [PAH] and the lack of alternative oral therapy."[29]

110. On November 20, 2001, the FDA approved Tracleer to treat PAH. Tracleer became Actelion's first and flagship product, and the first oral product approved to treat PAH.

[29] FDA Pharmacology review, part 3, p. 33 of 62, under "Recommendation . . . ."

111. Tracleer received two regulatory exclusivities. Because it was a new chemical entity, it was entitled to five years of regulatory exclusivity (expiring on November 20, 2006). Tracleer was also given Orphan Drug status, which expired seven years after approval (on November 20, 2008). These regulatory exclusivities — a lawful form of monopoly — guaranteed that Tracleer would not face competition from generics until late 2008 at the earliest.

112. Actelion also submitted the '740 patent for listing in the FDA's Orange Book as covering Tracleer. The '740 patent expired on November 20, 2015.[30]

B. 2001–2006: Actelion initially distributes Tracleer through the Tracleer Access Program (TAP).

113. In the FDA's letter approving the Tracleer NDA, the agency notified Actelion that, "based on information from pre-marketing studies, FDA has determined that Tracleer (bosentan) poses a serious and significant public health concern," namely risks of liver toxicity and of birth defects if the drug was taken by pregnant patients.[31]

114. The FDA told Actelion that a "Tracleer Access Program is an important part of the post-marketing risk management for Tracleer," and specified eight component parts of that prescribed program, including ". . . (3) Distribution of Tracleer through a restricted distribution network."[32]

115. The Tracleer Access Program (TAP) specified that "TAP triages the prescription to a Specialty Distributor," and that, to be approved to sell Tracleer, each specialty distributor must

[30] If a generic were able to file an ANDA, it could choose to file a paragraph IV certification challenging the '740 patent (arguing, for example, that the patent was invalid or unenforceable). Since Actelion blocked generics from filing ANDAs, none faced that choice.

[31] Center for Drug Evaluation and Research, Approval Package for: Application Number 21-290, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-290_Tracleer_Approv.pdf.

[32] *Id*.

agree to a defined set of rules, including inserting patient reminders in the patient's prescription package, writing to the prescribing physician providing details regarding the prescription, reminders to patient about the need for liver function tests and pregnancy testing in appropriate cases, and tracking cessations in the prescription including adverse medical events.[33] The TAP makes no reference to Actelion needing to pre-approve, or having veto power over, sales made by the distributor to generic companies.

C. 2007–2008: The FDA determines that a Risk Evaluation and Mitigation Strategy (REMS) was already in effect for Tracleer.

116. In 2007, six years after Actelion launched Tracleer with the restricted distribution "Tracleer Access Program," Congress passed the FDAAA.[34] Section 901 of the FDAA created new section 505-1 of the FDCA, titled "Risk evaluation and mitigation strategies," discussed above at SectionV.C. Again, the law included a provision explicitly forbidding NDA holders from using elements of REMS to block or delay approval of a generic product. It went into effect on March 25, 2008.

117. Two days later, on March 27, 2008, the FDA published a notice in the Federal Register addressing the new law. The notice: (1) explained that the FDA had determined that some approved drug products already had an approved REMS program in effect (although the term "REMS" may not have been used to describe the programs before the statute was enacted), and (2) asked those drug's sponsors to submit a proposed REMS program by September 21, 2008.

118. Tracleer was one of the twenty drugs on the FDA's "already have a REMS" list.

---

[33] *Id*.

[34] Pub. L. No. 110-85, 121 Stat. 823.

119. On September 19, 2008, Actelion submitted a supplemental NDA and a proposed REMS as requested by the FDA (it was later amended). The REMS included a Medication Guide, ETASU, and the timetable for submission of assessments.

120. The proposed REMS was substantially similar to the "Tracleer Access Program." The goals of the Tracleer REMS were:

1. To inform prescribers, patients, and pharmacists about the risks of Tracleer;
2. To minimize the risk of hepatotoxicity in patients who are exposed to Tracleer;
3. To minimize the risk of fetal exposures in female patients who are exposed to Tracleer; and
4. To educate prescribers, patients, and pharmacies on the safe-use conditions for Tracleer.

121. On November 20, 2008, Tracleer's orphan drug exclusivity lapsed. The only remaining exclusivity was from the '740 patent (which would expire on Nov. 20, 2015).

D. 2009: Actelion's newly proposed REMS goes into effect.

122. The FDA has noted that, in approving Actelion's proposed REMS on August 7, 2009, in accordance with Section 505-1 of the FDCA, it had determined that a REMS was necessary for Tracleer "to ensure the benefits of the drug outweigh the risks of hepatotoxicity and teratogenicity."[35]

123. The FDA identified seventeen specific data points to be addressed in Actelion's future REMS assessment plans, including that Actelion should provide data on "distribution data from the certified pharmacies." The FDA did not suggest that Actelion should not sell samples to generics, nor that Actelion should prevent certified pharmacies from distributing Tracleer to

[35] Center for Drug Evaluation and Research, Application Number: 209279Orig1s000, Risk Assessment and Risk Mitigation Review(s), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209279Orig1s000RiskR.pdf.

generics seeking to purchase samples. The FDA simply asked Actelion to report to whom (whether entities or patients) Tracleer was distributed to.

124. The label approved along with the REMS stated:

> Because of the risk of liver injury and birth defects, Tracleer is available only through a special restricted distribution program call the Tracleer Access Program (T.A.P.), by calling 1 866 228 3546. Only prescribers and pharmacies registered with T.A.P. may prescribe and distribute Tracleer.[36]

125. The label also explained that only prescribers and pharmacies registered with T.A.P. may prescribe and distribute Tracleer.

126. The ETASU included:

1. Healthcare providers (HCPs) who prescribe Tracleer will be specially certified;

2. Pharmacies that dispense Tracleer will be specially certified, and must agree to "Not transfer Tracleer to any pharmacy, practitioner, or healthcare setting not certified by Actelion";[37] and

3. Tracleer will be dispensed to patients with evidence or other documentation of safe-use conditions.

127. Actelion said that it would "monitor the distribution of Tracleer to ensure that the drug is only shipped to certified pharmacies."[38]

128. To enroll in T.A.P., pharmacies and practitioners had to sign a form indicating that they agreed to, among other things,

---

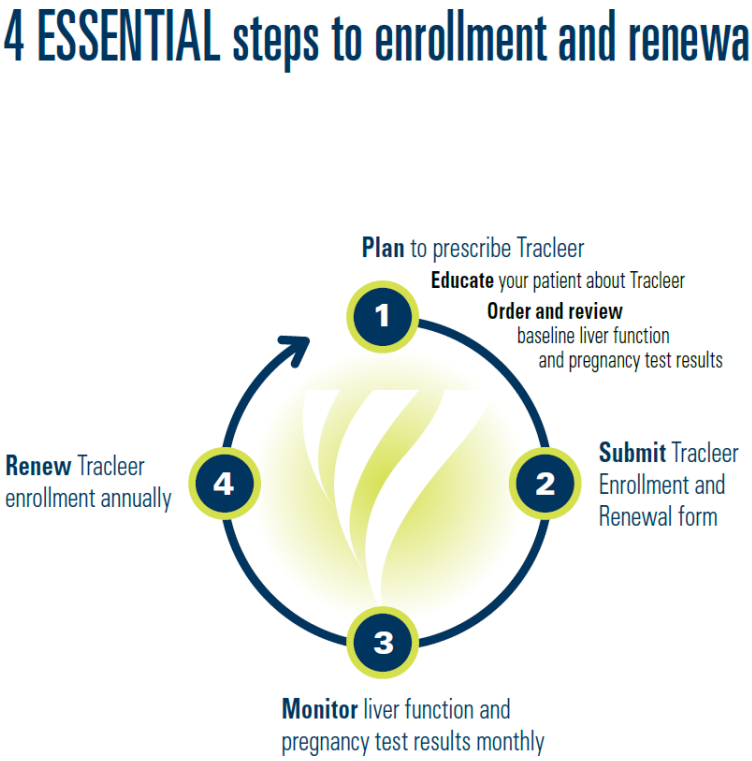
[36] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021290s016lbl.pdf.

[37] *See, e.g.*, Tracleer REMS Inpatient Pharmacy Enrollment Form, http://www.tracleerrems.com/pdf/pharmacies/Tracleer%20REMS%20Inpatient%20Pharmacy%20Enrollment%20Form.pdf.

[38] https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021290s018REMS.pdf.

- "Review and discuss the Tracleer Medication Guide and the risks of bosentan (including the risks of teratogenicity and hepatotoxicity) with every patient prior to prescribing Tracleer;"
- Review pretreatment liver function tests for each patient;
- Confirm that females of childbearing age are not pregnant before prescribing; and
- "Enroll all patients in T.A.P. and renew patients' enrollment annually thereafter."[39]

129. Actelion visually depicted a prescriber's responsibility as follows:[40]



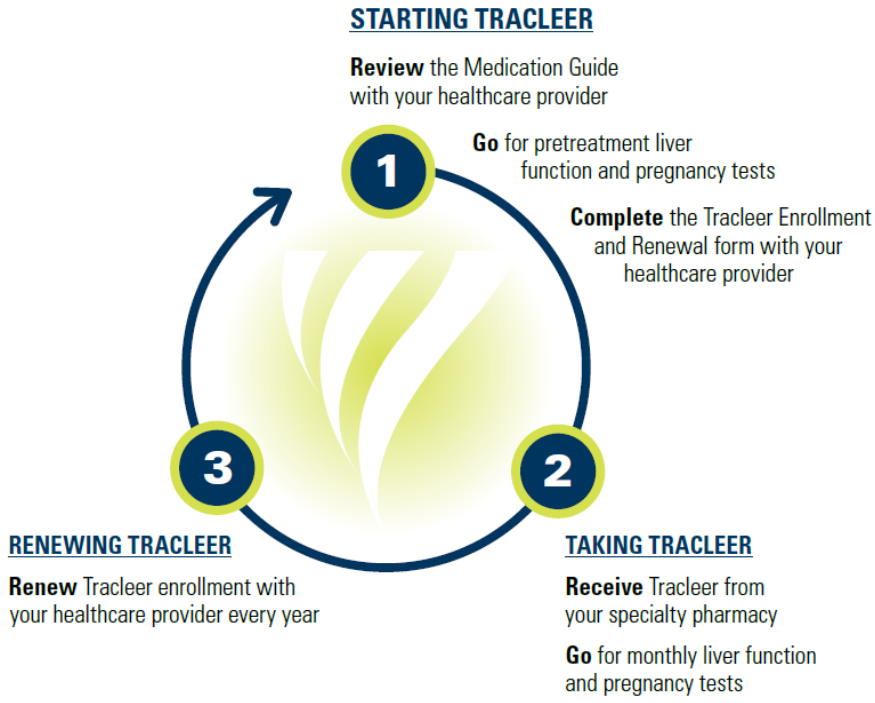
130. For patients to enroll in T.A.P., they had to provide (among other things) their insurance information, identify their prescriber, and certify that "I have read and agreed to the Patient Agreement on the back of this form. I have reviewed the Medication Guide with my

[39] *Id.*

[40] *Id.*

prescriber, I consent to be enrolled in the Tracleer Access Program, and I agree to comply with the program for as long as I am prescribed Tracleer." The Patient Agreement included an authorization to disclose personal, medical, and health information to Actelion and its employees, distributors, agents, and contractors; and an authorization to use this protected health information to "implement the T.A.P.," to establish benefit eligibility; communication with healthcare providers, health plans, other payers, and pharmacies about medical care; provide support services; and to "help find ways to pay for Tracleer, or for treatment or healthcare operations in progress."[41]

131. Actelion visually depicted the rules for patients as follows:[42]



132. In the earlier 2007 version of the patient enrollment form for T.A.P. (pre-REMS), the "Authorization for Use of Disclosure of Health Information" included an authorization for

[41] *Id.*

[42] *Id.*

Actelion to "use and disclose any and all individually identifiable health information," but, in closing, states,

> I know that I may refuse to sign this authorization. My decision not to sign this authorization will not affect my ability to get treatment from my health care providers….[43]

There is no similar opt-out language included in the 2009 (post-REMS) version of the enrollment form.

E. Actelion prevents its distributors from selling to generic companies under the guise of REMS while providing samples to non-competitors for research.

133. Actelion distributes Tracleer through certified distributors/wholesalers. Actelion has entered into contractual agreements with each distributor under which such participants agree with Actelion not to supply Tracleer to any entity without Actelion's approval. Put differently, distributors are precluded from supplying Tracleer to generic companies and others as a condition of doing business with Actelion. Actelion itself has described these as unilateral conditions imposed on distributors.

134. Actelion then closely monitors its distributors' sales of Tracleer.

135. Actelion has acknowledged that its restrictions make it so that generic manufacturers cannot buy samples downstream.

136. While Actelion, at times, has stated that it imposed these restrictions because of its REMS, the FDA did not require Actelion to impose exclusive distribution agreements that prevented generic manufacturers from accessing samples of Tracleer. This extreme form of restricted distribution was Actelion's brainchild, intended to prolong its Tracleer monopoly.

[43] https://www.rxhope.com/PAP/pdf/actelion_tracleer_0209.pdf.

1. Actelion provides access to Tracleer samples to researchers.

137. Over the past twenty years, including since the Tracleer REMS went into effect, Actelion has allowed access to Tracleer samples — directly or indirectly — for at least 47 publicly disclosed clinical studies conducted by entities *other than Actelion.* Studies have been conducted by universities, research hospitals, the National Institute of Health, and large brand-name pharmaceutical companies (such as Novartis).

138. Actelion's representations to would-be generic competitors that it was prohibited from providing samples outside the REMS program were false. Among other things, Actelion provided samples for use in studies outside of its Tracleer Access or REMS programs. For example, in 2001 Actelion sponsored and provided bosentan for a placebo-controlled study led by researchers at the University of California at San Diego and conducted in several countries, including the United States. Two hundred and thirteen PAH patients participated, including over 200 women, 114 of whom were given bosentan (instead of placebo). Actelion also funded a 2007-2008 University of California San Francisco (UCSF) study of morbidity and mortality among 616 patients with Idiopathic Pulmonary Fibrosis treated with bosentan over a one-year period. The UCSF study included male patients from around the world, including 185 in the U.S. who were given bosentan. From 2008 to 2012, Actelion also co-sponsored a University of Cincinnati-based study of Tracleer's effects on 43 U.S. men and women suffering from Sarcoidosis. Actelion's purported safety concerns thus ring hollow when it provides samples to non-competing research organizations.

139. Despite its limited distribution REMS, Tracleer was a hugely successful product for Actelion, accounting for a large majority of the company's revenues. By the end of 2009, global sales of Tracleer were just short of $1.4 billion a year, and Tracleer was being sold commercially in 58 countries worldwide.

140. Between August 7, 2009 and October 20, 2017, the REMS was updated seven times. None of those changes sanctioned nor required Actelion to not sell samples to a generic manufacturer, to prevent its distributors from selling samples to generic companies, or otherwise to obstruct generic applications and approvals.

F. 2011–2012: Generics seek access to Tracleer samples to Conduct Bioequivalence Testing.

1. Zydus attempts to buy samples from Actelion.

141. In November 2009, Zydus Pharmaceuticals (USA) Inc. (a domestic corporation) ("Zydus") and its partner, Cadila Healthcare Ltd. (an international company) ("Cadila"), sought to purchase U.S. samples of Tracleer from a pharmaceutical wholesaler for the purposes of conducting bioequivalence testing for an anticipated U.S. ANDA. The wholesaler told them that they could not sell them the U.S. version of Tracleer.

142. In December 2010, Zydus and Cadila again sought to buy U.S. Tracleer samples, this time from a different wholesaler. Again, they were told that the wholesaler could not provide U.S. Tracleer samples.

143. On June 7, 2010, Zydus sent a letter to Actelion requesting to purchase Tracleer samples at prices that would have been profitable for Actelion. In its letter, Zydus explained the following with respect to its request for Tracleer samples:

- The samples are "for bioequivalence testing purposes."
- [Zydus] "will pay Actelion Ltd. the wholesale acquisition cost (WAC) of the requested drug product and will reimburse Actelion Ltd. for any shipping costs."
- [Zydus and Cadila] "commit[] that [their] procedures for conducting bioequivalence testing … will fully comply with FDA requirements. Zydus Pharmaceuticals (USA) Inc.'s controls with respect to TRACLEER® (bosentan) used in bioequivalence testing will be comparable to the T.A.P.© - Tracleer Access Program and will comply with the prescribing and

dispensing instructions in the approved TRACLEER® (bosentan) package insert."[44]

2. Apotex writes Actelion, requesting samples.

144. Apotex Inc. ("Apotex") first attempted to purchase samples of Tracleer from wholesale distributors, and was refused.

145. On January 21, 2011, generic drug maker Apotex wrote to Actelion Pharmaceuticals, Inc., requesting to buy sample Tracleer for investigation.

146. Apotex explained that:

- 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 US FDA."
- The samples would not be used "for commercial sale and will not be sold in the U.S. to any patients."
- "All reasonably necessary controls will be put into place to control the access and handling of these bottles."
- Apotex promised that it would take all reasonable steps to control access to and proper handling of the samples under the REMS.[45]

147. For the samples, Apotex was "willing to pay the price per bottle at market value."[46]

148. While Apotex asked for a response within the next few weeks, it received none.

---

[44] Defendants Zydus Pharm. (USA) Inc.'s and Cadila Healthcare Ltd.'s Answer, Affirmative Defenses, Counterclaim and Jury Demand, at Answer ¶ 39, *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. July 11, 2013), ECF No. 80.

[45] Answer, Affirmative Defenses, and Counterclaim of Defendants Apotex Inc. and Apotex Corp., at Answer ¶ 41, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Nov. 27, 2012), ECF No. 24.

[46] Actelion Brief in Support of Motion for Judgment on the Pleadings [44-1], at 112, *Actelion Pharm. Ltd. v. Apotex Corp.*, No. 12-05743 (D.N.J. Jan. 16, 2013), ECF No. 44-1.

149. On April 12, 2011, having received no response from Actelion, Apotex sent a follow-up letter, reiterating its request for samples to be used for bioequivalence testing. It again indicated that it was willing to pay full price. Apotex said the samples would be used "to investigate/experiment with and/or to develop a generic equivalent of Tracleer® Tablets to be submitted as an ANDA to the US FDA."[47] Apotex repeated that it would institute all appropriate safeguards to comply with the REMS, and that the Tracleer samples would not be re-sold: "The samples are not for commercial sale and will not be sold in the U.S. to any patient."[48]

150. Apotex again asked for a response within the next few weeks. Actelion never responded.

3. Apotex informs the FDA it cannot obtain American samples and thus it intends to use Canadian samples.

151. On April 21, 2011, Apotex sent a letter to the FDA describing its efforts to purchase Tracleer from Actelion. Actelion also informed the FDA that, as a fallback, it had obtained samples of the Canadian version of Tracleer (also manufactured by Actelion) and intended to conduct its bioequivalence testing by comparing its product to the Canadian samples. 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]

152. On May 10, 2011, Apotex submitted its bioequivalence study protocol to the FDA. The protocol described how the bioequivalence study would be performed. It contemplated that the study would only involve male subjects to minimize the risk of fetal exposure to bosentan and described other steps that would be taken in acknowledgement of the REMS governing Tracleer.

---

[47] *Id.* at 115.

[48] Apotex Answer, ECF No. 24, at ¶ 41.

[49] *Id. at* ¶ 48.

4. Actavis writes Actelion, requesting samples.

153. On September 6, 2011, another generic company, Actavis, Inc., sent a letter to Actelion Ltd., also requesting samples of Tracleer for analytical and bioequivalence studies. Like Apotex, Actavis offered to pay fair market value for the drug products and to reimburse Actelion for all reasonable costs associated with the request.

154. Actavis explained that it had been unable to buy the drug product through other market channels because of the restricted distribution program, and promised to comply with the REMS.

5. Actelion refuses to sell samples to Actavis.

155. On September 20, 2011, Actelion Ltd. responded to Actavis, noting that the FDCA does not require Actelion to "relinquish its right to choose with whom it does business" and advising that Actelion was reserving that right, "which exists independently of the restricted distribution program for Tracleer," and advising that it had decided to deny Actavis's request.[50]

6. Roxane writes Actelion, requesting samples.

156. On January 12, 2012, a third would-be generic competitor, Roxane Laboratories, Inc., requested sample Tracleer from Actelion. Roxane's letter explained that it planned to use the sample "solely for developmental purposes to meet FDA requirements in support of an ANDA filing."[51] Roxane offered to buy the samples at market price.

157. Roxane approached Actelion directly because after trying to buy samples from traditional wholesale distribution outlets, Roxane discovered that Tracleer was unavailable through normal distribution channels.

[50] Actelion Brief, ECF No. 44-1, at 165.

[51] *Id*. at 151.

158. Actelion had refused to allow Roxane (or other generics) to purchaser samples from the wholesalers to whom Actelion distributes Tracleer, citing their REMS or restricted distribution program.

159. Roxane explained that 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.

7. Actelion refuses to provide samples to Roxane.

160. On February 10, 2012, Actelion responded to Roxane that Actelion "has the right to choose with whom it does business" and "has concluded that it will not be fulfilling Roxane's request."[52]

8. The FDA approves Apotex's BE study protocols, but requires it to use U.S. samples.

161. On February 21, 2012, the FDA sent Apotex comments on Apotex's proposed bioequivalence study protocol. It recommended certain changes to the protocol to ensure that the controls constituted an adequate substitute to those in the REMS governing Tracleer. It did not comment on Apotex's intent to use Canadian Tracleer.

162. On May 21, 2012, the FDA stated that Apotex's proposed protocol was acceptable, provided that Apotex adopted a number of recommendations. One of its recommendations was that the studies "should be performed using the approved U.S. product as the reference product. It is not acceptable to use an approved Canadian drug product as described in your protocols."[53]

[52] Roxane Labs., Inc.'s Answer, Affirmative Defenses, and Counterclaim Complaint at Counterclaim, at Answer, ¶ 68, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Nov. 27, 2012), ECF No. 25.

[53] Roxane Answer, ECF No. 24, at ¶ 53.

9. Roxane buys and uses Canadian samples in a study.

163. In approximately March of 2012, Roxane obtained samples of Canadian Tracleer and conducted a pilot bioequivalence study of its prospective generic product using the foreign samples.

G. Summer 2012: Generics continue to request samples and announce intention to sue.

1. Apotex again requests samples, Actelion refuses.

164. On June 26, 2012, given the FDA's insistence that Apotex use U.S. samples, Apotex tried to obtain such samples yet again. Apotex sent a third letter to Actelion, again requesting Tracleer samples.

165. Apotex noted that Actelion had not responded to its earlier requests to purchaser Tracleer, and that it 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.

166. The letter noted that it had been seventeen months since Apotex first requested samples for bioequivalence purposes, and that "Actelion may not deny access to its RLD to thwart efforts by generic manufacturers from bringing competing products to market."[54]

167. Apotex explained that, while it 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."[55]

168. On July 2, 2012, Actelion responded to Apotex, announcing that it had decided not to fulfil Apotex's request for Tracleer tablets.

[54] Actelion Brief, ECF No. 44-1, at 118.

[55] Apotex Answer, ECF No. 24, at ¶ 56.

169. Actelion replied that the Tracleer REMS "do not provide for the sale of Tracleer tablets to Apotex," that "Actelion has the right to choose with whom it does business and to whom it will sell its products," and that Actelion was reserving that right "which exists independently of the REMS program for Tracleer."[56]

2. Apotex again informs the FDA it cannot obtain U.S. Tracleer samples.

170. In August 2012, Apotex submitted a revised bioequivalence protocol incorporating all of the FDA's earlier recommendations, save one. Apotex explained that, because of Actelion's refusal to sell Apotex the requested samples of Tracleer, Apotex has been unable to procure the approved U.S. product to use in its bioequivalence study.

3. Apotex sends Actelion a draft complaint.

171. On August 1, 2012, Apotex wrote back to Actelion, noting that "Actelion's 'right to choose with whom it does business and to whom it will sell products' is not unlimited." Apotex continued, "[a]s a monopolist, Actelion may not thwart competition by withholding drug samples that are necessary for generic pharmaceuticals to bring competing products to market."[57] Apotex informed Actelion that it intended to file a civil action seeking injunctive relief, declaratory relief, and money damages. Apotex enclosed a draft complaint and threatened to sue under Section 2 of the Sherman Act if Actelion continued its refusal to sell Tracleer samples.

4. Roxane again requests samples, Actelion refuses, and announces it intends to file suit.

172. Also, on August 1, 2012, Roxane again wrote Actelion, urging Actelion to reconsider its refusal to sell Tracleer samples to Roxane for development purposes. Roxane stated that "Roxane has been unable to purchase this product, as it normally does in the ordinary course

[56] Actelion Brief, ECF No. 44-1, at 143.

[57] *See* Apotex Answer, ECF No. 24, at ¶ 48.

of business, from pharmaceutical wholesalers due to Actelion's restrictions. Accordingly, Roxane requested to purchase supply from Actelion directly."[58] Roxane was willing to pay the retail published price that Actelion was charging "or, frankly . . . any price that was within the realm of reasonableness."[59] Roxane explained that Actelion's refusal to sell Roxane samples violated antitrust laws, and that Roxane was prepared to "pursue all available options, including notifying the Federal Trade Commission and/or asserting antitrust and related claims against Actelion."[60]

5. Actelion strings along the generics and requests information about their ANDAs to further its anticompetitive ends.

173. On August 9, 2012, Actelion replied to both Roxane and Apotex. It reiterated its refusals to sell (or permit others to sell) samples of Tracleer to Roxane on the alleged grounds that (1) it sought to protect it intellectual property rights, and (2) that doing so would violate REMS distribution restrictions. It sought "clarification" regarding both companies' ANDA products and their communications with the FDA, while again claiming an unfettered right to choose with whom it does business and, on that basis, refusing to sell to Roxane or Apotex.

174. On August 17, 2012, Apotex responded to Actelion's letter. Apotex noted that "several of Actelion's requests for 'clarification' appear unrelated to a good faith evaluation of Apotex's request and instead seem calculated to allow Actelion to obtain proprietary or strategic information belonging to Apotex, to which Actelion is not entitled."[61] Apotex nevertheless answered several of Actelion's questions, and then requested a final decision from Actelion

[58] Roxane Answer, ECF No. 25, at ¶ 34.

[59] Transcript of Hearing on Motions at 49, *Actelion v. Apotex,* 12-cv-5743 (D.N.J. Oct. 17, 2013), ECF No. 93.

[60] Complaint for Declaratory Judgment ¶ 31, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Sept. 14, 2012), ECF No. 1.

[61] Actelion Brief, ECF No. 44-1, at 140.

regarding provision of the samples by August 25, 2012. Apotex indicated that it planned to file suit against Actelion if the answer was negative.

175. On August 21, 2012, Actelion wrote back to Apotex, claiming that Actelion remained open to considering Apotex's request but that to do so Actelion needed copies of Apotex's final testing protocols "to insure that it indeed incorporates the necessary safeguards consistent with the Tracleer REMS." Actelion also demanded "[w]ritten confirmation from the FDA that it would be acceptable under the REMS for Actelion to supply Apotex with Tracleer samples for use in BE [bioequivalence] testing consistent with the final protocols." Actelion challenged Apotex's "suggesti[on] that Actelion is required, as a matter of law, to sell it a patented product," and proposed a face-to-face meeting for further discussion.[62]

H. 2012–2013: Actelion and the generic companies litigate, seeking competing declaratory relief.

1. Actelion sues Apotex and Roxane.

176. In September of 2012, Actelion sued Apotex and Roxane in the United States District Court of New Jersey.

177. At the time Actelion sued, Tracleer's average monthly wholesale price was about $3,000.

178. Actelion represented that Apotex and Roxane had demanded samples from Actelion so that they could develop competing products; that Actelion had not supplied the samples requested; and that Apotex and Roxane had threatened to file lawsuits (potentially seeking an injunction forcing Actelion to sell the generics samples and/or asserting antitrust claims) in order to obtain Tracleer samples.

[62] *Id*. at 149.

179. Actelion argued that the relief it expected Apotex and Roxane to seek would be "in direct contravention of . . . the REMS for Tracleer" and "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."[63] Actelion sought a judgment that Actelion had no duty to deal with Apotex or Roxane and that it was under no obligation to supply Tracleer samples to prospective generic competitors.

2. Apotex and Roxane counterclaim, alleging antitrust violations.

180. On November 27, 2012, Apotex and Roxane each answered and counterclaimed.

181. Apotex represented that it had identified the opportunity and need for a generic equivalent of Tracleer, and that it *had already developed* a generic drug that it believed to be bioequivalent to Tracleer, but that it needed samples of Tracleer in order to perform the required bioequivalence testing (and thereafter file an ANDA).

182. Apotex confirmed that it had repeatedly sought to purchase samples, and Actelion had repeatedly denied those requests. Apotex stated that it had entered into good faith negotiations with Actelion in an attempt to resolve the dispute without resorting to litigation.

183. Apotex explained that, but for Actelion's refusal to sell it samples, Apotex would have filed an ANDA for a generic bosentan product by late 2011, and that it would have been in a position to obtain approval of that ANDA, at a minimum, before the protection for the '740 patent expired in November 2015.

[63] Actelion Complaint for Declaratory Judgment, at ¶ 4, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Sept. 14, 2012), ECF No. 1.

184. Apotex asserted six affirmative defenses, including failure to state a claim, estoppel based on Actelion's own acts and omissions, and that Actelion's claims were barred by the FDA and antitrust laws, as well as a failure to plead a claim under the Declaratory Judgment Act.

185. In its counterclaim, Apotex alleged that "Actelion has abused its monopoly power by denying Apotex the ability to purchase Tracleer samples for bioequivalence testing and [therefore] to submit an ANDA to FDA for a generic bosentan product."[64] Apotex asserted six causes of action (including three premised on violations of antitrust law) and sought a "preliminary and permanent mandatory injunctive relief . . . compelling Actelion to sell Apotex sufficient quantities of Tracleer at market prices so that Apotex can perform bioequivalence testing."[65]

186. Roxane's answer and declaratory judgment alleged that Actelion was using REMS and distribution restrictions as a pretext to block or delay generic competition in violation of FDA regulations, the antitrust laws, and state law. Roxane asserted twelve affirmative defenses, including failure to state a claim, lack of injury suffered by Actelion, and that Roxane's acts and omissions are protected under FDA regulations and other law.

187. Roxane alleged that Actelion had not only refused to sell it samples, but that Actelion had also prohibited its distributors from selling samples to Roxane. Roxane represented that "Actelion . . . refuses to allow Roxane to purchase samples either from Actelion or the wholesalers to whom Actelion distributes these drugs, citing their REMS. . . ."[66]

188. Roxane explained that it had FDA approved safety protocols in place, and that it had already conducted a pilot bioequivalence study using Canadian Tracleer.

---

[64] Apotex Counterclaim, ECF No. 24, at ¶ 56.

[65] *Id*. at ¶ 30.

[66] Roxane Counterclaim, ECF No. 25, at ¶ 10.

189. Roxane also pointed out that Actelion's Tracleer sales accounted for 90% of Actelion's total sales in 2012, and that the prospect of a generic manufacturer developing a generic version of Tracleer that would erode those sales was a major threat to Actelion. Roxane stated that Actelion's conduct had cost Roxane (and those who pay for these drugs) hundreds of millions of dollars by "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."[67]

3. Actavis intervenes and counterclaims, also alleging antitrust violations.

190. On November 27, 2012, Actavis moved to intervene as a defendant and counter-plaintiff in the pending litigation. That motion was granted on December 19, 2012, and Actavis filed an answer and counterclaims on December 26, 2012.

191. In its counterclaim, Actavis represented that Actelion had refused to permit it to acquire necessary samples; that it was unable to obtain samples from other sources; that at no time had Actelion specified or offered to even discuss what specific safeguards would address its safety concerns, or what safeguards Actavis would have to meet in order to obtain testing samples from Actelion. Actavis, like Apotex and Roxane, asserted that Actelion's purported safety concerns were a pretextual fig leaf behind which Actelion tried to hide its true goal: blocking or delaying generic competition.

4. Actelion moves for judgment on the pleadings; Apotex, Roxane, and Actavis oppose.

192. On January 16, 2013, Actelion moved to dismiss and simultaneously moved to stay discovery.[68]

---

[67] *Id*. at ¶ 3.

[68] In opposing Actelion's motion to stay, the generics also reminded the Court that Actelion had an interest in prolonging the litigation for as long as possible: "As a monopolist with the exclusive right to manufacture and sell the . . . drug product[] at issue, Actelion has an

193. Actelion's primary arguments were (1) the antitrust laws do not obligate Actelion to sell samples to firms with which it chooses not to do business, or to help potential rivals enter the marketplace; (2) there was no history of dealing between the parties; (3) there are other paths to the marketplace available to the potential generic competitors, including filing an NDA of application under 505(b)(2) (and so Tracleer samples are not an "essential facility"); (4) Actelion has a patent for Tracleer; (5) Congress twice refused to impose an explicit duty to sell samples; and (6) the drugs pose significant health and safety risks requiring distribution restrictions as a condition of FDA approval. In short, Actelion argued that it was under no legal obligation to sell samples to its potential generic rivals when doing so would help those rivals get to market and create generic competition.

194. Actelion argued, in part, that the FDA, via the REMS, "*required*" Actelion to make the distribution arrangements it in fact made with Tracleer distributors. But, in truth, the only restriction imposed on Tracleer dispensers in the REMS is framed in terms of the kinds of *patients* to whom they may dispense. There is simply no restriction in the REMS or elsewhere imposed by the FDA that Tracleer dispensers can *only* sell to patients.

195. As to Actelion's arguments that generics could seek approval through the NDA of 505(b)(2) route, it would be impossible to do so without obtaining samples. First, for products

---

overwhelming economic interest in perpetuating the status quo for as long as possible. Its request for a discovery stay is just another tactic to further delay the development of competing generic products." Defendants and Counterplaintiffs' Joint Sur-reply in Oppositions to Plaintiffs and Counterdefendants' Motion to Stay Discovery, at Motion to Stay 7-8, *Actelion Pharmaceuticals. Ltd. v. Apotex Inc.,* No. 12-05743 (D.N.J. Feb. 19, 2013), ECF No. 53.[68] *FTC's Brief as Amicus Curiae*, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Mar. 11, 2013), ECF No. 61-2. The FTC noted that while it had not yet filed an enforcement action to address REMS-based withholding of samples, it continues to investigate and that this case in particular "may have much broader implications for the Commission's competition mission and the interests of consumers." *Id*. at 2-3.

approved under 505(b)(2) to be deemed AB-rated (and therefore substitutable for the brand), they must still show bioequivalence to the brand drug — and so samples would still be required. While products can be approved under 505(b)(2) without showing bioequivalence, they would not be substitutable (thus undermining the intent of the Hatch-Waxman framework) and would still require establishing a bioavailability "bridge" to the brand product in order to take advantage of the brand's safety and efficacy showings — which, again, would require samples.

196. On March 4, 2013, the generics jointly opposed Actelion's motion to dismiss. The generics argued that they sufficiently alleged violations of Section 2 of the Sherman Act because: (1) they adequately alleged that Actelion's refusal to provide samples was exclusionary; (2) they adequately alleged that Actelion's refusal to provide samples was an unjustified refusal to deal (under *Trinko* and *Aspen Skiing*, neither of which required prior dealing between the parties); (3) they adequately alleged that access to Tracleer samples was an essential facility (still good law post-*Trinko*); (4) that patent law does not *per se* trump antitrust law and, by statute, is more appropriately considered *after* the filing of an ANDA; (5) that any professed safety concern is pretextual given Actelion's long history of providing samples to brand-name drug manufacturers and research hospitals; and (6) that Actelion's argument that generics could have obtained approval through another regulatory path, or that the samples were not strictly necessary, only raised disputes of fact that cannot properly be resolved at the motion to dismiss stage.

5. Both the FTC and the Generic Pharmaceutical Association file amicus briefs supporting the generics' arguments.

197. On March 11, 2013, the Federal Trade Commission, the entity in charge of federal antitrust enforcement, filed an *amicus* brief that largely tracked the arguments made by the generics.[69]

198. In its *amicus* brief, the FTC called Actelion's alleged conduct "a troubling phenomenon," noting "the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition."[70]

199. The FTC noted that the unique regulatory framework that facilitates development and adoption of generic drugs "depends on generics firms' ability to access samples of brand products."[71]

200. The FTC concluded that "Actelion's position that it has a virtually absolute right to block generic access to its products . . . poses a significant threat to competition in the pharmaceutical industry" and that "Actelion's legal position, if adopted, could prove costly for consumers of prescription drugs."[72] It then described the regulatory framework; explained why actions that block generic access can violate antitrust laws; articulated why refusing to sell samples

[69] *FTC's Brief as Amicus Curiae*, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Mar. 11, 2013), ECF No. 61-2. The FTC noted that while it had not yet filed an enforcement action to address REMS-based withholding of samples, it continues to investigate and that this case in particular "may have much broader implications for the Commission's competition mission and the interests of consumers." *Id*. at 2-3.

[70] *Id*. at 1.

[71] *Id*.

[72] *Id*. at 1, 2.

to generic rivals may constitute exclusionary conduct; and explained that conducting bioequivalence testing would not infringe Actelion's patent for Tracleer.

201. In its *amicus* brief, also filed March 11, 2013, the Generic Pharmaceutical Association explored the history and policy behind the Hatch-Waxman amendments, and noted that Actelion's actions in refusing to sell samples of Tracleer to generic companies undermined the statute's purpose: "In this action, Actelion seeks to give branded drug makers unreviewable power to decide whether to allow generic competition or maintain their monopoly. . . . It is no exaggeration to say that accepting Actelion's position would subject the current robust and competitive generic drug market to the whims of branded drug makers, rendering the ANDA process all but a dead letter . . . ."[73]

6. The FDA re-approves Apotex's safety protocols; Actelion still will not provide samples.

202. In May of 2013, while the motion to dismiss was pending, Apotex asked the FDA to approve the safety protocols it used in its bioequivalence testing. Later that month, Apotex received a letter from the FDA approving its safety measures. Apotex again contacted Actelion, reiterating its request for samples and attaching the FDA's letter. Actelion replied: "This changes nothing. You don't get it."[74]

[73] *Brief of Amicus Curiae Generic Pharmaceutical Association in Support of Defendants and Counterclaim Plaintiffs,* at 11, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Apr. 1, 2013), ECF No. 59-3. The *amicus* brief further noted, "If Congress meant to give branded drug makers unreviewable discretion to deny potential generic entrants access to the reference samples necessary to complete the ANDAs that made the generic-drug revolution possible, it could hardly have chosen a more obscure and indirect method than the REMS safety protocols. *Id*. at 14.

[74] Transcript of Motions Hearing, ECF No. 93. at 45.

7. Zydus moves to intervene.

203. On July 2, 2013, Zydus and Cadila filed a consent motion seeking to intervene in the litigation because Actelion had similarly denied it access to Tracleer samples.[75]

204. Zydus represented that it had been trying to obtain U.S. Tracleer samples since at least 2010; that it had repeatedly tried to purchaser Tracleer from wholesale distribution channels so that it can conduct the necessary bioequivalence testing; that Tracleer distributors have not and will not supply Tracleer without Actelion's approval; and that, as a result, Zydus and its partner Cadila "had to abandon their efforts to formulate a generic bosentan drug product for the United States market when it became apparent that FDA would only accept bioequivalence studies that compared a generic bosentan drug product to the version of Tracleer marketed in the United States."[76]

205. Zydus reported that, between November 2009 and December 2010, two different pharmaceutical wholesalers confirmed that they could not sell the U.S. Tracleer product to Zydus.

206. An order approving Zydus's intervention was entered on July 9, 2013.

---

[75] Consent Order Granting the Intervention of Zydus Pharm. (USA) Inc., and Cadila Healthcare Ltd. as Defendant and Counterplaintiff, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. July 2, 2013), ECF No. 75-1. In the interim, an additional company, Johnson Matthey Inc., moved for leave to intervene as a defendant and counterclaimant, alleging that Actelion had denied its request for samples of a different drug, Zavesca (generic name miglustat). That motion was granted by a consent order dated April 2, 2013. Consent Order Granting Johnson Matthey Inc,'s Motion to Intervene, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Apr. 2, 2013), ECF No. 67. Johnson Matthey's claims with regard to Zavesca samples parallel the claims of Apotex, Roxane, Actavis, and Zydus, but are not related to bosentan and therefore are not detailed here.

[76] Defendants Zydus Pharm. (USA) Inc., and Cadila Healthcare Ltd.'s Answer, Affirmative Defenses, Counterclaim and Jury Demand at Counterclaim, at ¶ 41, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. July 2, 2013), ECF 75-3.

I. Summer 2013: Apotex obtains a letter from the FDA approving its BE protocols.

207. On July 31, 2013, the FDA issued a "sample determination letter" to Actelion about Tracleer. This letter stated that the FDA had received a request from Apotex for help in obtaining supplies of branded Tracleer for the purposes of testing a proposed generic bosentan product against Tracleer; that the generic applicant had submitted study protocols that the FDA had determined included safety precautions for testing comparable to those set forth in the Tracleer REMS program; and that the FDA will not consider it a violation of the REMS for Actelion to provide the generic applicant a quantity of Tracleer sufficient to allow the generic to perform the testing necessary to support its ANDA and otherwise meet the requirements for approval.

208. The FDA also reminded Actelion that the FDCA prohibits an NDA holder from using any ETASU component of REMS programs to block or delay approval of a would-be generic competitor's product. The FDA stated that a "sufficient quantity" of Tracleer should be supplied to the generic applicant to conduct the necessary testing. The FDA clarified that the quantity provided should be no less than the amount requested by the prospective generic applicant.

J. Fall of 2013: The Court denies Actelion's motion to dismiss and the parties quickly settle.

209. On October 17, 2013, the District Court heard oral argument on Actelion's motion for judgment on the pleadings. During the hearing (and in post-hearing orders), the Court denied Actelion's motion to dismiss, ordered that the action shall proceed with discovery, and set a telephone conference with the Magistrate to discuss a proposed discovery schedule.

210. The Court refused to rule, as a matter of law, that Actelion's refusal to sell samples to its generic competitors was not illegal and could not, on the facts pleaded, constitute a violation of Section 2 or Section 1 of the Sherman Act. The Court observed:

> *Trinko* can't repeal Section 2. It survives. It's there and it's available, if the facts allow it, to prevent the improper maintenance

> and extension of a monopoly through improperly motivated conduct.
>
> ***
>
> If the [generics] can prove that [Actelion] is motivated not so much by safety concerns but instead motivated by the desire to use the REMS or REMS equivalent, to use exclusive distribution agreements and to use a [sic] otherwise legitimate refusal to deal together to maintain and extend a monopoly, then they may very well make out a Section 2 claim.[77]

211. In so holding, the Court made the following statements:

- "I'm not entirely comfortable with the notion that, on the limited facts available to me, that you always have a right under all circumstances to refuse to sell samples to generic companies."[78]
- "[Y]our client did not say, 'I won't sell to you unless you go to the FDA, get their approval for me to sell it to you, and approval for your protocols, and, by the way, you're going to have to pay . . . for that. I'm not doing it.' You simply said 'We're just not going to sell,' right?"[79]
- "The problem here is—or the concern, I think, would be that the refusal to sell samples, coupled with the very restrictive—the exclusive distribution agreement, indeed, the banning of sales, unapproved sales, coupled together, mean that the patentholder is extending its patent into the expiration period at patent level prices because it's effective excluded any generic competition?"[80]
- "[D]oesn't the regulatory system kind of assume that samples will be obtained in the normal course?"[81]
- "[W]hat I'm having difficulty [with] is . . . the notion that [the defendants' interpretation] somehow would allow a brand name manufacturer who has, I will call it, Section 2 intent to . . . confer upon them some kind of Section

[77] Transcript of Motions Hearing, at 116-17, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Oct. 31, 2013), ECF No. 96.

[78] *Id.* at 11.

[79] *Id.* at 19.

[80] *Id.* at 31.

[81] *Id.* at 33.

> 2 immunity where . . . conduct beyond [] a mere refusal to sell suggests an intent to extend or maintain a monopoly."[82]

212. The Court asked Actelion, point blank, whether, if the FDA issues a letter acknowledging that a generic's study protocols were adequate, Actelion would still refuse to sell samples to generics looking to conduct bioequivalence testing. Actelion, after some hemming and hawing about how it still would not have an obligation to sell to generics, eventually answered "yes."[83]

213. The court indicated that it would be preparing a substantive written opinion to supplement its order.

214. During the hearing, the parties referred to the existence of settlement discussions, but represented that "[t]here has been no progress made. There was an offer, it has been rejected . . . ."[84]

215. Two weeks later, on November 1, 2013 — before the Court issued its promised substantive written opinion — Actelion and Apotex settled on undisclosed terms. They dismissed all claims and counterclaims with prejudice.

216. Following a December 2013 settlement conference convened by the U.S. Magistrate Judge for the District Court, Actelion settled with the remaining generics in February 2014, also on undisclosed terms.

217. The settlements flowed from Actelion's refusal to provide samples. Had Actelion provided samples to the generics, there would have been no lawsuit over access to Tracleer U.S. samples. Any agreement among Actelion and the generics as to when generics would come to

---

[82] *Id.* at 38.

[83] *Id.* at 19.

[84] *Id.* at 19.

market — outside of the litigation settlement context — would have been a naked market allocation agreement between or among competitors (and unlawful under federal antitrust law). The settlement agreements (and the terms agreed to therein) are consequences of Actelion's anticompetitive actions.

K. 2013–2016: The FDA repeatedly confirms that providing samples will not violate the Tracleer REMS.

218. On September 1, 2015, the FDA issued two more sample determination letters, each relating to a different generic company's request for Tracleer U.S. samples. The letters contained the same information as its initial letter.

219. On October 16, 2015, the FDA issued a fourth sample determination letter, referring to yet another generic company's request for Tracleer U.S. samples. Again, the letter was virtually identical in substance to the earlier letters.

220. On January 29, 2016, the FDA issued a fifth sample determination letter, addressing a fifth generic company's request for Tracleer U.S. samples, and conveying the same information. Thus, even after its 2013 and 2014 settlements, Actelion continued to withhold samples of Tracleer from would-be generic competitors.

221. In total, the FDA issued five Safety Determination Letters to Actelion concerning requests for sample quantities of U.S. Tracleer. Upon information and belief, each letter refers to a different would-be generic applicant's request for samples.

222. Each letter informs Actelion that it would not violate the REMS by providing samples and advises Actelion to provide a sufficient quantity of Tracleer to allow generics to conduct the necessary testing.

223. In each of the five letters, the FDA told Actelion that the specific protocols each generic company proposed to use in its clinical trials of Tracleer and its generic product were adequate to protect the safety of test subjects.

L. Had Actelion not prevented the generics from obtaining Tracleer U.S. samples, one or more Tracleer generics would have been available in November 2015.

224. The '740 patent was set to expire November 20, 2015. But for Actelion's refusal to allow the generics to purchase samples, one or more generics would have been available in November 2015.

225. In 2011, the median review time to approval for ANDAs was 30 months. In 2012, it was 31 months. In 2013, it was 36 months.[85]

226. In February 2013, Apotex, Roxane, and Actavis represented that their "efforts to develop and market generic alternatives to Actelion's products have already been delayed for months, or, in some cases, years"[86] and that — in the absence of Actelion's anticompetitive actions — generic entry should occur, at the very latest, when the '740 patent expired on November 20, 2015.

1. Apotex would have launched in November 2015.

227. In and around 2012, and while the parties were litigating, Apotex was one of the top ten generic companies, by sales, in the U.S. Apotex employed over 7,500 employees worldwide and sold products in 115 countries and territories. It produced more than 300 generic

[85] Press Release, Generic Pharm. Ass'n. (GPhA), Statement by David Gaugh, Senior Vice President, Sciences and Regulatory Affairs, GPhA, Regarding the Senate HELP Hearing on GDUFA (Jan. 28, 2016), https://www.pharmacytimes.com/association-news/statement-by-david-gaugh-senior-vice-president-sciences-and-regulatory-affairs-gpha-regarding-the-senate-help-hearing-on-gdufa.

[86] Defendants and Counterplaintiffs' Joint Memorandum in Opposition to Plaintiffs' and Counterdefendants' Motion to Stay Discovery, at 2, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Feb. 5, 2013), ECF No. 49.

pharmaceuticals in thousands of dosages and formulations. Apotex had 235 approved ANDAs in the U.S. and filed 40-50 new ANDAs annually. Apotex had also spent over $800 million in litigation costs in 1,000 lawsuits over the past ten years to bring generics to market sooner.

228. During litigation, Apotex represented that — if it had access to the necessary samples — it would have filed an ANDA by late 2011 and would have obtained approval and launched no later than November 2015:

> 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.[87]

229. During oral argument, Apotex's counsel represented that the time from ANDA filing to approval "can be, you know, at least two years, maybe 30 months."[88] "So every month of delay that they buy now by preventing potential generic competitors from getting access to drugs that they need for bioequivalence is another months later than the process is pushed down the road. Because the FDA is going to take the time that the FDA needs to evaluate the ANDA, and it doesn't happen overnight."[89]

2. Actavis would have launched in November 2015.

230. As of 2012, when the parties began litigating:

- Actavis marketed more than 750 products globally, operating in more than 60 countries;
- Actavis's generics business reported net revenues of $4.45 billion, accounting for over 75% of the company's total revenues and making it one of the top give generic companies in the world;

[87] Apotex Counterclaim, ECF No. 24, at ¶ 59.

[88] Transcript of Hearing on Motion to Stay, at 18, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. Apr. 29, 2013), ECF No. 71.

[89] *Id.*

- Actavis launched more than 1,000 generics produced globally, including 13 exclusive launches in the U.S.;
- Actavis filed 45 new ANDAS with the FDA; and
- Actavis had more than 185 ANDAs on file, including 49 first-filer opportunities (33 of which were potentially exclusive).

231. By November 2012, Actavis had actively developed a proposed generic bosentan product. It had made a considerable investment in doing so, including conducting various required studies, developing a prototype, and manufacturing "pilot bio-batches." Actavis represented that "once bioequivalence studies are complete, [Actavis] will seek FDA approval."[90]

232. Actavis publicly represented in its 2012 Annual Report that, but for Actelion's wrongful conduct, Actavis would have promptly completed studies showing the bioequivalence of its formulation with Tracleer and filed an acceptable ANDA with the FDA in late 2011 or early 2012.

233. Given mean approval times, Actavis's ANDA would have very likely been approved inside of 36 months, or in any event well before the Tracleer patent expired, and would have launched on or around November 20, 2015.

3. Roxane would have launched in November 2015.

234. Roxane intended to file an ANDA for bosentan.

235. Roxane stated in its litigation with Actelion that "In order to prepare its bosentan product . . . and file its ANDA[], Roxane needed to secure samples of bosentan . . . for use in bioequivalence studies."[91]

[90] Memorandum in Support of Motion of Actavis Elizabeth LLC to Intervene as Defendant and Counterplaintiff at 12, No. 12-05743 (D.N.J. Nov. 27, 2012), ECF No. 27-1.

[91] Roxane Counterclaim, ECF No. 25, at ¶ 66.

236. In 2011, Roxane tried to obtain Tracleer samples through normal distribution channels but was unable to do so. From then on, it repeatedly sought to purchase samples from Actelion at market rates. Actelion refused to sell Roxane the requested samples.

237. In the absences of Actelion's conduct, Roxane would have filed an ANDA and would very likely have obtained approval and launched on or around November 20, 2015.

4. Zydus would have launched by November 2015.

238. Zydus intended to file an ANDA for Tracleer, and sought samples from wholesalers and Actelion from 2009 on.[92] After repeatedly being denied access to samples, it stopped pursuing its ANDA.

239. In the absence of Actelion's conduct, Zydus would have filed an ANDA and would have obtained approval and launched on or around November 20, 2015.

5. Actelion anticipated, and prepared for, generic competition as early as November 2015.

240. The '740 patent was set to expire November 20, 2015. Actelion expected multiple generic competitors to launch at that time (if not before).

241. Brand companies may compete with generics – once a generic launches — by selling its own generic product (an "authorized generic") manufactured under its NDA. These are often the brand pills in a different bottle sold at a lower price point; sometimes the brand may hire another company to manufacture the authorized generic (under the NDA). Selling a "generic" product permits the brand company compete for some percentage of the generic sales.

242. Upon information and belief, at some point in 2015, Actelion and the FDA discussed the possibility of Actelion launching an authorized generic version of Tracleer.

[92] Zydus and Cadila Counterclaim, ECF No. 80, at ¶ 37.

243. On December 4, 2015, in approving a modification to the Tracleer REMS, the FDA noted that "[a]n authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission."[93]

244. In the same letter, the FDA reminded Actelion that the FDAAA "prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval [of an ANDA]. . . . A violation of this provision . . . could result in enforcement action." Enforcement actions can include warning letters, injunctions, criminal prosecution under section 301 of the FDCA, or criminal files under The Criminal Fine Enforcement Act of 1994.

245. On October 20, 2017, the Tracleer REMS were modified to add an authorized generic for Tracleer Tablets.

246. To date, as a result of Actelion's anticompetitive conduct, no generic versions of Tracleer have received FDA approval, even though Tracleer is a billion-dollar drug and its patent has been expired for nearly three years.

M. Actelion's scheme destroyed competition and caused damages to Plaintiff and the class.

247. In enacting the Hatch-Waxman scheme, Congress determined that purchasers and consumers were best served by accelerated generic entry into the market. Blocking a generic manufacturer's access to drug samples obstructs a clear market benefit.

[93] December 4, 2015 Letter from Mary Ross Southworth, Deputy Dir. for Safety, Office of Drug Evaluation I, Center for Drug Evaluation and Research to Frances Duffy-Warren, Assoc. Dir., Drug Regulatory Affairs, at 14. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021290Orig1s027,s029ltr.pdf.

248. Samples of the brand drug (*i.e.*, the FDA-approved, U.S. version, of the reference-listed drug) are essential. Nothing else will do. Without these samples, a generic company cannot satisfy the FDA's bioequivalence requirements, cannot file an ANDA, cannot obtain FDA approval, cannot launch a generic drug, and cannot compete.

249. Generic companies could not have obtained samples of Tracleer through a cooperative prescribing physician or pharmacist. A physician who wrote a prescription for Tracleer tablets, or a pharmacist who dispensed them, outside the usual course of their professional practice and/or other than to a bona fide patient could have faced felony charges under federal and state law, as well as de-licensure. A company that obtained samples by those routes could also have been held criminally liable.

250. Generic companies could only have obtained the necessary samples from Actelion or a certified distributor. Actelion prevented generics from purchasing samples through either path: Actelion refused to sell samples to the generics directly. Actelion also prevented its distributors from selling samples to the generics by withholding its consent and/or outright prohibiting them from doing so. Obtaining controlled substances, including bosentan, without "a prescription issued . . . in the usual course of professional treatment or in legitimate and authorized research," is a violation of federal law with potential criminal liability for physicians and pharmacists who knowingly write or fill prescriptions outside those bounds.[94] Many states also prohibit physicians from writing prescriptions outside the usual course of professional treatment, and/or pharmacists from knowingly filling them.[95]

---

[94] *See* 21 C.F.R. 1306.04 and 21 U.S.C. § 829.

[95] *See, e.g.*, Cal. Health and Safety Code §§ 11173, 11153; Mass. Gen. Laws Ch. 94C, § 19; N.Y. Public Health Law §§ 3331, 3335; Ohio Admin. Code 4729-5-30; Or. Admin. R. 855-019-0210.

251. Actelion had no legitimate interest at stake in excluding generic companies' access to samples of U.S. Tracleer — other than maintaining its monopoly.

252. Actelion's interest in protecting its intellectual property rights cannot justify its refusal to allow generics to purchase samples. Federal law provides that pre-market testing done by a generic manufacturer does not constitute an act of infringement.[96] In contrast, by statute, the filing of an ANDA constitutes a technical act of infringement (such that it permits a brand company with good cause to sue for infringement, and in turn a generic to challenge the patent or explain why it does not infringe). Here, withholding the sample prevented the generics from filing an ANDA, so there could be no act of infringement.

253. It made no economic sense for Actelion to refuse to allow generics to purchase its product. Actelion is in the business of selling drugs. The generics offered to pay market price and, in some instances, additional costs. Forgoing those sales is to forgo profits from those sales. Refusing to make a sale at the market price or higher makes no sense — unless one is trying to harm its competitors.

254. Actelion used the Tracleer REMS for its anticompetitive ends. It had no legitimate safety concern that could not have been alleviated given discussions between the parties or imposing reasonable conditions of the sale of the product (not that it ever tried to pursue this path with generics). In fact, Actelion did sell, or permit to be sold, samples to other research entities outside of the REMS scheme. Meanwhile, the FDA repeatedly confirmed that allowing the generics to purchase Tracleer samples would not violate the REMS or ETASU. Actelion's safety concerns were pretextual; Actelion discriminated against the generics as would-be customers because they had decided to compete with it.

[96] *See, e.g.,* 35 U.S.C. § 271(e)(1).

255. The only explanation for Actelion refusing to sell Tracleer samples to the generics is that it did so to block or delay competitors from entering the market and thereby prolong its monopoly. This conduct was irrational but for its anticompetitive effects.

256. Actelion's conduct in preventing the generics from obtaining samples had detrimental effects on consumers and the market. As a result, access to less expensive generic versions of the critically important drug Tracleer have been excluded from the market for years after its only patent expired. Actelion's conduct gave purchasers no choice but to pay for branded Tracleer at supracompetitive prices.

257. There is no concern that allowing the generic to access samples of the brand would lessen the incentive for both entities to invest in developing their products. Actelion had already manufactured quantities of Tracleer and put them into public commerce. It would not have had to, for example, embark on a separate process for creating a new product to provide to the generics. It simply had to not veto distributors' efforts to sell the product to the generics. Allowing access to samples would only serve to bring the generics less expensive product to market sooner.

258. There is no legitimate, non-pretextual, procompetitive justification for Actelion's refusal to sell samples of Tracleer to generics.

259. Actelion engaged in a prior course of dealing with entities that wished to purchase samples, including research entities who wanted to study the drug. Yet it refused to permit the generics from obtaining samples.

260. It is not surprising that Actelion had not engaged in a prior course of dealing with the generics as (1) Tracleer was the first drug product Actelion had ever sold in the U.S., (2) generic companies typically only seek to purchase branded drugs in connection with pursuing their ANDAs, and (3) there would have been no reason for Actelion to deal with the generics before

receiving their requests for samples. The requests for samples were likely the first opportunity for any business to be done between Actelion and the generics. The generics are seeking to *enter* the market; that they have not been in the market earlier is a result of Actelion's conduct.

261. Actelion has acknowledged that its refusal to allow the generics to buy Tracleer samples (either from itself or from its distributors) was intended to impede its competitors and prolong its monopoly:

- ". . . companies such as Actelion are under no duty to deal with a competitor."[97]
- "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."[98]
- "[T]here are . . . business justifications for declining access."[99]
- "The sole purpose of these proposed judicially-forced sales is to make it easier for the potential generic competitors to test and copy Actelion's products."[100]
- "Actelion is under no duty to sell its patented products to potential competitors . . . ."[101]
- "[T]he generics . . . want access to the very product that they want to test, copy, and then introduce into that market to compete with Tracleer."[102]
- ". . . it's perfectly appropriate for a monopolist to decide it does not want to set up – help a competitor set up and take away its business. That is legitimate for a monopolist to do. . . . and I think Ms. Reeves even quoted

[97] Actelion Complaint, ECF No. 1, at ¶ 35.

[98] *Id.* ¶ 36.

[99] *Id.* ¶ 45.

[100] Actelion Brief, ECF No. 44-1, at 1.

[101] *Id.* at 3.

[102] Transcript of Motions Hearing, ECF No. 96, at 31.

> the portion of *Christy* that talks about the only motive pled there was a motive to make more money. There's nothing wrong with that."[103]

262. Apotex, Roxane, and Actavis have all acknowledged the anticompetitive effects of Actelion's scheme, including the prejudice that would be suffered by the public by prolonging the litigation:

> [A] discovery stay would prejudice the public . . . by prolonging this litigation and further delaying the approval and sale of generic drugs that would compete with Actelion's Tracleer []. During an additional period of delay, Actelion would continue to reap monopolist's profits; patients would continue to pay artificially high prices for Tracleer []; and []Counterplaintiffs would continue to forego profits on generic versions of those drugs.[104]

263. Actelion's scheme was intended to impede generic competition to Tracleer, and it succeeded in doing so.

264. Actelion's overarching scheme has suppressed competition by blocking generics from the most efficient means of competition under the applicable statutes and regulations.

265. As a result of Actelion's conduct, Plaintiff and the class have been prevented from:

(a) purchasing less-expensive generic bosentan instead of more expensive branded Tracleer,

(b) purchasing generic bosentan at a lower price at an earlier time, and

(c) receiving discounts for purchases of branded bosentan, because earlier competition from generics at lower prices would likely have forced Actelion to reduce the price of branded bosentan to some degree, either directly or through discounts.

---

[103] *Id.* at 108.

[104] Counterplaintiffs' Joint Memorandum, ECF No. 49, at 1.

266. During the relevant period, Plaintiff and the class purchased substantial amounts of bosentan. Because of Defendants' illegal conduct, Plaintiff and the class were compelled to pay artificially inflated prices for their bosentan requirements. These prices were substantially higher than they would have been absent the illegal conduct alleged in this complaint.

267. Plaintiff and the class have thus sustained substantial damages to their businesses in the form of overcharges, the exact amount of which will be the subject of proof at trial.

N. Effect on Interstate and Intrastate Commerce

268. At all material times, Tracleer, manufactured and sold by Actelion, was promoted, distributed, sold and shipped in a continuous and uninterrupted flow of commerce across state lines and sold to customers located outside its state of manufacture.

269. During the relevant time period, in connection with the purchase and sale of Tracleer, monies as well as contracts, bills, and other forms of business communications and transactions were transmitted in a continuous and uninterrupted flow across state lines.

270. During the relevant time period, various devices were used to effectuate the illegal acts described above, including United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. Actelion's activities, as alleged in this complaint, were within the flow of, and have substantially affected, interstate commerce.

O. Actelion possesses monopoly power over bosentan.

271. At all relevant times, Actelion has maintained monopoly power over bosentan: it had the power to raise and/or maintain the price of bosentan at supracompetitive levels without losing substantial sales. Actelion also possessed complete control over the ability of competitors to obtain samples of the drug and thus enter the market in a way that is economically feasible, further adding to the strength of Actelion's monopoly power.

272. To the extent that Plaintiff and the class are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is Tracleer and therapeutically equivalent ("AB-rated") bosentan generics (none are currently on the market). This allegation is entirely consistent with Actelion's own description of the relevant market in this case, which it concedes is "[the] market for bosentan."[105]

273. Through the sale of Tracleer, Actelion has had a 100% market share in the relevant market at all times. As Actelion has stated, Tracleer is the "first and only approved dual endothelin receptor antagonist."[106] Tracleer is the only branded bosentan drug approved to treat PAH. There are no generic competitors to Tracleer and there are no other reasonably interchangeable drug products available to prescribing physicians for the indications for which Tracleer is prescribed.

274. Given the nature of the relevant market, Actelion needed to control *only* Tracleer and therapeutically equivalent generics of Tracleer — and no other products — to maintain the price of Tracleer profitably at supra-competitive levels.

275. Actelion used its market power to maintain premium pricing for Tracleer since the drug's inception. At all times, Actelion sold branded Tracleer well in excess of both marginal cost and of the competitive price, and has enjoyed unusually high profit margins. Tracleer is extremely expensive for the consumer, with an average monthly wholesale price of approximately $3,000.

276. Only the market entry of a competing, AB-rated generic equivalent version of Tracleer would make Actelion unable to profitably maintain its prices for Tracleer without losing substantial sales. However, the FDA approval process for NDAs serves as a significant barrier to new drug entry into this market. The only feasible way for a generic competitor to enter this

[105] *See* Transcript of Motions Hearing, ECF No. 96, at 32.

[106] Roxane Counterclaim, ECF No. 24, at ¶ 95.

market requires obtaining a sample of Tracleer, but Actelion has complete control over its distribution.

277. Actelion has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved bosentan drug products by — among other unlawful tactics—preventing potential competitors from obtaining samples and active pharmaceutical ingredient ("API") supplies, which are necessary for formulating a generic version of the drug. This conduct has caused output to be artificially low, raised competitors' costs, and/or kept the market price for FDA-approved bosentan artificially high.

278. Actelion's conduct has forced consumers who need bosentan to purchase Tracleer at artificially high and noncompetitive price levels and denied those consumers the availability of a lower cost generic bosentan product. Going forward, consumers who need bosentan will be forced to purchase Tracleer at artificially high and noncompetitive prices and will be denied the availability of a lower cost generic bosentan product.

279. Actelion has had a significant incentive to maintain its monopoly over bosentan and keep prices artificially high. 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.

280. The relevant geographic market is the United States and its territories.

281. At all relevant times, Actelion enjoyed high barriers to entry with respect to the above-defined relevant market.

282. A small but significant, non-transitory price increase to Tracleer by Actelion would not have caused a significant loss of sales to other drugs or products used for similar purposes, with the exception of therapeutically equivalent generic versions of bosentan, had any been available.

283. Bosentan does not exhibit significant, positive cross-price elasticity of demand with any other endothelin receptor antagonist used for treatment of PAH, but it would likely exhibit significant, positive cross-price elasticity of demand with AB-rated generic versions of Tracleer.

VII. CLASS ACTION ALLEGATIONS

284. Plaintiff brings this action on its own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the common law of unjust enrichment and the antitrust, unfair competition, and consumer protection laws of the states listed below (the "Indirect Purchaser States"), and as representative of a class defined as follows:

> All persons and entities in the Indirect Purchaser States and territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Tracleer or bosentan, other than for resale, at any time during the period from November 20, 2015 through and until the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

285. Excluded from the class are:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. all federal governmental entities;

c. all persons or entities who purchased Tracleer for purposes of resale;

d. fully insured health plans (*i.e.*, health plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

e. any "flat co-pay" consumers whose purchases of Tracleer were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. pharmacy benefit managers; and

g. all judges assigned to this case and any members of their immediate families.

286. Members of the class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiff believes that the class numbers in the dozens at least and is geographically spread across the nation. Further, the identities of members of the class will be readily identifiable from information and records in the possession of Actelion.

287. Plaintiff's claim is typical of the claims of members of the class. Plaintiff and all members of the class were damaged by the same wrongful conduct by Actelion, and all paid artificially inflated prices for Tracleer and were deprived of the benefits of competition from less expensive generic versions as a result of Defendants' conduct.

288. Plaintiff will fairly and adequately protect and represents the interests of the class. Plaintiff's interests are coincident with, and not antagonistic to, the class.

289. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

290. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual class members, because Defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

291. Questions of law and fact common to the class include:

(a) whether Actelion unlawfully maintained monopoly power through all or part of its overarching scheme;

(b) whether Actelion's anticompetitive scheme suppressed generic competition to Tracleer;

(c) as to those parts of Actelion's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Actelion's challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which bosentan is sold;

(d) whether direct proof of Actelion's monopoly power is available, and if available, whether it is sufficient to prove Actelion's monopoly power without the need to also define a relevant market;

(e) to the extent a relevant market or markets must be defined, what that definition is, or those definitions are;

(f) determination of a reasonable estimate of the amount of delay Actelion's unlawful monopolistic, unfair, and unjust conduct caused;

(g) whether Actelion's scheme, in whole or in part, has substantially affected interstate commerce;

(h) whether Actelion's scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and members of the Class in the nature of overcharges; and

(i) the quantum of overcharges paid by the Class in the aggregate.

292. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

293. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. CLAIMS FOR RELIEF

Claim I: Monopolization and Monopolistic Scheme Under State Law

294. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

295. At all relevant times, Actelion possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Actelion possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

296. Through its overarching anticompetitive scheme, as alleged above, Actelion willfully maintained its monopoly power in the relevant market using restrictive or exclusionary

conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiff and the class. Actelion's anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for bosentan in the United States.

297. Actelion accomplished its scheme by refusing to sell, and refusing to allow others to sell, samples of Tracleer to would-be generic competitors, thus delaying generic entry of Tracleer. It did so in order to lengthen the period in which Actelion's brand Tracleer could monopolize the market and make supra-competitive profits.

298. Had Actelion competed on the merits instead of unlawfully maintaining its monopoly in the markets for bosentan, one or more generics would have been available in November 2015. Plaintiff and the class members would have substituted lower-priced generic Tracleer for the higher-priced brand-name Tracleer for some or all of their Tracleer requirements, and would have paid substantially lower prices for brand-name Tracleer and generic Tracleer.

299. The goal, purpose, and effect of Actelion's overarching anticompetitive scheme was to block generic drugs from entering the market for bosentan, extend its dominance in that market, and maintain Tracleer's prices at supracompetitive levels.

300. Actelion's scheme substantially harmed competition in the relevant market.

301. There is and was no non-pretextual, procompetitive justification for Actelion's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Actelion could assert, the scheme is and was broader than necessary to achieve such a purpose.

302. But for Actelion's illegal conduct, competitors would have begun marketing generic versions of Tracleer beginning in November 2015.

303. By engaging in the foregoing conduct, Actelion intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a. Ariz. Rev. Stat. §§44-1401, *et seq.*, with respect to purchases of Tracleer in Arizona by class members and/or purchases by Arizona residents.

b. Cal. Bus. and Prof. Code §§ 17200, *et seq.,* with respect to purchases of Tracleer in California by class members and/or purchases by California residents.

c. D.C. Code Ann. §§ 28-4503, *et seq.*, with respect to purchases of Tracleer in the District of Columbia by class members and/or purchases by D.C. residents.

d. Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Tracleer in Florida by class members and/or purchases by Florida residents.

e. class members740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases of Tracleer in Illinois by class members and/or purchases by Illinois residents.

f. Iowa Code § 553.1, *et seq.*, with respect to purchases of Tracleer in Iowa by class members and/or purchases by Iowa residents.

g. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchases of Tracleer in Kansas by class members and/or purchases by Kansas residents.

h. Me. Rev. Stat. 10 § 1102, *et seq.*, with respect to purchases of Tracleer in Maine by class members and/or purchases by Maine residents.

i. Md. Com'l Law Code Ann. § 11-204(a), et seq., with respect to purchases of Tracleer in Maryland by Plaintiff the Government Employees Health Association.

j. Mass. Gen. Laws, Ch. 93A §§ 1, *et seq*., with respect to purchases of Tracleer in Massachusetts by class members and/or purchases by Massachusetts residents.

k. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchases of Tracleer in Michigan by class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases of Tracleer in Minnesota by class members and/or purchases by Minnesota residents.

m. Miss. Code §§ 75-21-3, *et seq.*, with respect to purchases of Tracleer in Mississippi by class members and/or purchases by Mississippi residents.

n. Neb. Code §§ 59-802, *et seq.*, with respect to purchases of Tracleer in Nebraska by class members and/or purchases by Nebraska residents.

o. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Tracleer in Nevada by class members and/or purchases by Nevada residents

p. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchases of Tracleer in New Hampshire by class members and/or purchases by New Hampshire residents.

q. N.M. Stat. §§ 57-1-2, *et seq.*, with respect to purchases of Tracleer in New Mexico by class members and/or purchases by New Mexico residents.

r. N.Y. G.B.L. § 340, *et seq.*, with respect to purchases of Tracleer in New York by class members and/or purchases by New York residents.

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Tracleer in North Carolina by class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Tracleer in North Dakota by class members and/or purchases by North Dakota residents.

u. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Tracleer in Oregon by class members and/or purchases by Oregon residents.

v. P.R. Laws tit. 10 § 260, *et seq.*, with respect to purchases of Tracleer in Puerto Rico by class members and/or purchases by Puerto Rico residents.

w. R.I. Gen. Laws §§ 6-36-7, *et seq.*, with respect to purchases of Tracleer in Rhode Island by class members and/or purchases by Rhode Island residents.

x. S.D. Codified Laws § 37-1-3.2, *et seq.*, with respect to purchases of Tracleer in South Dakota by class members and/or purchases by South Dakota residents.

y. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Tracleer in West Virginia by class members and/or purchases by West Virginia residents.

z. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Tracleer in Wisconsin by class members and/or purchases by Wisconsin residents.

304. As a direct and proximate result of Actelion's monopolistic conduct, Plaintiff and the class have suffered injury to their business and property in that they have paid more for bosentan than they would have paid in the absence of Actelion's unlawful conduct. Plaintiff and the class seek damages and multiple damages as permitted by law.

305. The injuries to Plaintiff and the class are the type of injury antitrust laws were designed to prevent, and injury flows from Actelion's unlawful conduct. The full amount of their damages is currently unknown, but will be determined after discovery and upon proof at trial.

306. Actelion's unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate.

Compliance with Notice Requirements

307. In accordance with the requirements of Arizona Revised Statute § 44-1415, Nevada Revised Statute § 598A.210(3), 5 Maine Revised Statute § 213(3), and New York General

Business Law § 340(5) on November 19, 2018, counsel sent letters by certified mail, return receipt requested, to:

a. Mark Brnovich, Attorney General of Arizona;

b. Adam Laxalt, Attorney General of Nevada;

c. Janet Mills, Attorney General of Maine; and

d. Barbara Underwood, Attorney General of New York,

informing them of the existence of this Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of this Class Action Complaint.

Claim II: Unfair Methods of Competition, and Unfair and Deceptive Acts, In Violation of State Consumer Protection Laws

308. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

309. Actelion engaged in unfair methods of competition, and unfair, unconscionable, and/or deceptive acts or practices to wrongfully perpetuate their concerted conduct to restrain trade in the relevant market.

310. As a direct and proximate result of Actelion's unfair, unconscionable, and/or deceptive conduct, Plaintiff and class members were: (1) denied the opportunity to purchase lower-priced generic Tracleer; and (2) paid higher prices for brand Tracleer than they would have paid but for Actelion's unlawful conduct.

311. The gravity of harm from Actelion's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and class members could not reasonably have avoided injury from Actelion's wrongful conduct.

312. There was and is a gross disparity between the price that the Government Employees Health Association, and the class members paid for Tracleer and the value they

received. Much more affordable generic Tracleer would have been available, and prices for brand Tracleer would have been far lower, but for Actelion's unfair, unconscionable, and deceptive conduct.

313. As a direct and proximate result of Actelion's anticompetitive, unfair, unconscionable, and/or deceptive conduct, the Plaintiff and class members were denied the opportunity to purchase generic Tracleer and forced to pay higher prices for brand Tracleer.

314. By engaging in such conduct, Actelion violated the following consumer protection laws:

a. Ariz. Rev. Stat. §§ 44-1521, *et seq.*, with respect to purchases of Tracleer in Arizona by class members and/or purchases by Arizona residents.

b. Cal. Bus. and Prof. Code §§ 17200, *et seq.,* with respect to purchases of Tracleer in California by class members and/or purchases by California residents.

c. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of Tracleer in the District of Columbia by class members and/or purchases by D.C. residents.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Tracleer in Florida by class members and/or purchases by Florida residents.

e. Ill. Comp. Stat. §§ 505/1, *et seq.*, with respect to purchases of Tracleer in Illinois by class members and/or purchases by Illinois residents.

f. Kan. Stat. §§ 50-623, *et seq.*, with respect to purchases of Tracleer in Kansas by class members and/or purchases by Kansas residents.

g. Me. Rev. Stat. 5 §§ 207, *et seq.*, with respect to purchases of Tracleer in Maine by class members and/or purchases by Maine residents.

h. Mass. Gen. Laws, Ch. 93A §§ 1, *et seq*., with respect to purchases of Tracleer in Massachusetts by class members and/or purchases by Massachusetts residents.

i. Minn. Stat. §§ 325F.68, *et seq.*, with respect to purchases of Tracleer in Minnesota by class members and/or purchases by Minnesota residents.

j. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Tracleer in Nebraska by class members and/or purchases by Nebraska residents.

k. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of Tracleer in Nevada by class members and/or purchases by Nevada residents.

l. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of Tracleer in New Hampshire by class members and/or purchases by New Hampshire residents.

m. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases of Tracleer in New Mexico by class members and/or purchases by New Mexico residents.

n. N.Y. G.B.L. § 349, *et seq.*, with respect to purchases of Tracleer in New York by class members and/or purchases by New York residents.

o. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Tracleer in North Carolina by class members and/or purchases by North Carolina residents.

p. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Tracleer in Oregon by class members and/or purchases by Oregon residents.

q. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Tracleer in Rhode Island by class members and/or purchases by Rhode Island residents.

r. S.D. Codified Laws § 37-24-6, *et seq.*, with respect to purchases of Tracleer in South Dakota by class members and/or purchases by South Dakota residents.

s. Va. Code §§ 59.1-196, *et seq.*, with respect to purchases of Tracleer in Virginia by class members and/or purchases by Virginia residents.

t. Vt. Stat. 9, § 2453, *et seq.*, with respect to purchases of Tracleer in Vermont by class members and/or purchases by Vermont residents.

u. W.Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Tracleer in West Virginia by class members and/or purchases by West Virginia residents.

315. Plaintiff and class members have been injured in their business and property by reason of Actelion's anticompetitive, unfair, unconscionable, and/or deceptive conduct. Their injury consists of paying higher prices for Tracleer than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Actelion's unlawful conduct.

316. On behalf of itself and the proposed class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

Compliance with the Written Demand Requirements of West Virginia and Massachusetts

317. On November 19, 2018, counsel sent a demand letter to Jane Griffiths, Global Head, Actelion Pharmaceuticals Ltd.; Actelion Clinical Research, Inc.; and Serge Messerlian, President, Actelion Pharmaceuticals US, Inc. This demand letter satisfies the requirements of West Virginia Code § 46A-6-106(c). The demand letter, which was sent via certified mail, return receipt requested, identified the claimants as "purchasers of Tracleer" in individual and representative capacities; described the unfair or deceptive acts or practices committed by Actelion; described the injury suffered (increased prices for Tracleer because of Actelion's failure

to provide samples to would-be generic competitors); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other sanctions); and requested an offer to cure within the statutorily prescribed time.

318. The demand letter requirement of Section 9 of Massachusetts General Laws Annotated Chapter 93A does not apply as to Actelion because, upon information and belief, Actelion has not identified a place of business or assets within Massachusetts. In an abundance of caution, however, Plaintiff, on behalf of itself and all others similarly situated, served on Actelion a written demand for relief, as described in the prior paragraph, on November 19, 2018.

Claim III: Declaratory and Injunctive Relief Under Section 2 of the Sherman Act

319. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

320. Plaintiff's allegations comprise a violation of Section 2 of the Sherman Act, in addition to the state laws *supra*.

321. Pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), Plaintiff and the class seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described in the preceding paragraphs violates Section 2 of the Sherman Act.

322. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, Plaintiff and the class further seek equitable and injunctive relief to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

IX. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on its own behalf and on behalf of the proposed class, prays for judgment against Defendants and that this Court:

1. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the class, and appoint Plaintiff as the named representative of the class;

2. Award Plaintiff and the class damages (*i.e.,* three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

3. Grant Plaintiff and the class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Actelion's unjust enrichment;

4. Grant permanent injunctive relief:

   a. Enjoining Actelion from continuing their illegal conduct;

   b. Enjoining Actelion from engaging in future anticompetitive conduct with the purpose or effect of delaying the entry of generic bosentan or other generic drugs; and

   c. Requiring Actelion to take affirmative steps to dissipate the continuing effects of their prior unlawful conduct;

5. Award Plaintiff and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

6. Award such other and further relief as the Court deems just and proper.

X. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed class, demand a trial by jury of all issues so triable.

Dated: November 20, 2018

/s/ E. David Hoskins
E. David Hoskins, Esq., No. 06705
The Law Offices of E. David Hoskins, LLC
16 East Lombard Street, Suite 400
Baltimore, Maryland 21202
(410) 662-6500 (Tel.)
(410) 662-7800 (Facsimile)
davidhoskins@hoskinslaw.com

Thomas M. Sobol (*pro hac vice* forthcoming)
Kristen A. Johnson (*pro hac vice* forthcoming)
Gregory T. Arnold (*pro hac vice* forthcoming)
Hannah Schwarzschild (*pro hac vice* forthcoming)
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
tom@hbsslaw.com
kristenj@hbsslaw.com
grega@hbsslaw.com
hannahs@hbsslaw.com

Mark Fischer (*pro hac vice* forthcoming)
Jeffrey Swann (*pro hac vice* forthcoming)
Robert C. Griffith (*pro hac vice* forthcoming)
RAWLINGS & ASSOCIATES, PLLC
1 Eden Pkwy
La Grange, KY 40031
Telephone: (502) 814-2139
mdf@rawlingsandassociates.com
js5@rawlingsandassociates.co
rg1@rawlingsandassociates.co

John D. Radice (*pro hac vice* forthcoming)
RADICE LAW FIRM, P.C.
34 Sunset Blvd
Long Beach, NJ 08008
Telephone: (919) 749-3980
jradice@radicelawfirm.com

Counsel for Plaintiff the Government Employees Health Association and the Proposed Class

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Government Employees Health Association

(b) County of Residence of First Listed Plaintiff Jackson County, MO
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
E. David Hoskins, Esq.; No. 06705; 16 East Lombard Street, Suite 400 Baltimore, Maryland 21202; (410) 662-6500

DEFENDANTS

Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc.

County of Residence of First Listed Defendant Arlesheim (Switzerland)
(IN U.S. PLAINTIFF CASES ONLY) Camden County

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☒ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
15 U.S.C. § 1 et seq.

Brief description of cause:
Violation of Sherman Antitrust Act

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $ >500,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. George Russell, III DOCKET NUMBER 1:18-cv-03560-GLR

DATE 11/20/2018

SIGNATURE OF ATTORNEY OF RECORD E. David Hoskins

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Government Employees Health Association *Plaintiff(s)*	)	
v.	)	Civil Action No.
Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. *Defendant(s)*	)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Actelion Pharmaceuticals Ltd.
Gewerbestrasse 16
CH-4123 Allschwil
Switzerland

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

E. David Hoskins
The Law Offices of E. David Hoskins, LLC
16 East Lombard Street, Suite 400
Baltimore, MD 21202
(410) 662-6500

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Government Employees Health Association *Plaintiff(s)*	)	
v.	)	Civil Action No.
Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. *Defendant(s)*	)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Actelion Pharmaceuticals US, Inc.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

E. David Hoskins
The Law Offices of E. David Hoskins, LLC
16 East Lombard Street, Suite 400
Baltimore, MD 21202
(410) 662-6500

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Government Employees Health Association *Plaintiff(s)*	)	
v.	)	Civil Action No.
Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. *Defendant(s)*	)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Actelion Clinical Research, Inc.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

E. David Hoskins
The Law Offices of E. David Hoskins, LLC
16 East Lombard Street, Suite 400
Baltimore, MD 21202
(410) 662-6500

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset