UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

EMBLEMHEALTH, INC., individually and on behalf of all others similarly situated, Plaintiff, v. ALEXION PHARMACEUTICALS, INC. and ALEXION PHARMA INTERNATIONAL OPERATIONS LTD. Defendants.	Civil Action No.

CLASS ACTION COMPLAINT AND JURY DEMAND

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EmblemHealth, Inc., on behalf of itself and all others similarly situated, brings this complaint against Alexion Pharmaceuticals, Inc. and Alexion Pharma International Operations Ltd. alleging the following based on personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

1. This civil action alleges that Alexion Pharmaceuticals, Inc., a Boston-based drug company and wholly owned subsidiary of the global drug company AstraZeneca, violated antitrust law by monopolistic acts that unlawfully delayed the introduction of biosimilar competition for eculizumab, a humanized monoclonal antibody that treats a range of rare blood and immune disorders.

2. Starting in 2007, Alexion sold eculizumab under the brand name Soliris to treat the debilitating condition called paroxysmal nocturnal hemoglobinuria ("PNH") with protection from competition under a 2002 issued composition patent, U.S. Patent No. 6,355,245 (the "'245 patent"). The '245 patent claims eculizumab, a biologic pharmaceutical comprising an anti-C5 antibody having a specified sequence of heavy and light chains.

3. Knowing Soliris sales were protected from competition by the 2002 government-issued patent and knowing that patients suffering the rare disease treated by the drug have no other therapeutic choice, Alexion charges one of the single highest drug costs in U.S. history, upwards of $500,000 per patient per year. By 2016, U.S. net product sales exceeded $1 billion per year, and by 2019 those sales had doubled to over $2 billion per year.

4. Alexion's 14-year grant of patent protected Soliris sales should have concluded after March of 2021 upon the expiration of its 2002 eculizumab patent. But in the years before that expiration, Alexion's senior management and scientists unlawfully procured a second set of five patents, once again claiming eculizumab, and with a expiration dates well into the future.

5. To accomplish the unlawful re-patenting of eculizumab, Alexion defrauded a U.S. patent examiner, repeatedly and falsely representing to him that, prior to 2007 when Alexion started its second wave of patent applications, the scientific community did not know the full amino acid sequence of eculizumab. The deception included concealing from the patent examiner many of Alexion's own pre-2007 publications that disclosed outright the exact sequence of eculizumab by providing a simple roadmap for its assembly. And Alexion falsely represented that its own '245 patent failed to teach the eculizumab amino acid sequence, all the while concealing from the examiner that Alexion had previously taken the position the '245 patent "claimed" eculizumab. From Alexion's falsehoods, the PTO examiner incorrectly allowed claims in a set of five related patents—three in 2017 and two in 2020—that once again covered eculizumab and known methods of using it.

6. Equipped with these late-issued patents, Alexion then asserted them against its would-be competitors as a basis to delay biosimilar competition to Soliris sales. The efforts to enforce the patents was a sham. While wielding the patents against its competitors could, and did, delay biosimilar entry, no reasonable litigant would ever have expected success on the eventual merits as the patents re-patenting eculizumab assuredly would be found invalid, whether in federal court litigation or proceedings challenging the patents before the U.S. Patent Trial and Appeal Board.

7. Alexion's scheme worked. Alexion used its fraudulently acquired patents to extract settlements from its first would-be competitor and to delay its second would-be competitor with costly and prolonged litigation. This first settlement pushed out biosimilar entry for eculizumab until March 2025—four-years beyond the expiration of the '245 patent.

8. U.S. purchasers of eculizumab—one of the most expensive drugs in the world—have paid supra-competitive prices for eculizumab due to Alexion's unlawful acts. During the

period of expected delay and impairment of biosimilar competition, the overpayments are estimated to exceed $2 billion.

9. Emblem was damaged by Alexion's unlawful conduct. Alexion sells eculizumab to a group of authorized specialty distributors, who in turn sell to specialty pharmacies, hospitals, health care providers, and infusion therapy providers, who then provide it to patients (who typically pay for the drug using third-party payers—also known as end payers—and other forms of payment). Emblem and members of the proposed class are end payers for Soliris. They are the last links in the pharmaceutical distribution chain and were overcharged for eculizumab due to Alexion's unlawful conduct.

10. The complaint alleges violation of federal and state antitrust and related laws. Injunctive relief is sought to, among other things, enjoin Alexion's ongoing use of the fraudulently acquired patents. Monetary relief is sought for overcharges caused by Alexion's wrongdoing, and, where appropriate, these damages should be doubled or trebled under law.

II. PARTIES

11. Plaintiff EmblemHealth, Inc. ("Emblem") is a not-for-profit corporation organized and existing under the laws of the State of New York, with its principal place of business at 55 Water Street, New York, NY 10041.

12. Emblem has purchased Soliris for its members for several years and anticipates continuing to purchase Soliris for its members through at least 2029.

13. Emblem purchases prescription drugs at third-party pharmacies where Emblem's health plan members have prescriptions filled. Emblem incurs substantial costs associated with its members' transactions at these third-party pharmacies.

14. The defendant Alexion Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 121 Seaport Boulevard, Boston, MA. On information and belief,

Alexion Pharmaceuticals, Inc. holds the legal title to the eculizumab patents described in this complaint. Alexion Pharmaceuticals, Inc. is wholly owned by AstraZeneca PLC.

15. The defendant Alexion Pharma International Operations Limited is a limited company incorporated in Ireland with its principal place of business at College Business & Technology Park, Blanchardstown Road North, Dublin 15, Ireland. On information and belief, Alexion Pharma International Operations Limited is the sole beneficial owner of the economic rights to the eculizumab patents described in this complaint via an exclusive license to patents and applications owned by Alexion Pharmaceuticals, Inc.

16. Alexion Pharmaceuticals, Inc. and Alexion Pharma International Operations Limited are collectively referred to as "Alexion."

III. JURISDICTION AND VENUE

17. This action alleges violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, and of state antitrust, consumer protection, and related laws. This action seeks injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and seeks monetary relief pursuant to state laws. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), § 1332(d)(2) (class action exceeding $5 million), § 1337(a) (antitrust enforcement), and § 1367(a) (supplemental jurisdiction).

18. Venue is proper in this district pursuant to 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because, during the class period, Alexion was headquartered, resided, transacted business, was found, or had agents in this district, and a substantial portion of the alleged activity affecting interstate trade and commerce discussed below has been carried out in this district. In fact, Alexion is actively seeking employees for dozens of positions in the Boston area.

19. This Court has personal jurisdiction over Alexion. Alexion conducts business throughout the United States, including in this district, and has purposefully availed itself of the laws of the United States. Alexion Pharmaceuticals, Inc. maintains its principal place of business in Boston.

20. During the class period, Alexion manufactured, sold, and shipped Soliris in a continuous and uninterrupted flow of interstate commerce, which included sales of Soliris in this district, advertisement in media in this district, monitoring prescriptions of Soliris by prescribers within this district, and employment of Alexion employees in this district.

21. Alexion, throughout the United States and including in this district, has transacted business, maintained substantial contracts, or committed overt acts in furtherance of its illegal scheme. Alexion's unlawful conduct has had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

22. Aside from sales of Soliris, Alexion transacts substantial business in this district, including business related to promotion and development of Soliris and to the unlawful scheme alleged here.

23. By reason of the unlawful activities alleged herein, Alexion substantially affected commerce throughout the United States, causing injury to Emblem and class members. Alexion directly and through its agents, engaged in activities to suppress competition, drive up brand sales, and fix, raise, maintain, and/or stabilize the price of Soliris in the United States. This conduct unreasonably restrained trade and adversely affected the market for the sale and purchase of eculizumab throughout the United States, including in this district.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The relevant federal regulatory structure encourages competition among pharmaceutical companies.

24. Drugs generally fall into one of two categories: small molecule or biologic. The majority of drugs are small molecule and manufactured using chemical processes. Biologics, in contrast, are derived from biological sources such as animals or microorganisms, and the resulting molecules are larger and sometimes more complex.

25. Biologics like Soliris are not new. For example, vaccines are biologics, and the first vaccines were first developed in the late eighteenth century. Another common biologic—insulin—was first isolated in the 1920s. Nonetheless, technological advances in the past few decades have exponentially expanded the number of biologics available.

26. Due to the differences between biologic and small molecule drugs, as well as biologics' more recent proliferation, distinct federal regulatory frameworks govern the approval and sale of (1) new biologics and their copies, and (2) new small molecule drugs and their copies.

27. The Food and Drug Administration (FDA) regulates small molecule drugs under the Food, Drug, and Cosmetic Act (FDCA), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984.[1] Under the FDCA, a drug company must file a New Drug Application (NDA) with the FDA before it can market a new small molecule drug. The first company to market a new small molecule drug usually holds patent or regulatory exclusivity, which prevents competition for a limited time. During this monopolistic period, the first entrant can—and almost always does—charge supracompetitive prices. The theory behind

[1] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

these government-granted exclusivities (indeed, the U.S. patent system in general) is that the promise of monopolistic profits will drive innovation.

28. After the period of exclusivity expires, however, other drug companies are free to sell copies of the first entrant's product, known as generic drugs. Enacted in 1984, the Drug Price Competition and Patent Term Restoration Act—more commonly known as the Hatch-Waxman Act—governs the approval of generic small molecule drugs. Under the Hatch-Waxman Act, generic drug manufacturers must file abbreviated NDAs (ANDAs) with the FDA to obtain approval for their bioequivalent copies of the NDA holder's drug (known as the branded or reference product). Because a generic is an exact copy of the reference drug, it competes solely on price—all other product features are identical. To compete for market share with the established brand, generics typically enter the market at far lower prices.

29. The approval process for new biologic drugs is similar, but not identical, to the pathway for new small molecule drugs. The Biologics Price Competition and Innovation Act (BPCIA)—signed into law as part of the Affordable Care Act in 2010—governs the approval of both new biologics and their copies.[2] Under 42 U.S.C. § 262(a), a biologic manufacturer must submit a Biologic License Application (BLA) to the FDA before it can market its drug.[3] The FDA may grant the BLA if, among other things, the manufacturer has demonstrated that the biologic is "safe, pure, and potent."[4]

30. Because biologics are derived from living matter, copies of the reference biologic are not identical in the same way that small molecule generics are identical to the brand product (reference and generic small molecule drugs share the exact same chemical structure).

[2] Pub. L. No. 111–148, § 7001, 124 Stat. 119, 804 (2010).

[3] 42 U.S.C. § 262(a).

[4] 42 U.S.C. § 262(a)(2)(C)(i)(I).

Nonetheless, copies of biologics, known as biosimilars, have no clinically meaningful differences in safety, purity, or potency as compared to their reference biologics.

31. Like the Hatch-Waxman Act, the BPCIA provides an abbreviated FDA-approval process for biosimilar drugs. Despite certain differences, the goal of this abbreviated approval pathway is the same as that of the Hatch-Waxman Act: to lower drug prices through robust competition.[5]

32. To obtain approval, a biosimilar manufacturer may submit an abbreviated BLA (aBLA) demonstrating that its biosimilar is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."[6]

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[5] In its February 2009 proposed budget, the Obama Administration emphasized that "[p]rescription drug costs are high and rising" and proposed "accelerate[d] access" with a "legal pathway for generic versions of biologic drugs." Office of Mgmt. & Budget, Exec. Off. of the President, *A New Era of Responsibility* 28 (2009). Similarly, when debating the yet-enacted BPCIA in June 2009, Senator Sherrod Brown explained, "[p]erhaps nowhere [is the need to bring down costs and increase access] more obvious than the area of biopharmaceuticals or so-called biologics . . . . With costs to biologics ranging anywhere from $10,000 to $200,000 per patient per year, biologic treatments pose a significant financial challenge for patients, for insurance companies, for employers who are paying the bills, and for Federal and State governments that are also paying the bills." 155 Cong. Rec. S6793 (daily ed. June 18, 2009). Representative Frank Pallone similarly stated that "[i]f biologics are the future, then we should do everything we can now to control costs while aiding innovation, just like Hatch-Waxman did." *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 2 (2009).

[6] 42 U.S.C. § 262(i)(2); *see also* 42 U.S.C. § 262(k)(2)(A). More specifically, the aBLA must contain information showing that:

i. "the biological product is biosimilar to a reference product based upon data derived from [certain kinds of studies];

ii. the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

iii. the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

iv. the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

33. A biosimilar manufacturer may not submit an aBLA until four years after the reference product is first licensed, and an aBLA may not be approved until twelve years after the reference product is first licensed.[7] Put another way, the manufacturer of a new biologic enjoys a statutory twelve-year monopoly over its biologic without biosimilar competition. Thereafter, biosimilars are free to compete.

34. Under certain circumstances, pursuant to the BPCIA, the FDA can also designate a biosimilar as "interchangeable," meaning the biosimilar "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."[8] Depending on the relevant state's laws, an interchangeable biosimilar may be substituted for the biologic at the pharmacy without a new prescription in the same way that generics are.[9] To obtain an interchangeability designation, a biosimilar applicant must submit to the FDA data sufficient to demonstrate that its product "is biosimilar to the reference product [and] can be expected to produce the same clinical results as the reference product in any given patient . . . ."[10]

35. The first biosimilar approved as interchangeable to the reference product enjoys an exclusivity period. The length of the exclusivity period depends on (a) whether, at the time the FDA granted the biosimilar maker's application for interchangeability, any patent infringement litigation related to that application (i) had already concluded, (ii) was ongoing, or

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v. the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent."

42 U.S.C. § 262(k)(2).

[7] 42 U.S.C. § 262(k)(7).

[8] 42 U.S.C. § 262(i)(3).

[9] FDA, *Biosimilar and Interchangeable Biologics: More Treatment Choices* (Aug. 17, 2023), https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices.

[10] 42 U.S.C. § 262(k)(4).

(iii) had not yet begun; and (b) the date on which the interchangeable biosimilar was first commercially marketed.[11]

36. In 2019, the FDA issued final guidance to assist applicants in demonstrating that a biosimilar is interchangeable pursuant to the BPCIA.[12] In August 2024, the FTC submitted a comment to the FDA, supporting efforts to reduce the regulatory burdens for obtaining interchangeability status and writing that "[i]ncreasing the number of biologics that are designated as 'interchangeable' could improve competition and uptake for biosimilars."[13]

B. Generic and biosimilar competition lowers drug prices.

37. The effect of small molecule drug competition on the market is well-established. Once a reference drug's patent(s) expire and the manufacturer faces competition, brand sales plummet as the market moves to the significantly more affordable generic products. Generic entrants will capture 80% or more of the market within the first six months, 90% of the market within a year, and eventually near 100% of the market.

38. The largest price drop for pharmaceutical products occurs when the number of generic competitors rises from one to two. Prices continue to decline as the number of generic manufacturers increase.

39. These price drops translate into savings for consumers and health plans. According to the U.S. Generic and Biosimilar Medicines Savings report, in 2022, the use of

[11] 42 U.S.C. § 262 (k)(6); Memo. from Dr. Mustafa Ünlü to Dr. Nikolay P. Nikolov (Oct. 3, 2023) (on file with the FDA), https://www.fda.gov/media/173749/download?attachment.

[12] FDA, *Considerations in Demonstrating Interchangeability With a Reference Product: Guidance for Industry* 1, 4 (May 20, 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry.

[13] Comment of the United States Federal Trade Commission, "Considerations in Demonstrating Interchangeability with a Reference Product: Update; Draft Guidance for Industry," Docket No. FDA-2017-D-0154 (Aug. 20, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/08/ftc-submits-comment-supporting-proposed-fda-guidance-interchangeable-biosimilar-drugs.

generic and biosimilar drugs saved consumers about *$408 billion*, which includes $130 billion in Medicare savings, as well as an estimated $2.9 trillion over the past 10 years.[14]

40. Biosimilar competition is a relatively recent source of healthcare savings. The FDA approved the first biosimilar in 2015, and, as of December 2023, the FDA had approved only 45 biosimilars. While there are some differences in distribution, pharmacy-counter substitution, and prescription writing practices of biosimilar and generic drugs, the same general principle applies: biosimilar competition, like generic competition, lowers drug prices and saves healthcare dollars. According to the FDA, as of 2021, biosimilars in the United States "launched with initial list prices 15% to 35% lower than comparative list prices of the reference products."[15] According to the 2023 U.S. Generic and Biosimilar Medicines Savings report, "biosimilars, on average, are priced more than 50 percent lower than the brand biologics [sic] price at the time of biosimilar launch."[16] And the "[b]rand biologics respond to biosimilar entry by lowering their prices to date, by 25 percent on average."[17]

41. Numerous studies have estimated the amount of savings (determined by estimated price reductions, penetration, and the like) resulting from the introduction of biosimilars. A 2014 Rand study examining individual biosimilars' price impact and market penetration found that with a market penetration of 60% and price reduction of 35% there

[14] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report*, at 7 (2023), https://accessiblemeds.org/resources/reports/2023-savings-report-2/.

[15] FDA, *FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes* (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes.

[16] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report*, at 30 (2023), https://accessiblemeds.org/resources/reports/2023-savings-report-2/.

[17] *Id.*

would be $44 billion in savings over those ten years.[18] The review study also noted that 60% market penetration was a conservative estimate.[19]

42. Thus far, actual savings have far exceeded expectations. A more recent Rand review from 2022, projecting U.S. savings from biosimilar entry from 2021-2025, found that total estimated savings from 2014 to 2025 would amount to $102.5 billion, $38.4 billion of which was projected savings from 2021-2025 from expanded biosimilar competition.[20]

43. The 2023 U.S. Generic and Biosimilar Medicines Savings report found that biosimilars generated $23.6 billion in savings since 2015, including more than $9.4 billion in 2022 alone.[21] And a third study estimated that biosimilar entry could result in $100 billion in savings between 2020 and 2024.[22] These results were also confirmed by the 2022 Rand study published in the American Journal of Managed Care and a 2023 IQVIA study. Assuming a higher biosimilar entry probability ($46.5 billion), higher biosimilar volume share ($48.3 billion), lower biosimilar prices ($52.8 billion), and lower prices for reference biologics ($82.4 billion), the study found potential savings could reach $124.2 billion between 2021 and 2025.[23]

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[18] Andrew W. Mulcahy et al., *The Cost Savings Potential of Biosimilar Drugs in the United States, Rand Corp.*, at 7 & n.17 (Nov. 3, 2014), https://www.rand.org/pubs/perspectives/PE127.html.

[19] *Id.*

[20] Andrew W. Mulcahy et al., *Projected US Savings from Biosimilars, 2021-2025*, 28 Am. J. Managed Care 329, 331 (2022), https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025.

[21] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report*, at 27 (2023), https://accessiblemeds.org/resources/reports/2023-savings-report-2/.

[22] IQVIA Instit., *Biosimilars in the United States 2020-2024* 17 (2020), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2020-2024.

[23] Andrew W. Mulcahy, et al., *Projected US Savings from Biosimilars, 2021-2025*, 28 Am. J. Managed Care 329, 334 (2022), https://pubmed.ncbi.nlm.nih.gov/35852882/.

In 2023, an IQVIA study concluded that savings from biosimilars would balloon to $181 billion between 2022 and 2027.[24]

C. New products might be entitled to a limited period of patent exclusivity.

44. A drug manufacturer can hold patents covering a biologic drug, its therapeutic uses, and the processes used to manufacture it, among other things. Such patents can constrain an aBLA applicant's ability to market its biosimilar even after the expiration of the BPCIA's 12-year exclusivity period.

45. To be valid, a patent must claim a novel invention.[25] If the matter claimed in the patent application "was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention," the applicant is not entitled to the patent and the PTO should deny the application.[26] Prior patents, publications, and other publicly known material before the filing date of the patent are known as "prior art." Over time, prior art accumulates—patents issue, publications reveal new discoveries, and new drugs go on sale. An application for a new patent is judged against any prior art that came after the "priority date"—the date by which the invention's novelty is judged.

46. The patent examination process is *ex parte*, meaning that the patent examiner engages in a dialogue with the applicant alone. The public, third parties, and even researchers in the same field are not a part of the patent examination process. As a result, the patent process is not an adversarial proceeding, and it lacks the safeguard of adverse parties pushing to present more facts to the examiner.

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[24] IQVIA Instit., *Biosimilars in the United States 2023-2027* (2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.

[25] 35 U.S.C. § 102.

[26] 35 U.S.C. § 102(a).

47. Because the proceedings are *ex parte*, federal regulation *requires* a patent applicant to be maximally forthcoming with patent examiners regarding relevant prior art. Federal regulation demands that patent prosecutors disclose to patent examiners "all information known to be material to patentability," including any prior art.[27] Known as the duty of disclosure, good faith, and candor, this requirement applies to each: (1) "inventor named in the application"; (2) "attorney or agent who prepares or prosecutes the application"; and (3) "[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application."[28] The purpose of this duty is to ensure that the patent prosecution process unfolds in a non-adversarial manner: the patent examiner is allowed to trust that the applicant has disclosed all relevant prior art, drawing his or her attention to the facts necessary to fairly evaluate the application.

48. Deceiving the PTO, engaging in inequitable conduct—including misleading a patent examiner or giving inaccurate statements during the prosecution—or violating the duty of disclosure renders the patent invalid.

49. The PTO's decision to issue a patent is not a substitute for a fact-specific assessment of whether (i) the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

[27] 37 C.F.R. § 1.56(a).

[28] 37 C.F.R. § 1.56(c).

50. Because patents enable a first entrant to exclude competition and charge supracompetitive prices, it is crucial that any patent covering a brand drug, including a biologic, be valid and lawfully obtained.

D. Regulatory frameworks permit challenges to drug patents.

51. The existence of one or more patents purporting to cover a drug product does not guarantee market exclusivity. Patents are routinely invalidated or held unenforceable, whether through PTO reexamination, PTO *inter partes* proceedings, federal district court rulings of law, or federal district court jury verdicts. A patent holder always bears the burden of proving infringement.

1. *Inter partes* review.

52. First entrants—both for small molecule and biologic drugs—often obtain patents on their new drugs shortly before they seek FDA approval, during the approval process, or immediately afterward. Patents obtained in this timeframe may claim and cover a genuine technological breakthrough. These original patents become "prior art," limiting the scope of follow-on patents that the manufacturers may obtain. As the number of patent filings for a drug grows, so does the volume of prior art with which the patent applicant must contend. Later-issued patents (should) be narrow and are more difficult to obtain. They are also inherently weaker patents, more susceptible to invalidation: predecessor patents in the same family often render them obvious and thus not entitled to a valid patent.

53. For decades, many drug manufacturers manipulated the patent system, overwhelming under-resourced PTO patent examiners into issuing meritless patents. A white paper examining federal district court patent cases in Westlaw and LexisNexis from 2007 to 2011 found that, in 86% of cases that reached a decision on the validity of a patent, the patent

claims challenged *were invalid and/or not infringed.*[29] The biotechnology field, which includes biologic drugs, has an even higher invalidity rate. An academic paper that examined all substantive decisions rendered by any court in any patent case filed in 2008 and 2009 found that biotechnology patent holders prevailed only *5.6% of the time.*[30] The authors concluded that their "data set suggests that the biotechnology patents that reach a merits ruling overwhelmingly lose."[31] They added that, "[o]f the litigated patents in our data set, biotechnology patents are much more likely to be invalidated than any other type of patent, and they are less likely than average to be infringed."[32]

54. Concerned that invalid patents were being issued and improperly enforced, to the detriment of both innovation and the economy, Congress passed the Leahy-Smith America Invents Act (AIA) in 2011. A centerpiece of the AIA is the *inter partes* review system, which (1) allows patent challenges through an administrative process that differs from traditional patent litigation, and (2) expands the universe of potential patent challengers.

55. The *inter partes* review process enables any member of the public to challenge an issued patent without first committing an act of infringement. A panel of administrative law judges—who possess both specialized legal and technological knowledge—then reviews the validity of the issued patent. These administrative law judges belong to the Patent Trial and Appeals Board (PTAB)—the same board that decides appeals of patent examiner rejections of patent applications. The only limitation on *inter partes* review is that a petitioner may only

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[29] Morgan Lewis, *White Paper Report: U.S. Patent Invalidity Study* (2012), https://www.morganlewis.com/-/media/files/publication/presentation/speech/smyth_uspatentinvalidity_sept12.pdf?rev=3a7b8e0fd5c0476ba154ee8a9d96a773.

[30] John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. Chi. L. Rev. 1073, 1073, 1097–98 (2015), https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=5876&context=uclrev.

[31] *Id.*

[32] *Id.* at 1137.

challenge the validity of a patent based on obviousness or anticipation—a petition cannot be based on other grounds for invalidity, such as inequitable conduct or double patenting.[33]

56. The PTAB will grant a request for *inter partes* review only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition."[34] The PTAB must decide the review within one year of the institution date.[35]

57. Although a step in the right direction, *inter partes* review has not cured the problem of invalid patent issuance. In July 2018, Dr. Scott Gottlieb, then-Commissioner of the FDA, observed that biosimilar competition was "anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they'll be available to patients here. These delays can come with enormous costs for patients and payors."[36] He added that "patent thickets that are purely designed to deter the entry of approved biosimilars are spoiling this sort of competition."[37]

2. Patent litigation.

58. One way that the maker of a biosimilar drug can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

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[33] 35 U.S.C. § 311(b).

[34] 35 U.S.C. § 314(a).

[35] 35 U.S.C. § 316(a)(11).

[36] FDA, *Remarks from FDA Commissioner Scott Gottlieb, M.D.* (Jul. 18, 2018), https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas.

[37] *Id.*

59. A patent is invalid or unenforceable when: (i) the disclosed invention is anticipated and/or obvious in light of earlier prior art – i.e., it is not novel; (ii) its claims are indefinite, lack sufficient written description, or fail to properly teach how to make and use (enable) the claimed invention; (iii) an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information, or submits materially false information to the PTO during prosecution; and/or (iv) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

60. An assessment of whether a patent is obvious and therefore invalid is based on the prior art that existed as of the priority date of the claimed invention. "Prior art" refers to patents, published patent applications, and other non-patent sources, such as journal articles, which are publicly available. The "priority date" might be the date of the application for the claimed invention, or it could be an earlier date if the current patent application is a continuation of an earlier one.

3. **The BPCIA patent dance.**

61. Like the Hatch-Waxman Act, the BPCIA implicitly acknowledges that a biologic manufacturer might abuse the patent system to forestall competition. To remedy this problem, the law provides a framework for challenging invalid patents or arguing non-infringement.

62. In general, a patent owner may not file an action for patent infringement until another person "makes, uses, offers to sell, or sells" a product that infringes the patent within the United States.[38] But the Hatch-Waxman Act and the BPCIA enable the patent holder (the brand manufacturer) to bring an infringement action *before* the biosimilar or generic manufacturer begins to sell their allegedly infringing product. Both laws provide that a patent

[38] 35 U.S.C. § 271(a).

infringement lawsuit may take place prior to the ANDA or aBLA applicant's launch,[39] and both laws lay out procedures for resolving the ensuing patent action.

63. Under the Hatch-Waxman Act, a brand manufacturer obtains notice that a generic intends to make a product implicating its patents through a notification process involving a public reference manual known as the "Orange Book." Brand manufacturers submit a list of the patents they believe cover their drugs to the FDA, which, in turn, lists them in the Orange Book. When a generic drug files an ANDA, it must state whether its generic product will implicate those patents and provide notice of any potential infringement to the brand.

64. An equivalent reference exists for biologic drugs—the "Purple Book." However, unlike the Orange Book, the Purple Book does not contain a definitive list of patents covering the biologic reference product. Instead, the BPCIA lays out a five-step set of pre-litigation exchanges—known as the patent dance—that may culminate in patent litigation if the parties do not resolve their disputes. The BPCIA also provides remedies for such patent infringement, including injunctive relief and damages.[40]

65. If the parties comply with all steps of the patent dance, once those steps are complete, the first phase of BPCIA litigation finally begins. Within 30 days of the list exchange, the patent holder "shall bring an action for patent infringement with respect to" each patent either agreed to or on the exchanged lists.[41]

66. Under certain circumstances, the reference product sponsor need not wait to file a lawsuit. *First*, as stated above, submitting an aBLA constitutes an act of infringement, sometimes referred to as "artificial" infringement, which may result in injunctive relief and

[39] 35 U.S.C. § 271(e)(2)(C); 42 U.S.C. §§ 262(l)(6), (l)(8), (l)(9)(B)–(C).

[40] 35 U.S.C. § 271(e)(4).

[41] 42 U.S.C. §§ 262(l)(6)(A), (B).

damages.[42] *Second*, if an aBLA applicant fails to provide the aBLA and other required information under subsection (l)(2)(A), the reference product sponsor (the brand manufacturer) may bring an action under 28 U.S.C. § 2201 for declaratory judgment of infringement, validity, or enforceability of any patent that claims the relevant biologic product or its use.[43] *Third*, if the aBLA applicant provides the aBLA and requisite information under subsection (2)(A), but the applicant fails to complete a later step in the patent dance, the reference product sponsor may also bring an action under 28 U.S.C. § 2201 for declaratory judgment of infringement, validity, or enforceability of any patent included in the 3A list.[44]

67. The BPCIA also requires an aBLA applicant to provide the patent holder at least 180-days' notice before commercially marketing its biosimilar.[45] Upon receiving such notice, the reference product sponsor may file for a preliminary injunction prohibiting the manufacture or sale of the biosimilar until adjudication of the validity, enforcement, and/or infringement of any patent on the reference sponsor's original 3A list or in the aBLA applicant's list provided under subsection (3)(B).[46] The injunctive relief of BPCIA litigation thus concerns all patents that the patent holder alleges are relevant.

68. Once the 180-day notice period has expired, and provided the FDA has approved the aBLA, the aBLA applicant may launch its biosimilar regardless of whether the patent litigation has been resolved. Such a launch is known as an "at-risk" launch. A manufacturer that

[42] 35 U.S.C. §§ 271(e)(2)(C), (e)(4).

[43] 42 U.S.C. § 262(l)(9)(C).

[44] 42 U.S.C. § 262(l)(9)(B).

[45] 42 U.S.C. § 262(l)(8)(A). The notice need not be after the FDA approves the aBLA applicant's licensure. *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 3 (2017).

[46] 42 U.S.C. § 262(l)(8)(B).

launches at-risk accepts the possibility that it will have to pay damages to the patent holder if the patents are found valid, enforceable, and infringed.

69. When in 1984 Congress passed the Hatch–Waxman Act for the purpose of enabling expedited generic drug approval, one of the benefits brand drug makers received in exchange was that holders of patents on approved patented products could seek an extended term of patent protection to compensate for the delay in obtaining FDA approval. This restoration period does not recover the full time lost from the patent term due to FDA's premarket approval process, but it does ameliorate the loss incurred when patent terms tick away while the patented product is awaiting FDA's regulatory approval for marketing.

70. Of course, under the Act the patent for which the applicant is seeking an extension must *claim* the FDA approved drug product.[47]

E. End payers are typically the most efficient enforcer of state antitrust laws.

71. In the pharmaceutical area, direct and indirect (sometimes "end payer") purchasers and competitors may seek to enforce antitrust laws against alleged wrongdoing on the part of drug manufacturers.

72. *Drug wholesalers as antitrust enforcers.* Over the years, private enforcement of federal antitrust laws has included actions brought by proposed classes of direct purchasers. Direct purchasers of pharmaceuticals are typically drug wholesalers, who purchase drugs from drug manufacturers in bulk and resell them to pharmacies and hospitals. However, several facts

[47] See 35 U.S.C. § 156(a) (stating "[t]he term of a patent which claims a product . . . shall be extended in accordance with this section from the original expiration date of the patent"); *id.* at §156(d)(1) ("the owner of record of the patent or its agent shall submit an application" which must contain "the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product . . . ." *See also Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 758 (Fed. Cir. 1997) ("the text of section 156 states in relevant part, "[t]he term of a patent *which claims* a product, a method of using a product, or a method of manufacturing a product shall be extended . . .") (emphasis in original).

of U.S. pharmaceutical wholesaling teach that: (i) drug wholesalers are increasingly unlikely to bring proposed direct drug purchaser antitrust class actions; (ii) wholesalers are unlikely to do so especially with respect to specialty pharmaceuticals; and (iii) wholesalers rarely enforce state antitrust laws as the focus of any enforcement efforts.

73. The defendants in this case treat Soliris as a specialty pharmaceutical and distribute the product through distribution agreements that provide significant buy-side revenue to Alexion's contracted distributors.

74. *First*, increasing consolidation of U.S. drug wholesalers has led to fewer and fewer wholesalers distributing manufacturers' drug products. While this trend has been underway for quite some time, recent consolidations have created a situation where, even for non-specialty drug products, it is common to have fewer than 30 wholesalers directly purchasing a pharmaceutical product from the drug manufacturer. Indeed, today, 90 percent of prescription drugs in the United States are distributed by three drug wholesalers: AmerisourceBergen, Cardinal Health, and McKesson Corporation. And for specialty drugs, the number of direct purchasers is typically much smaller. As a result, use of the class action mechanism can be more challenging (due to the smaller proposed class size) than when the number of direct drug purchasers was larger. While direct purchaser cases still are (and should be) certified, in recent years, courts have denied certification of a handful of proposed direct drug purchaser classes based on their ostensible lack of numerosity. And, in the wake of these denials, numerous direct drug purchasers did not file follow-on individual suits. This means that non-class direct drug purchaser actions enforce only some of the anticompetitive harm from the alleged violation. The fact that direct drug purchaser cases challenging delayed generic entry almost always (if not always) begin as class actions further underscores the importance of the class action mechanism to the efficiency of antitrust law enforcement.

75. *Second*, wholesalers increasingly make a considerable amount of their revenues from the "buy side" of drug transactions, i.e., from the side of the transaction with the drug manufacturer. Through payments for services rendered in distribution services agreements and other arrangements, wholesalers can reduce the accounting cost of drugs significantly. Some of these payments look like traditional arrangements between a supplier and wholesaler (e.g., prompt pay discounts, stocking allowances, and the like). But, through distribution service agreements, wholesalers also perform a variety of other services for the manufacturer and, in return, receive buy-side fees and other benefits. Common services include inventory management, meeting service targets with customers, and submitting data to the manufacturer about customer purchasing of the manufacturer's drugs. While specific drug-purchasing decisions are ultimately governed by the needs of the wholesaler's customers, the substantial buy-side revenues direct drug purchasers increasingly earn from the drug manufacturers dampens their incentive to bite (i.e., sue) the hand that feeds them.

76. Furthermore, the buy-side economics can be particularly important to direct drug purchasers in the case of specialty distribution drugs. Drug wholesalers compete to be one of the relatively few wholesalers with whom a specialty drug manufacturer will contract for the limited distribution network of a specialty drug. Specialty drugs are typically more expensive than non-specialty brand and generic drugs and thus provide the wholesaler an opportunity to earn significant buy-side revenues. As a result, distribution agreements with specialty drug manufacturers can often account for more than *half* of the wholesaler's buy-side gross margin. And total buy-side economics is a significant driver of wholesaler total net revenues. Thus, again, the lucrativeness of specialty pharmaceutical distribution contracts mitigates direct drug purchasers' willing to sue to specialty pharmaceutical producers (like Alexion).

77. *Third*, direct drug purchasers are not efficient enforcers of *state* antitrust laws. Under the Clayton Act, direct purchasers have a nationwide, treble damages monetary remedy for violations of federal antitrust laws, including the Sherman Act. As a result—and given the similarity of substantive state and federal antitrust law—direct purchasers typically have little incentive to pursue state law damages remedies.

78. In sum, the combination of these factors significantly decreases the likelihood that direct drug purchasers will sue the drug manufacturers to vindicate antitrust violations—especially where the higher drug prices that the antitrust violations enable mainly harm end payers (consumers and health insurers).

79. *Biosimilar (and generic) competitors as antitrust enforcers.* Over the years, while there has been some private enforcement of antitrust laws by would-be generic competitors, several features of the pharmaceutical industry and generic/biosimilar entry render would-be generic/biosimilar competitors inefficient enforcers of antitrust laws, particularly with respect to *Walker Process* fraud allegations.

80. *First*, competitor antitrust actions typically seek damages based on valuation of how much the competitor would have earned absent the alleged antitrust violation. And this valuation is typically dwarfed by the much larger damages the wrongdoer's purchasers have suffered by way of overcharges. This is because a generic or biosimilar competitor is only seeking to recover their own damages: the lost profits that company would have been able to earn if allowed onto the market at any earlier date. Purchasers of medications that are overpriced as a result of anticompetitive conduct are seeking to recover the amount they overpaid as a result of *all* generic or biosimilar competition being excluded and/or delayed from the market. In other words, the damages of multiple generic manufacturers, not just one, and not simply lost profit. As a result, a purchaser class action poses a higher risk to brand antitrust

violators (via higher potential damages award) than competitor actions. And competitors have less of a financial incentive to bring such lawsuits (based on their lower potential damages recoveries) than purchasers of overpriced drugs. In sum, while competitors may have some self-interest in enforcing antitrust laws, that interest is typically much less than that of the proposed purchaser class here.

81. *Second*, competitor challenges to brand company patents often prioritize attacks on the patent(s) based on lack of infringement rather than unenforceability (i.e., inequitable conduct or *Walker Process* fraud). This is because if a competitor wins a lawsuit declaring that its product does not infringe the brand's patents, that lawsuit *only* allows that competitor onto the market. If the competitor wins a lawsuit declaring the brand's patent(s) invalid based on inequitable conduct or fraud, then that lawsuit allows *all* competitors to enter the market. And, all things equal, a would-be competitor would prefer to gain market entry for its *own* product only rather than open the market for *all* would-be competitors. Prevailing on a challenge to infringement does the former, while prevailing on an argument that the patent was procured by fraud opens the market for all. As a result, competitor patent challenges often place less emphasis on challenges to the patent's overarching enforceability.

82. *Third*, the primary goal of the would-be competitor is market access, not litigating a lawsuit for a damage recovery. As a result, manufacturing competitors who challenge the brand's patents often settle for entry dates that are later than the date they would have been able to come to market absent the asserted patents, but earlier than the entry date the asserted patents allow. In exchange for the negotiated entry date, such settlements require the competitors to release all other claims—including antitrust claims—against the brand manufacturer. Thus, competitor settlements of patent infringement claims with brand manufacturers typically compromise any potential for enforcement of related antitrust actions.

83. This is particularly true for biosimilar companies. Biosimilar companies make significant investments pursuing aBLA or BLA approval and market access, and they need to recoup those investments through early launch of their product. When faced with actual or threatened litigation by a brand biologic company, biosimilar companies (regardless of the merits of the litigation threat) face real world pressure to settle. The consequence of this pressure is the biosimilars' abandonment of meritorious claims of anticompetitive behavior by the brand. As a result, especially for biologic drug products, there are strong reasons for competitors not to enforce antitrust laws for strategic business reasons.[48]

84. To date, the FDA has approved two biosimilar versions of Soliris. Amgen (approved on May 28, 2024 as an interchangeable biosimilar to Soliris)[49] and Samsung Bioepis (on July 22, 2024),[50] the two companies responsible for manufacturing and commercializing the biosimilars have reached settlements with Alexion. It appears that in each settlement, Alexion demanded—and each biosimilar acceded to granting Alexion—a release for all claims. Tellingly, no would-be competitor to Alexion for eculizumab has sought to enforce the antitrust laws. Put another way, the conduct of the biosimilar eculizumab manufacturers supports the plaintiffs' allegations that biosimilar competitors are not the most efficient enforcers of antitrust claims.

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[48] While in a 2009 decision the Second Circuit remarked—without citing any empirical support—that patent fraud cases are "typically brought as counterclaims in patent infringement suits," *see In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 689 (2d Cir. 2009), two years later the Federal Circuit cut back on the ability of ostensible patent infringers to do so. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (stating that this "court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public").

[49] https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-two-rare-diseases.

[50] https://www.centerforbiosimilars.com/view/fda-approves-epysqli-as-second-soliris-biosimilar. Samsung's product had previously been approved by the European Commission in May 2023.

85. *Drug end payors as antitrust enforcers.* Over the years, private enforcement of antitrust laws for alleged violations causing delayed or impaired generic/biosimilar entry, and thus higher drug prices, has typically included claims brought by drug end payers. As between the three groups of potential private enforcers—direct drug purchasers, competitor manufacturers, and end payer purchasers—the empirical, regulatory, and legal fact is that end payers for prescription drugs: (i) are efficient enforcers of antitrust laws; (ii) for biologics and specialty drug products, are likely the most efficient enforcer of antitrust laws; and (iii) as to state antitrust laws, are the most efficient private enforcer group.

86. *First*, in the United States, pharmaceutical end payers are the last stop in the drug payment chain and thus suffer the final, legal overcharge. They do not pass on their overcharges to any further downstream party. As a result, no other private enforcers have as clear a claim to ultimate antitrust injury.

87. *Second*, drug end payers are especially efficient enforcers of *state* antitrust laws that provide an "*Illinois Brick* repealer" damages remedy to indirect purchasers. Indeed, courts recognize that end payer enforcement is the very "purpose of *Illinois Brick* repealer statutes."[51]

[51] *See, e.g., D.R. Ward Const. Co. v. Rohn & Haas Co.*, 470 F. Supp. 2d 485, 503 (E.D. Pa. 2006). State courts interpreting *Illinois Brick* repealer statutes regularly pronounce that plaintiffs' antitrust standing must be assessed in light of the clear legislative directive to extend recovery to indirect purchasers. *See, e.g., Brown v. Hartford Healthcare Corp.*, No. 03-cv-22-6152239, 2023 WL 7150051, at *6 (Super. Ct. Conn. Oct. 26, 2023) ("[A]n antitrust standing analysis must be consistent with the legislature's rejection of federal antitrust law's prohibition of indirect purchaser claims and the passing-on defense."); *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 629 (Minn. 2007) ("We do not believe that the legislature repudiated *Illinois Brick* and invited indirect purchaser suits only for courts to dismiss those suits on the pleadings based on the very concerns that motivated *Illinois Brick*."); *Knowles v. Visa U.S.A., Inc.*, No. 03-cv-707, 2004 WL 2475284, at *5 (Super. Ct. Me. Oct. 20, 2004) ("Maine's adoption of an *Illinois Brick* repealer further suggests that the court should not deny standing just because plaintiffs are not participants in the actual market where trade was allegedly restrained.").

88. *Third*, drug end payors typically do not have direct product supply arrangements with drug manufacturers. Thus, they do not have the kind of reluctance direct purchasers would, and do, have about suing drug manufacturers.

89. *Fourth*, end payers often have the motivation to address restraints of trade that impact important medications given the drugs' medical importance to their members.

90. *Finally*, the empirical fact is that private enforcement of antitrust laws for pharmaceutical restraints on competition is far more often undertaken by purchasers, not competitors. Generics have asserted an antitrust counterclaim in only a small, single-digit percent of the thousands of Hatch-Waxman patent litigation lawsuits filed against them by brand drug companies. And purchasers assert antitrust claims predicated on *Walker Process* fraud significantly more often than manufacturing competitors.

91. In this case, the most efficient enforcer of antitrust laws is the proposed class of Soliris end payers. The plaintiff end payers and their counsel investigated, discovered, developed, and filed the case. No other potential enforcer of the implicated laws did so. For this case, the efficient and only enforcer is drug end payors.

92. In summary, due to myriad dynamics faced by biosimilar competitors and direct purchasers, these actors are not only unlikely, but, indeed, *have not* enforced antitrust laws based on alleged *Walker Process* violations. The most efficient enforcers—and the only available private enforcer here—is pharmaceutical end payors.

V. FACTS

A. The scientific development of eculizumab.

93. Eculizumab is an FDA-approved biologic that doctors prescribe to treat several rare blood and immune disorders, including paroxysmal nocturnal hemoglobinuria ("PNH"), atypical hemolytic uremic syndrome ("aHUS"), generalized myasthenia gravis ("gMG") and

neuromyelitis optica spectrum disorder ("NMOSD"). It is given by intravenous ("IV") infusion, often at an infusion center or at home with the aid of a nurse or other medical professional. Typically, the dosing schedule requires initial weekly infusions of eculizumab for five weeks and then regular infusions every two weeks thereafter.

94. Infusion providers order Soliris either through an authorized specialty distributor or through a specialty pharmacy. In either case, Soliris is directly shipped from Alexion to the infusion provider.

95. Eculizumab treats disorders involving the complement system—a part of the immune system that defends the body against injury and infection and helps it heal. The complement system targets foreign invaders and helps activate inflammation to prevent infection. Malfunctioning of the complement system can have serious negative health impacts.

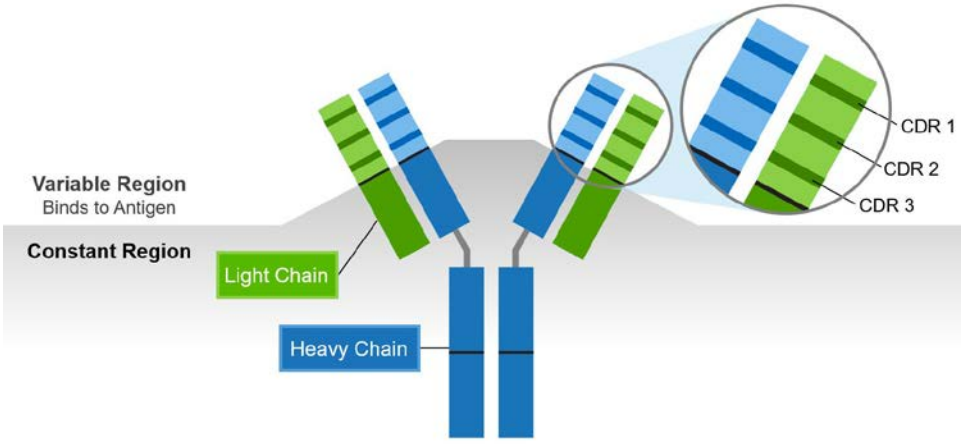
96. Eculizumab treats disorders that involve cleaving—or splitting—of a complement protein called C5. When the C5 protein splits, it is converted to C5a and C5b and can cause destructive results. For example, in PNH, a rare bone marrow disorder treated by eculizumab, a genetic mutation causes C5 cleaving that makes red blood cells susceptible to destruction by the complement system (called hemolysis). This can result in life-threatening effects such as hemolytic anemia, bone marrow failure, and thromboembolic episodes. Likewise, in aHUS—another disorder treated by eculizumab—C5 cleaving causes the complement system to attack and destroy red blood cells. In sum, eculizumab works by binding to the C5 protein of the complement system and preventing it from cleaving, suppressing the problematic complement activation that results.

1. Antibody structure and the humanization of antibodies.

97. Eculizumab is a humanized monoclonal antibody. A monoclonal antibody is a laboratory-made protein that mimics an antibody—a type of protein—that the human body naturally produces (i.e., clones of one antibody—monoclonal).

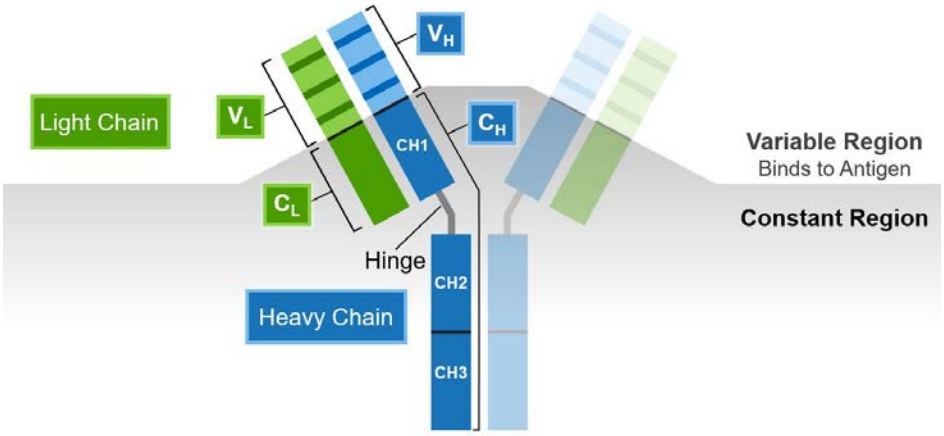
98. "Eculizumab" refers to humanized antibodies derived from the mouse antibody 5G1.1. The term "humanized" means the antibody has a human framework, into which segments from a non-human monoclonal antibody (e.g., mouse) are inserted.

99. For these purposes, an antibody consists of two pairs of amino acid chains referred to as heavy and light chains. Each chain has a constant and a variable domain. The variable domains contain subportions responsible for antigen recognition called Complementarity-Determining Regions ("CDRs"); there are three CDRs each in the variable domains of each heavy and light chain, as shown below:



Basic domain structure of antibody

100. The variable regions of the heavy and light chains are abbreviated as "V_H" and "V_L." The constant region of the heavy chain is broken up into subregions called CH1, CH2, and CH3. CH1 is separated from CH2 and CH3 by a hinge region, as shown below.



Basic domain structure of antibody

101. By the 1990s the process of "humanization" of antibodies—in which mouse antibodies to human targets were converted into mostly human sequences while retaining target-binding function—was well known and routinely practiced by artisans developing antibodies for use as therapies in humans. Indeed, by 2007 more than a dozen antibodies had been approved by the FDA for therapeutic use in humans, including several humanized antibodies. Such antibodies were the basis of pharmaceutical compositions that were most commonly formulated in sterile, preservative-free single use dosage forms and administered by IV infusion.

2. Eculizumab development and naming history.

102. Eculizumab was developed more than 30 years ago. In the mid-1990s, a group of scientists from Alexion used recombinant technologies to develop anti-C5 antibodies. By 1995, Alexion had successfully developed eculizumab. The scientists filed an application with the PTO seeking patent protection for anti-C5 antibodies, including eculizumab.

103. When Alexion scientists first identified a mouse antibody that specifically binds C5, they gave it the name "5G1.1." This mouse antibody was then "humanized," meaning that the CDR domains responsible for C5 binding were grafted into a human "framework" variable region, using techniques that were well-developed by the mid-1990s.

104. The resulting humanized antibody maintains fully mouse sequences in each of its six CDR domains but otherwise uses human sequences for the variable region to varying degrees; Alexion gave this antibody the name "h5G1.1".

105. After confirming that the humanized antibody variable domain retained its C5-binding function, Alexion scientists assembled it into a full-length antibody of the human IgG4 isotype, which they named "h5G1.1 HuG4."

106. Soon after creating this antibody, Alexion set about improving it by modifying the constant region to give it a hybrid IgG2/IgG4 backbone. Alexion sought to reduce or eliminate binding by the constant region of the IgG4 isotype to other proteins such as FcR and C1q that are involved in human immune responses and the complement system, by replacing it with comparable IgG2 sequences. Specifically, the improved antibody contained the CH1 and hinge region from IgG2 and the CH2 and CH3 regions from IgG4.

107. Alexion called this antibody "h5G1.1 HuG2/G4." In a companion patent application describing the same work, Alexion referred to this antibody interchangeably as "h5G1.1 G2/G4" and "h5G1.1 CO12 HuG2/G4."

108. By 2002, Alexion had obtained a unique name for this antibody pursuant to the World Health Organization's guidelines for international nonproprietary names ("INNs"). Under INN rules in place since the 1990s, antibodies are named as follows: A random prefix of a few letters chosen by the product sponsor for uniqueness (in this case "ecu-") is followed by a "sub-stem" indicating its function (immunomodulators use "-li-"), followed by another sub-stem indicating humanization ("-zu-"), finally followed by the stem "-mab" applied to all monoclonal antibodies.[52] Thus, Alexion's antibody received the nonproprietary name ecu-li-zu-mab.

[52] *Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances*, Programme on International Nonproprietary Names (INN), Division of Drug Management & Policies, World Health Organization, Geneva (1997), at 031–32.

B. Alexion procures the '245 eculizumab patent.

109. From the mid-1990s to early March 2002, Alexion prosecuted its patent application for anti-C5 antibodies, including eculizumab.

110. On March 12, 2002, the application issued as U.S. Patent No. 6,355,245 B1, entitled "C5-specific Antibodies for the Treatment of Inflammatory Diseases." The named inventors for the '245 patent were ten Alexion employees, including Mark J. Evans (a senior Alexion scientist), Russell P. Rother (an Alexion vice president) and Thomas C. Thomas (another scientist). This patent is generally referred to herein as the "'245 patent," although it is also sometimes referred to as the "'245 eculizumab patent" or "Evans 2002".

111. The '245 patent specifically discloses the variable regions for the original mouse 5G1.1 antibody and constructs for the humanized version. And it specifically teaches the critical CDR sequences for the heavy and light chains of the original mouse antibody 5G1.1, which binds C5 (a protein which plays an important role in inflammatory and cell killing processes), as well as variable domain sequences for humanized forms of 5G1.1. The specification, taken against well-known technologies in the field, taught eculizumab.

112. As intended by Alexion, its scientists and its patent prosecutors, claims 1-7, 9, 10, 12-15, 17, 19 and 23 of the '245 patent claim eculizumab because the specification, coupled with the knowledge of an ordinary scientist in this area, discloses the full sequence of the eculizumab amino acid structure.

113. Beginning with the issuance of the '245 patent on March 12, 2002, Alexion had original patent protection for eculizumab for the next 17 years, until an original expiration date of March 12, 2019.

C. The relevant prior art and public knowledge concerning eculizumab.

114. Following Alexion's development of anti-C5 antibodies including eculizumab, during the late 1990s and early 2000s, Alexion scientists and others authored numerous publications about anti-C5 antibodies, eculizumab and its therapeutic applications.

115. *Thomas 1996.*[53] In 1996, several Alexion scientists—including Evans, Rother and Thomas, inventors of the '245 patent—authored a journal article giving foundational information about the engineering of anti-C5 antibodies. In their publication, they describe the IgG4 isoform of 5G1.1.

116. *Mueller 1997.*[54] Mueller 1997 is a journal article, authored, *inter alia*, by Alexion's Evans, which discusses regions of the IgG2/G4 constant domain heavy chain.

117. *Mueller PCT 1997 (WO 97/11971).*[55] On April 3, 1997, an international patent application filed by a group of Alexion scientists—including Evans and Rother—was published. Mueller PCT 1997 discloses sequences for antibodies, including a full-length antibody containing a hybrid IgG2/G4 heavy chain constant region. Mueller PCT 1997 describes using "h5G1.1 CO12 **HuG2/G4 mAb**" and expressly teaches the amino acid sequences for the constant regions of SEQ ID NOS:2 and 4 referenced in the later Alexion patents. (This reference would later be concealed from the PTO patent examiner who was reviewing the applications that would lead to the 2017 Alexion patents).

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[53] Thomas C. Thomas et al., *Inhibition of Complement Activity By Humanized Anti-C5 Antibody and Single-Chain Fv*, 33 Molecular Immunology 1389 (1996)("Thomas").

[54] John P. Mueller et al., *Humanized Porcine VCAM-Specific Monoclonal Antibodies with Chimeric IgG2/G4 Constant Regions Block Human Leukocyte Binding to Porcine Endothelial Cells*, 34 Molecular Immunology 441 (1997)("Mueller 1997").

[55] World Intellectual Property Organization International Publication No. WO 97/11971 issued to John P. Mueller et al. (filed Sept. 27, 1996, published Apr. 3, 1997) ("Mueller PCT").

118. *Alexion's submission to the Chemical Abstracts Services (CAS) 1999.* On February 14, 1999, Alexion submitted the amino acid sequence of eculizumab to Chemical Abstracts Services (CAS), a division of the American Chemical Society. This submission made the sequence publicly accessible in the Scientific & Technical Information Network (STN) database. Alexion acknowledged, during European Patent Office (EPO) proceedings, that the sequence for eculizumab was publicly available before Feb. 3, 2004, stating the "sequence for eculizumab was submitted to [CAS] and entered into their STN database on 14 February 1999[.]"(This CAS submission was not provided to the examiner during the prosecution of the 2017 Alexion patents).

119. *Alexion 2002 press release.*[56] On March 15, 2002, Alexion issued a press release announcing the issuance of the '245 patent, which Alexion said "cover[s] the composition and use of Alexion's lead drug candidate[] eculizumab (formerly known as 5G1.1)." This announcement publicly disclosed to the lay public that eculizumab had valid U.S. patent protection. (This release was not provided to the examiner during the prosecution of the 2017 Alexion patents).

120. *Bowdish 2003 (U.S. Patent Application Publication No. 2003/0232972 A1).*[57] Bowdish 2003 is a U.S. patent application, published on December 18, 2003. Katherine S. Bowdish, Senior Vice President at Alexion, authored the application. Bowdish 2003, through its incorporation of the '245 patent, discloses both the light chain sequence and the heavy chain sequence claimed in the later Alexion patents. Specifically, it discloses light chain sequence SEQ ID NO: 69 (shown as SEQ ID NO:4 in the later 2017 Alexion patents), and by reference to

[56] Alexion Press Release, *Alexion Issued Key C5 Complement Inhibitor Patent for Inflammatory Diseases* (Mar. 15, 2002).

[57] U.S. Patent Application Publication No. 2003/0232972 A1 issued to Katherine S. Bowdish et al. (filed Dec. 2, 2002, published Dec. 18, 2003).

the '245 patent, discloses the full heavy chain sequence SEQ ID NO: 67 (shown as SEQ ID NO:2 in the later 2017 Alexion patents).

121. *Hillmen 2004.*[58] In 2004, Peter Hillmen, a consultant to Alexion (along with collaborators with funding from Alexion and Alexion's Rother), published findings on eculizumab in patients with paroxysmal nocturnal hemoglobinuria (PNH). The article disclosed that eculizumab was a useful treatment for PNH.

122. *Tacken 2005.*[59] On August 15, 2005, Alexion scientists—including Rother—published a journal article that refers to eculizumab as Alexion's "potential product," and specifically identifies eculizumab as the h5G1.1 antibody. Tacken 2005 teaches that eculizumab contains an IgG2/IgG4 constant region, and identifies it as "the same" as that discussed in Mueller 1997—the sequence of which was disclosed in Mueller PCT. And it notes that the antibody is "specific for the human terminal complement protein C5." (This reference was concealed from the patent examiner during the prosecution of the three 2017 Alexion patents).

123. *Bell 2005 (U.S. Patent Application Publication No. 2005/0191298 A1).*[60] On September 1, 2005, Bell 2005 was published, with Alexion's Leonard Bell and Russell P. Rother listed as inventors. It teaches the treatment of PNH using eculizumab. Bell teaches that the antibody h5G1.1 *is* eculizumab. And Bell 2005 states, "Methods for the preparation of h5G1.1-mAb, h5G1.1-scFv and other functional fragments of hi5G1.1 are described in [the ']245 and . . . Thomas [1996], the disclosures of which are incorporated herein in their entirety by this

[58] Hillmen et al., *Effect of Eculizumab on Hemolysis and Transfusion Requirements in Patients with Paroxysmal Nocturnal Hemoglobinuria*, at 350.

[59] Paul J. Tacken et al., *Effective induction of naive and recall T-Cell responses by targeting antigen to human dendritic cells via a humanized anti–DC-SIGN antibody*, 106 Blood 1278 (2005).

[60] U.S. Patent Application Publication No. 2005/0191298 A1 issued to Leonard Bell et al. (filed Feb . 3, 2005, published Sep. 1, 2005).

reference. The antibody h5G1.1-mAb is currently undergoing clinical trials under the trade name eculizumab."

124. *Hill 2005.*[61] As a follow up to Hillmen 2004, this article, supported by and including authors from Alexion, reported the results of a 1-year follow-up study designed to assess the long-term efficacy and safety of eculizumab in patients with PNH.

125. *Summary.* By 2007, Alexion had procured patent coverage for eculizumab by obtaining the '245 patent because multiple claims in the patent claimed eculizumab, and a scientist of ordinary skill in the field would know the complete structure of eculizumab. And along with the '245 patent, numerous other publications by Alexion—including Mueller PCT 1997, Bowdish 2003, and Tacken 2005—disclosed the humanized IgG2/G4 monoclonal antibody (*i.e.*, eculizumab), and its complete sequence comprised of light chain (SEQ ID NO:4) and heavy chain (SEQ ID NOS:2). The use of eculizumab for PNH had been widely disclosed.

126. Bowdish 2003 provided the framework for the humanized IgG2/G4 eculizumab antibody. It explicitly disclosed the light chain sequence (SEQ ID NO: 69 in Bowdish; SEQ ID NO:4 in the patents), and it incorporates the CDR3 region (Complementarity-Determining Region 3) from the '245 patent to complete the heavy chain (SEQ ID NO: 67 in Bowdish; SEQ ID NO:2 in the patents) (and as recited in the later Alexion patents (SEQ ID NOS: 2 and 4). The CDR region is a critical part of an antibody's variable domain, which is responsible for recognizing and binding to a specific target, such as an antigen. Together, and read properly and completely, Bowdish 2003 and the '245 patent disclosed the complete amino acid sequence of the antibody.

[61] Hill et al., *Sustained response and long-term safety of eculizumab in paroxysmal nocturnal hemoglobinuria*, 106 BLOOD 2559–65 (2005).

127. Tacken 2005 expressly identifies and describes eculizumab as an anti-C5 antibody and Alexion's "potential product." A skilled artisan seeking the sequence of eculizumab would have relied on Tacken 2005, and its clear teaching from 2005 that eculizumab has the IgG2/IgG4 constant domain cited in Mueller 1997, and disclosed in full in Mueller PCT 1997.

128. Mueller PCT 1997, the companion patent application for Mueller 1997, expressly disclosed the full amino acid sequence for the IgG2/IgG4 constant domain heavy chain used in the "h5G1.1 HuG2/G4" antibody. A routine alignment of the IgG2/G4 constant domain heavy chain from Mueller PCT and Bowdish would confirm that the antibody disclosed in Bowdish has *precisely* the sequence of eculizumab.

129. In sum, publications and statements by Alexion and others before 2007 clearly disclosed that the humanized 5G1.1 antibody *with* a hybrid G2/G4 constant domain *was* eculizumab. Alexion's own disclosures along with third-party publications, all established that the amino acid sequence, dosing regimens, and clinical efficacy of eculizumab were anything but novel.

D. The FDA approval for Soliris (eculizumab).

130. On June 27, 2003, Alexion's investigational new drug application became effective.

131. On September 15, 2006, Alexion submitted to the FDA a biologics license application for Soliris (eculizumab) (BLA 125166/0).

132. On March 15, 2007 Alexion filed application PCT/US2007/006606 (the "2007 application"). The 2007 application sought further patent protection for eculizumab for the treatment of PNH.

133. The very next day, on March 16, 2007, the FDA approved the BLA for Soliris (eculizumab) for treatment of PNH.

E. The '245 patent term extension to protect Soliris (eculizumab) sales.

134. On May 11 2007, following the FDA approval for marketing of Soliris, Alexion filed an application under 35 U.S.C. §156 and 37 C.F.R. §1.740 for an extension of the term of the '245 patent with the Office of Patent Legal Administration at the PTO ("OPLA"). The application indicated "the current expiration date of this patent is seventeen years from the issue date, or March 12, 2019" and that the "extension request is for a period of 735 days to March 16, 2021, which is fourteen years from the BLA approval date." Alexion identified the approved product as "Soliris™ a formulation of eculizumab for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis." And it identified as the patent for which extension is sought as U.S. Patent No. 6,355,245.

135. In a "Statement of Patent Claim Coverage of Approved Product," Alexion explicitly represented to the OPLA that "U.S. Patent No. 6,355,245 claims the Approved Product"," i.e., Soliris (eculizumab). And Alexion represented that the "applicable patent claims" of the '245 patent were "claims 1-7, 9, 10, 12-15, 17, 19 and 23."

136. Alexion further set forth the manner in which each of those sixteen claims of the '245 patent "read on" the claimed Approved Product, i.e., Soliris (eculizumab). As support for its assertion that the first independent claim (claim 1) of the '245 patent claimed eculizumab Alexion cited Hill 2005, Thomas 1996 and Hillmen 2004.

137. Alexion also represented to the OPLA, in a statement of eligibility, that Alexion "believes that U.S. Patent No. 6,355,245 is eligible for extension under 35 U.S.C. §156 because it satisfies all of the requirements for such extension" including that "U.S. Patent No. 6,355,245 claims a product" and that the Approved Product was "Soliris™ a formulation of eculizumab for

the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis."

138. In filing the application, Alexion signed a statement acknowledging its duty to disclose material information to the PTO.

139. On June 19, 2007, the OPLA wrote the FDA regarding the "application for patent term extension of U.S. Patent No. 6,355,245" and requesting confirmation "that the product identified in the application, Soliris™ (Eculizumab), has been subject to a regulatory review period." The confirmation was needed because the OPLA needed a determination that the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act.

140. On May 6, 2008, the FDA wrote the OPLA regarding "the application for patent term extension for U.S. Patent No.6,355,245 filed by Alexion Pharmaceuticals, Inc., under 35 U.S.C. § 156" in which the "human biological product claimed by the patent is Soliris (eculizumab) . . . ." In the letter, the FDA advised the OPLA that the patent term extension application had been timely filed.

141. On May 28, 2008, the OPLA sent a letter to the FDA notifying it of Alexion's request for a "patent term extension of U.S. Patent No.6,355,245." The transmittal states the "patent claims a product that was subject to regulatory review," that Alexion was eligible for a patent term extension, and thus, a determination by the FDA of the applicable regulatory review period was necessary.

142. On February 20, 2009, the FDA issued a letter to the OPLA regarding "the application for patent term extension for U.S. Patent No. 6,355,245, filed by Alexion Pharmaceuticals, Inc., under 35 U.S.C. § 156 et seq." and determining that "the regulatory

review period for Soliris (eculizumab), the human biological product claimed by the patent" was a total of 1,360 days.

143. On March 4, 2009, the FDA published notice of a determination of regulatory review period for the purposes of a patent term extension for Soliris. The notice indicated that the Soliris BLA had been approved on March 16, 2007, and that on May 6, 2008, the FDA had advised the OPLA that this human biological product had undergone a regulatory review period.

144. On September 30, 2009, the FDA wrote the OPLA "in regard to the patent term extension application for U.S. Patent No. 6,355,245 filed by Alexion Pharmaceuticals, Inc. under 35 U.S.C. § 156. The patent claims Soliris (eculizumab), biologics license application (BLA) 125166/0." The FDA indicated that earlier that year it had published notice of the patent term extension request, and that the FDA had received no petition in response.

145. On November 23, 2009, the OPLA of the PTO issued a patent term extension for the '245 patent, stating that "[a] determination has been made that U.S. Patent No. 6,355,245, which claims the human biologic drug product Soliris® (Eculizumab), is eligible for patent term extension under 35 U.S.C. § 156." The period of extension was determined to be 735 days. Since the original expiration date was March 12, 2019, the original term of the '245 patent was extended to March 16, 2021.

146. In sum, in administrative proceedings from 2007 to 2009 for a patent term extension initiated by Alexion, Alexion had represented to the FDA and to the OPLA of the PTO that multiple claims in the '245 patent in fact claim Soliris (eculizumab). And in response, the CDER section of the FDA and the OPLA of the PTO relied on those representations to issue a two-year extension of the patent term for the '245 patent to cover sales of Soliris (eculizumab) from March 2019 through mid-March 2021.

147. The representations of Alexion to the FDA and the OPLA in seeking the patent term extension were true. The '245 patent claimed Soliris (eculizumab) because with the '245 patent (i.e., the specification and claims) one of skill in the art would have been guided to make the full sequences of the eculizumab antibody. And Alexion and its scientists—including Bell, Evans, Rother, and Thomas—believed that to be true.

148. For over a decade, Alexion would represent in its public securities filings that Alexion had patent coverage for the sales of Soliris, stating that "[w]ith respect to Soliris, we own an issued U.S. patent that covers the eculizumab composition of matter and will expire in 2021, taking into account patent term extension." That patent was the '245 patent.

F. The launch and sales of Soliris.

149. After the March 2007 FDA approval of Soliris, the product was launched into the U.S. marketplace. It was quickly successful.

150. In 2008, its first full year after the Soliris launch, Alexion's global net sales reached $259 million.

151. In 2011, the FDA approved Soliris to treat aHUS, its second approved indication. Alexion's CEO reported that the new indication offered an opportunity "at least as large" as the opportunity with the original PNH indication. Indeed, by 2018, sales for Soliris to treat aHUS eclipsed sales for PNH.

152. From 2007 to 2015, Soliris was Alexion's *only* FDA approved product, and it remained its flagship drug for more than a decade—even after Alexion launched new products in 2015. By 2015, Alexion's total cumulative global sales since 2007 had reached nearly $9.5 billion and in 2015 alone totaled nearly $2.6 billion globally and $951 million in the U.S.

153. Even with the introduction of new products in 2015, Soliris was still Alexion's lifeline; for example, Alexion earned only $12 million in sales in 2015 on its approved product,

Strensiq, while earning $2.59 *billion* globally on Soliris. In 2018, when Alexion's Strensiq and Kanuma products had been on the market for three years, U.S. sales for Soliris totaled approximately $1.59 billion while Strensiq U.S. sales totaled only $374 million and Kanuma even less with $51 million. In February 2017, Alexion stated that since it "launched Soliris in the U.S. in 2007, substantially *all of our revenue* has been attributed to sales of Soliris" and that it "anticipate[d] that Soliris product sales [would] continue to contribute a significant percentage of [its] total revenue over the next several years." Alexion warned that it "depend[ed] heavily on the success" of Soliris and that if "sales were adversely affected, our business may be materially harmed."

154. Listed among the factors impacting Soliris's commercial success and Alexion's "ability to generate revenues" was "the introduction and success of competing products[.]" Alexion was right that its dependence on Soliris would continue; by 2019, Soliris still accounted for 79% of all of Alexion's revenue.

155. Meanwhile, public pressure over Soliris pricing began to rise around the globe. Despite the relatively small patient pool—estimated to be between 5,000-8,000 patients—Soliris has been a blockbuster drug for Alexion, achieved through its status as one of the top ten most expensive drugs on the U.S. market. Not only does Soliris cost more than $650,000 per patient per year (as of 2021), but its administration at infusion centers can be even *more* expensive. For example, one medical center charges an additional $89,000 *per treatment* to a patient's health plan—and Soliris is indicated for use every two weeks.

156. Alexion recognized that its "products are significantly more expensive than traditional drug treatments and almost all patients require some form of third-party coverage to afford their cost." Indeed, Alexion "depend[s], to a significant extent" on "private third-

party payers"—like the plaintiff here—"to defray the cost of [its] products to patients," among others, such as government payers.

157. The biggest threat to Alexion's Soliris revenue was the end of market exclusivity upon expiration of its primary compound patent and entry of a competing biosimilar product as a result. As Alexion recognized in its 2016 regulatory filings before it acquired fraudulent patents, "[m]arket exclusivity…is based upon patent rights and certain regulatory forms of exclusivity" and "much of an innovative product's commercial value is realized while it has market exclusivity."

158. In other words, a major reason for Soliris's success was the lack of price competition. Soliris was the *only* approved therapy for treatment of PNH through 2018, until the launch of an additional Alexion product, Ultomiris. The first non-Alexion drug approved to treat PNH did not enter the market until 2021. There are currently *no* FDA-approved non-Alexion drugs for aHUS.

159. This lack of alternatives for the PNH market for nearly 14 years and the 13-year ongoing lack of any alternative for the aHUS market buttressed Alexion's ability to charge exuberant prices. As Alexion stated in its regulatory filings for 2015, it had "no competitors for the patient segments [Alexion] target[s]."

160. Soliris's pricing, and price increases, have drawn criticism. In 2015, Canada's Patented Medicines Price Review Board began an investigation into whether Alexion was abusing its monopoly power and charging excessive prices for Soliris, with the board ultimately finding that Alexion had excessively priced Soliris and ordering that Alexion decrease the price and forfeit excess revenues from 2009 through 2017. Alexion appealed and ultimately resolved the dispute by agreeing to pay more than $11.5 million in fines and charge a lower, set price for Soliris in Canada.

161. Subsequent media investigations spotlighted Soliris's high prices and alleged that such prices were not justified by research and development costs because "most of the research and development was done by university researchers working in academic laboratories supported by public funds." The Institute for Clinical and Economic Review—an independent Boston-based non-profit focused on drug pricing—recommended that Soliris, which cost more than $650,000 per year per patient at the time, receive a 97-98% discount due to its "extremely high" price far beyond "traditional cost-effectiveness thresholds in the U.S."

162. Of course, a reprieve from these sky-high prices seemed on the horizon: the launch of biosimilar eculizumab products would introduce competition into the market and impact prices. It was widely expected that Alexion would lose exclusivity for Soliris in March 2021, i.e., upon expiration of Alexion's composition patent.

G. The threat of competition begins to rear its head.

163. Alexion itself realized that Soliris was the most significant drug in its portfolio, telling investors in early 2017: "If we are not able to maintain revenues from sales of Soliris, or our revenues do not grow as anticipated, our results of operations and stock price could be adversely affected." But competition was on the horizon.

164. The first potential challenger to Alexion's patent monopoly was a major pharmaceutical company, Amgen, which has significant experience and success in launching biologic and biosimilar drugs.

165. In July 2016, Amgen told investors that it had submitted regulatory filings to initiate a Phase I trial, the first step in pursuing a biosimilar version of eculizumab.

166. In October 2016, Amgen's Chairman and CEO, Robert Bradway, stated that Amgen intended to "take [its Soliris biosimilar] through development and . . . have it available as soon as the patent – intellectual property patents have lapsed and enable us to launch it" in

2021. He was clear with investors: "So if your question is, are we serious about it? Do we intend to develop a molecule? Yes."

167. To head off this threat, Alexion engaged in unlawful acts to extend its monopoly position over Soliris—and the prices its monopoly created—into 2025.

H. Alexion embarks on its delay strategy.

168. When Soliris first launched in 2007 and through its yearly regulatory filings until 2017, Alexion had maintained that Soliris was covered by *one* composition patent, the '245 patent, stating that "[w]ith respect to Soliris, we own an issued U.S. patent that covers the eculizumab composition of matter and will expire in 2021, taking into account patent term extension." That patent was the '245 patent.

169. During this time, Alexion and the drug development community believed that the expiration of the '245 patent signaled the end of exclusivity for Soliris. In May 2016, Alexion's former CFO and executive vice president, Vikas Sinha, had told investors that "[t]here will be competition coming post '20, 2021 when our patent expiry takes place."

170. But over the course of the next four years, Alexion would defraud a PTO patent examiner to incorrectly issue a series of patents, three in 2017 (the "2017 patents") and two in 2020 (the "2020 patents."), all with an expiration date between March 15 and September 8, 2027, well after the 2021 expiration of the '245 patent.

171. Alexion's fraud was both commission and omission, all to convince the PTO examiner of the falsity that, prior to March 2007, the full amino acid sequence of eculizumab had not been publicly available. Alexion concealed key information and prior art, most of which Alexion itself had developed and published. And it filed false declarations and statements with the PTO, misrepresenting the scope and teachings of its own publicly revealed teachings about

eculizumab. The purpose and effect of Alexion's fraud was to obtain patents that it knew it was not entitled to and to then unlawfully use those patents to extend its eculizumab monopoly.

1. Fraudulent acquisition of the three 2017 Alexion patents.

172. On May 6, 2016, Alexion—now represented by different outside counsel than it had used for the '245 patent term extension—filed U.S. Patent Application 15/148,839 as a continuation application to the applications that dated back to a priority date of March 2007. Among the listed inventors were Leonard Bell (Alexion's founder and former CEO), Rother and Evans. The new lawyer was Jill Sloper of the law firm Nelson Mullins Riley & Scarborough LLP in Boston. The application eventually issued as U.S. Patent No. 9,718,880 ("the '880 patent"). The three claims of the '880 patent are directed to pharmaceutical compositions of eculizumab. Alexion is the assignee.

173. On August 16, 2016, a PTO examiner rejected the patent application, citing pre-2007 prior art, including the '245 patent, as teaching eculizumab. The office rejected claim 1 as obvious because, among other things, the '245 patent "teaches antibody 5G1.1, which is the same as eculizumab" and concluding that the discussed references make it "apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention."

174. On September 9, 2016, Attorney Sloper filed U.S. Patent Application No. 15/260,888 which eventually issued as U.S. Patent No. 9,725,504 ("the '504 patent"). The ten claims of the '504 patent are directed in general to methods of treating patients using eculizumab. Like the '880 patent, the listed inventors are Alexion's Bell, Rother, and Evans. Alexion is again the assignee.

175. On October 3, 2016, Attorney Sloper filed yet another patent application, U.S. Patent Application No. 15/284,105 which would eventually issue as U.S. Patent No. 9,732,149

("the '149 patent") with a single claim directed to a C5 binding antibody having specific amino acid sequences at the heavy and light chains, SEQ ID NO: 2 and 4, respectively. It is titled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement." Like the '880 and '504 patents, the listed inventors are Alexion's Bell, Rother, and Evans. Alexion is again the assignee.

176. On November 1, 2016, the examiner preliminarily rejected the '149 patent application on double patenting grounds over claims in the pending '880 patent application.

177. On December 22, 2016, the examiner rejected the '504 patent application, again finding the claims were anticipated and obvious over various printed publications, including Hillmen 2004, Thomas 1996 and the '245 patent, specifically stating that "Hillmen [2004] and Thomas [1996] collectively teach that the 5G1.1 antibody can be used to treat PNH, and [the '245 patent] provides the public with this antibody."

178. On January 19, 2017, Alexion sought to overcome the December 22nd rejection of the'504 patent application. In doing so, Alexion filed a false declaration and made false statements to the PTO examiner.

179. The declaration, signed by Dr. Leonard Bell (Alexion's co-founder), falsely stated that "prior to March 15, 2007, the complete structure of eculizumab was not disclosed to the public." He further falsely stated that the '245 patent "does not disclose or even hint at the unique non-naturally occurring, protein-engineered heavy chain . . . of eculizumab." He further falsely stated that Thomas 1996 does not "describe eculizumab." And he falsely summed up that "the complete structure of eculizumab was not available to the public on or before March 15, 2007 . . . ."

180. The remarks filed by Attorney Sloper in the January 2017 submission repeated Bell's false statements. She falsely stated that the '245 patent "fails to teach or in any way

suggest the unique, non-naturally occurring, protein-engineered full heavy chain of eculizumab . . . ." She also sought to distinguish the disclosure in Thomas 1996 (previously used by Alexion to show how eculizumab was disclosed in the '245 patent), by representing it discloses "a *naturally-occurring* IgG4 heavy chain and is therefore not eculizumab, but rather another antibody that is structurally and functionally different from eculizumab." In sum, she falsely represented that "none of Hillmen [2004] *et al.*, Thomas, *et al.* or [the '245 patent] teaches the complete structure of eculizumab. . . ."

181. The statements of Bell and Sloper were false. In fact, for many years Alexion had taken the position that the '245 patent *did* claim Soliris (eculizumab). After all, Alexion had sought, and procured, a patent term extension based on that exact proposition. And to the extent that not all teachings for the structure of eculizumab were explicitly set forth in the '245 patent, Alexion had taken the position—which was true—that with the '245 patent one skilled in the art would know the full amino acid sequence of eculizumab based on other public disclosures. And Alexion had repeatedly represented to the financial community that "[w]ith respect to Soliris, we own an issued U.S. patent that covers the eculizumab composition of matter and will expire in 2021 . . ." which patent was, of course, the '245 patent.

182. The statements of Bell and Sloper were also false for what they concealed from the PTO examiner. Bell and Sloper—and the other Alexion inventors during prosecution of the patents that would result in the 2017 Alexion patents—concealed from the PTO examiner (i) that the '245 patent did, in fact, claim eculizumab, just as Alexion had truthfully reported to the FDA and the OPLA of the PTO years earlier, (ii) the 2002 Alexion press release that announced the issuance of the '245 patent, which Alexion said "cover[s] the composition and use of Alexion's lead drug candidate[] eculizumab (formerly known as 5G1.1)", (iii) the repeated public securities filings that stated Soliris sales were protected by a patent that

claimed eculizumab, (iv) Mueller PCT 1997 that disclosed sequences for antibodies, including a full-length antibody containing a hybrid IgG2/G4 heavy chain constant region, (v) *CAS 1999* that registered the sequence for eculizumab to CAS which was then entered into their STN database, and (vi) Tacken 2005 that expressly identified and described eculizumab as an anti-C5 antibody and Alexion's "potential product" along with its clear teaching that eculizumab has the IgG2/IgG4 constant domain cited in Mueller 1997.

183. On January 25, 2017, attorney Sloper met with the examiner, arguing that the heavy chain sequence disclosed in Thomas 1996 is not the same as SEQ ID NO. 2 claimed in the '504 patent.

184. On February 15, 2017, Alexion addressed the original rejection of the '880 patent application. Once again, Alexion's representatives falsely repeated the misrepresentation that prior to 2007 the full amino acid sequence for eculizumab had not been disclosed to the public. Alexion made intentional, affirmative misrepresentations of fact, claiming that the claims were "drawn to pharmaceutical compositions comprising eculizumab as defined by its particular heavy and light chain sequences, which were *not* taught or suggested by the prior art" and stating "the complete structure of eculizumab was not disclosed in the prior art, nor available to the public" prior to March 15, 2007.

185. On April 4, 2017, the examiner again rejected the '880 patent application, in part because he believed that the disclosed references of Hillmen 2004, the '245 patent and Wang indicated that eculizumab was in public use, and that public availability of eculizumab was "considered sufficient to have placed one of skill in the art in possession of [Alexion's] currently claimed sequences for eculizumab."

186. On April 11, 2017, the examiner responded to Alexion's January 19th submission in the '504 patent application proceedings, stating he did not find Alexion's

arguments or the Bell declaration, "persuasive." The examiner again concluded that the claimed invention was obvious, noting among other things, that the '245 patent "teaches antibody 5G1.1, which is the same as eculizumab." Within this non-final rejection, the examiner reminded Attorney Sloper and the named inventors that "the reply to this requirement must be made with candor and good faith under 37 CFR 1.56."

187. On the same day, the examiner issued a rejection of the '149 patent application essentially on the same basis, again finding "the extensive number of both patent literature and NPL documents . . . indicates that eculizumab was wide-spread and well-known" and concluding that "eculizumab was effectively in the public domain." Here too, the examiner reminded Alexion that "the reply to this requirement must be made with candor and good faith under 37 CFR 1.56."

188. On May 12, 2017, in the context of the '880 patent application prosecution, Alexion responded to the rejection, and once again falsely claimed that eculizumab was not publicly known. Alexion again falsely represented to the examiner that "[n]either eculizumab nor its complete sequence, including the sequence of its unique, non-naturally occurring, protein-engineered heavy chain, was in the public domain prior to the March 15, 2007 effective filing date of the present application" and that "neither eculizumab nor its complete sequence were available to the public or in 'public use' prior to the March 15, 2007 effective filing date of the present application."

189. On June 7, 2017, the examiner issued a Notice of Allowance for the '880 patent. Alexion's deceptions had worked. The examiner noted that he relied upon Alexion's arguments that none of the references cited by Alexion "recite using an antibody which comprises a heavy chain consisting of SEQ ID NO:2 and a light chain consisting of SEQ ID NO:4 as currently recited and one of skill in the art would not have been easily guided to making antibodies with

these recited sequences." But in doing so, Alexion continued to conceal material prior publications discussed earlier. And Alexion only referred to the Hillmen 2004, '245 patent and Wang references, stating to the examiner—despite his earlier admonishment that future representation "must be made with candor and good faith under 37 CFR 1.56—that none "teach or suggest the complete sequence of eculizumab."

190. On June 13, 2017, seeking allowance of the still-pending '504 and '149 patent applications, Alexion doubled down on the material misrepresentations about what was publicly known about eculizumab. Alexion again falsely asserted that prior to March 15, 2007, the sequence of eculizumab was not publicly known or disclosed in the prior art and that the examiner's underlying premise for the examiner's prior rejections was "factually incorrect." Alexion falsely claimed that "neither eculizumab nor its complete sequence . . . was in the public domain prior to the March 15, 2007 effective filing date . . . ." And Alexion again only referred to the Hillmen 2004, '245 patent and Wang references, stating that none "teach or suggest the complete sequence of eculizumab."

191. On June 28, 2017, the examiner issued a Notice of Allowance for the '504 patent. Alexion's deceptions had worked again. With respect to whether the eculizumab antibody had been disclosed to the public before March 2007, the examiner, relying on Alexion's misrepresentations, wrote, "None of the applied references in the rejections recite using an antibody which comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4 as currently recited and one of skill in the art would not have been easily guided to making antibodies with these recited sequences."

192. On July 3, 2017, the examiner issued a Notice of Allowance for the '149 patent. Yet again, Alexion's deceptions had worked. With respect to whether the eculizumab antibody had been disclosed to the public before March 2007, the examiner, again relying on Alexion's

misrepresentations, wrote "None of the applied references in the rejections recite using an antibody which comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4 as currently recited and one of skill in the art would not have been easily guided to making antibodies with these recited sequences."

193. In July 2017, Ludwig Hantson, Alexion's then CEO, told investors that "Alexion delivered strong performance in the second quarter of 2017 while also executing on several initiatives to position the company for the future, including strengthening the Soliris patent portfolio . . ."

194. On August 1, 2017, the '880 patent issued.

195. On August 8, 2017, the '504 patent issued.

196. On August 15, 2017, the '149 patent issued.

197. Shortly thereafter, Hantson touted the extended monopoly that the three fraudulent 2017 patents allowed, reporting that "Alexion delivered strong commercial, R&D, and financial performance in the third quarter of 2017. We . . . strengthened our patent portfolio with three new U.S. patents for Soliris that extend protection into 2027. . . ."

2. Competition grows close as Amgen starts a Phase 3 pivotal study, and another would-be competitor appears.

198. But despite its successful efforts to mislead the PTO, Alexion saw continued risk to its cash cow.

199. By October 2018, Amgen's Executive Vice President of Research and Development told investors that Amgen was in the "start-up of the Phase 3 pivotal study." When asked why Amgen was focused on Soliris, Amgen's Senior VP of Global Development explained that the *price* of Soliris made it attractive and that Amgen had every intention of pursuing—and the ability to achieve—quick regulatory approval:

> [T]he interest in a biosimilar in this area is intense. Of all the areas that we're developing, biosimilars, I think—the enthusiasm has been greatest in this area, where the originator product is quite costly. And we think it's an area that's well-suited to our strategic model. We have, I think, demonstrated over the past few years that we are as good as any company in the world at discovering biologic molecules that faithfully reproduce the structural and performance attributes of the originator compound and then getting those drugs through the regulatory process in a hiccup-free fashion and then launching them around the world. And our first biosimilars, as you know, are in the market in Europe. So we see this is really right in our wheelhouse and a product that will be an important addition to our biosimilar portfolio.

200. By November 2018, another potential competitor, Samsung Bioepis ("Samsung"), had begun clinical trials concerning the pharmacokinetic, safety, tolerability, immunogenicity, and pharmacodynamic profiles of its eculizumab biosimilar, SB12.

201. Samsung was founded in 2012 as a joint venture between Samsung Biologics and Biogen and rapidly became one of the world leaders in biosimilar development. Biosimilar production is core to Samsung's mission, with Samsung describing itself as a "biopharmaceutical company dedicated to unlocking the potential of biosimilar medicines and transforming the way biologic therapies are brought to patients." Its portfolio contains eight commercially approved biosimilars and a pipeline of three biosimilars in various stages of development. These medicines cover a broad spectrum of therapeutic areas, including immunology, oncology, ophthalmology, and hematology. The company also boasts industry-first achievements such as being the first to secure European approval of four key biosimilars for autoimmune conditions.

3. Ahead of biosimilar competition, Alexion intentionally shifted the market from its Soliris product to its Ultomiris product.

202. Recognizing the threat of imminent competition and how significantly it relied on Soliris sales, Alexion also sought to shift its patients off Soliris and onto a new drug called Ultomiris.

203. Ultomiris was approved by the FDA for the treatment of PNH in December 2018 and aHUS in October 2019.

204. Ultomiris is a slightly bigger protein than Soliris and has a tweak that lets the body recycle and reuse it. It is also recommended at a higher dose than Soliris. Together, this means that Ultomiris is administered every eight weeks while Soliris is given every two weeks.

205. Alexion was clear (and public) about its intentions to use Ultomiris to protect its PNH/aHUS franchise against competition.[62] By 2020, ahead of the 2021 Soliris patent expiration, Alexion announced it had converted 70% of the market off Soliris and onto Ultomiris.

206. There remained, however, substantial sales of Soliris. By delaying its competitors' entry into the market by obtaining five fraudulent patents between 2017 and 2020, Alexion was able to both buy more time to maintain Soliris's supracompetitive price and shift the market onto Ultomiris before Soliris (and its price) was threatened by biosimilar competition. Indeed, in 2019 Soliris sales in the United States still exceeded $2 billion.

[62] "One of our **principal business objectives** is to facilitate the conversion of PNH and aHUS patients from SOLIRIS to ULTOMIRIS. . . . If we are unable to facilitate conversion to ULTOMIRIS prior to the loss of intellectual property or regulatory exclusivities for SOLIRIS, our **future revenues could be adversely impacted if we were to face biosimilar competition for SOLIRIS.**" SEC Form 10-K for Alexion Pharms., Inc. (2020) at 45–46, https://last10k.com/sec-filings/alxn/0000899866-21-000014.htm (emphasis added).

4. Amgen challenges the three 2017 patents

207. In February 2019, Amgen filed three petitions with the Patent Trial and Appeal Board (PTAB)—an administrative law body of the PTO comprised of administrative patent judges—challenging each of the three 2017 Alexion patents. In those petitions, Amgen pointed out how several references, including Tacken 2005 and Bowdish 2003, which had been concealed by Alexion during the patent prosecutions that led to the three 2017 Alexion patents, demonstrated that the full sequence of eculizumab had been made public before March of 2007.

208. The PTAB would eventually institute review of all three petitions. Institution by the PTAB meant that the Board found it reasonably likely that Amgen would prevail with respect to at least one of the challenged claims of each patent. In August, the PTAB released a schedule for the IPR trial concerning all three 2017 patents. The final oral argument was scheduled for June 1, 2020.

209. Since the filing of the Amgen's IPR petitions would have to be disclosed to the patent examiner, Alexion was now constrained to place Tacken 2005 and Bowdish 2003 before the patent examiner in connection with its still-pending '189 patent application, as well as any other applications it sought. As discussed below, although it did so, Alexion buried the references in a blizzard of paper and then offered series of mis-directions designed to lead the examiner away from an appreciation of their significance.

5. Alexion fraudulently acquires the two 2020 patents.

210. On April 29, 2019, Alexion submitted multiple Information Disclosure Statements to the PTO in conjunction with the still-pending application for the '189 patent. Among the dozens of references were the previously concealed references of Tacken 2005 and Bowdish 2003, along with the three Amgen IPR petitions.

211. On June 11, 2019, the examiner rejected the still-pending application for the '189 patent on the basis, among others, that the claims were obvious over various printed publications. Having now become aware of Bowdish 2003, the examiner pointed out that "[s]ubstituting the CDR3 from Evans [the '245 patent] into the heavy chain 5G1.1+ taught by Bowdish would result in a sequence having 100% sequence identity to currently claimed SEQ ID No.2. Bowdish also teaches that the light chain of 5G1.1+ (published SEQ ID NO: 69), which as shown supra has 100% amino acid sequence identify to currently claimed L chain SEQ ID NO:4." In short, the examiner found the combined teachings of Bowdish and the '245 patent made eculizumab obvious and unpatentable.

212. On December 11, 2019, Alexion responded to the examiner's June 19th rejection of the '189 patent application. In this submission, Alexion made a series of misrepresentations.

213. Alexion stated that prior to March 15, 2007, the literature "repeatedly and consistently" described eculizumab as only having an IgG4 heavy chain constant region. In particular, Alexion unequivocally *mis*represented that:

> the person of ordinary skill in the art would not have known that "eculizumab" had the uniquely-engineered amino acid sequence claimed in the present application. That is because the literature as of March 15, 2007 – shown by at least eight publications listed in Table 1 below consistently identified "eculizumab" as the antibody described in the "Thomas" publication . . . which has a naturally-occurring "IgG4" heavy chain constant region. Accordingly, a person of ordinary skill in the art as of March 15, 2007 would have had no doubt that "eculizumab" was Thomas's IgG4-isotpe humanized antibody, because the pertinent literature consistently and unambiguously said so[.]

214. And Alexion further made the additional factual misrepresentations that

> [l]ooking at this literature, a person of ordinary skill in the art of as March 15, 2007 would have believed that Thomas' IgG4 antibody was the *only* full-length humanized antibody shown to bind C5 and prevent its cleavage, that had been tested for safety and efficacy in treating PNH, and that had been submitted to the FDA for marketing approval . . . . In the published literature that

> followed Thomas, a person of ordinary skill in the art as of March 15, 2007 would have seen how researchers had fully established "eculizumab" – consistently identified as Thomas' IgG4 antibody - to be safe and effective in treating PNH, applying for FDA and European approval for that antibody under the tradename Soliris.

215. Alexion told the examiner that all the literature, including those contained in its Table 1, referred to eculizumab as an IgG4 antibody, citing to Thomas 1996. But this was false, and Alexion knew this was false.

216. Alexion failed to cite its *own* article Tacken 2005, which teaches that eculizumab contains an IgG2/IgG4 constant region, and *not* an IgG4 constant region. Tacken 2005 identified the IgG2/IgG4 constant region as "the same" as that discussed in the Mueller 1997 article—which was then disclosed through the teaching of the full sequence for the IgG2/IgG4 constant domain heavy chain in Mueller PCT--and it notes that the antibody is "specific for the human terminal complement protein C5." Tacken 2005, if considered, would have revealed that eculizumab has an IgG2/IgG4 constant domain, and would have led to the full sequence disclosed in Mueller PCT. However, Alexion and Sloper intentionally directed the examiner *away* from any consideration of Tacken 2005 and instead *to* Thomas 1996.

217. Alexion also misrepresented the teachings of Bowdish 2003 (which again, Alexion had not called to the examiner's attention during the prosecution of any of the three 2017 patents, but which came to the examiner's attention in 2019 and formed a basis for the June 11, 2019 rejection) and the '245 patent.

218. Alexion misrepresented that:

> nothing in Evans *et al.*, [the '245 patent] suggests or discloses constructing the uniquely engineered heavy chain constant region set forth in SEQ ID NO: 2, and one of ordinary skill in the art as of March 15, 2007 would not have been motivated to make the heavy chain constant region set forth in SEQ ID N0:2, since they would have understood from the literature that the IgG4 isotype antibody of Thomas was clinically successful.

219. This too was false.

220. Alexion then mispresented that a person skilled in the art would have no reason to look to Bowdish 2003 at all, and even if they had, they would not have arrived at eculizumab. Alexion misleadingly compared Bowdish's IgG2/G4 TPO-mimetic compound, which is a humanized antibody, with the '245 patent's mouse 5G1.1 sequence. Alexion misdirected the examiner by emphasizing Examples 7-10 of the '245 patent, which describe the mouse 5G1.1 antibody sequence, yet failed to discuss the more relevant humanized antibody constructs disclosed in Example 11.

> Evans *et al.* further describes the researchers' characterization of the "5G 1.1" mouse antibody, including its binding affinity, in vitro activity blocking complement inhemolytic assays, and the sequencing and cloning of the variable regions of the "5G 1.1 mouse antibody" (Evans *et al.*, Examples 7-10). But Evans *et al.* provides no such information for a full-length humanized antibody derived from the "5G 1.1" mouse antibody - which a person of ordinary skill in the art would have understood would have a different amino acid sequence and different clinical properties from the mouse antibody.

221. The '245 patent, however, teaches artisans how to build the humanized 5G1.1 antibody in Example 11. By focusing on the less relevant mouse sequences, Alexion created a misleading impression of mismatches with Bowdish's IgG2/G4 TPO-mimetic compound, which is a humanized antibody, with the '245 patent's mouse 5G1.1 sequence to create a mismatch with the sequences claimed in the follow-on patents. Alexion's misrepresentation that the '245 patent "provides no such information for a full-length humanized antibody derived from the '5G 1.1' mouse antibody" is further contradicted by Alexion's own undisclosed press release announcing the issuance of the '245 patent, which Alexion said "cover[s] the composition and use of Alexion's lead drug candidate[] eculizumab (formerly known as 5G1.1)." This announcement unequivocally publicly linked eculizumab to the humanized antibody disclosed in the '245 patent.

222. On December 27, 2019, again persuaded by the repeated factual misrepresentations made by Alexion that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, and having been misdirected to Thomas 1996 and away from Bowdish 2003, Tacken 2005 and Mueller PCT 1997, the examiner issued a Notice of Allowance for the '189 patent. In issuing this notice, the examiner explicitly noted that he had relied upon the representation made by Alexion that the '245 patent's "scaffold 5G1.1 mouse antibody variable regions of the whole 5G1.1 mouse antibody with the sequences of Bowdish's TPO mimetic compound would still have revealed a mismatch in amino acids beyond those that Bowdish identified as the TPO mimetic peptide insert."

223. On February 28, 2020, Alexion once again sought to acquire additional patent protection, filing Application No. 16/804,567 relating to the use of eculizumab to treat PNH. Again, the listed inventors include Alexion's Drs. Bell, Rother, and Evans. The application eventually issued as U.S. Patent No. 10,703,809 ("the '809 patent").

224. On March 5, 2020, Alexion submitted a series of Information Disclosure statements which, collectively listed more than 200 references. Included in this blizzard of paper were Mueller PCT 1997 and Tacken 2005.

225. On April 20, 2020, the examiner rejected the pending application noting, *inter alia*, that "Evans teaches that an anti-C5 antibody, 5G1.1, eculizumab, is effective [at certain doses]."

226. On April 27, 2020, Alexion submitted an amendment of claims, a terminal disclaimer, and remarks. In the remarks, Alexion once again misrepresented that the '245 patent "does *not* disclose or even mention 'eculizumab.' Nor is the only full-length anti-C5 antibody described in Evans – the 5G1.1 mouse antibody – the same antibody as eculizumab."

227. The terminal disclaimer indicated that the pending '809 patent application was simply a continuation of the 2017 patents and the '189 patent and has a substantively identical specification to those patents. Alexion represented to the examiner that those other patents were of an immediate and necessary relation to the claims in the '809 patent. So, the material misrepresentations and omissions that Alexion and Attorney Sloper had previously made, to the same examiner, in the prosecution of the 2017 patents and the '189 patent were also material to the '809 patent.

228. On May 28, 2020, again persuaded by the repeated factual misrepresentations made by Alexion that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, and having been directed to Thomas 1999 only, and away from Tacken 2005 and Mueller PCT 1997 on that issue, the examiner issued a Notice of Allowance for the '809 patent. In so doing, the examiner noted that it was specifically relying on Alexion's "characterization of Evans [the '245 patent] . . . that Evans [the '245 patent] does not disclose or mention 'eculizumab.'"

6. Alexion's misconduct during its pursuit of the five follow-on patents can only be explained by a deliberate attempt to mislead the examiner.

229. The omissions and misrepresentations made by Alexion, Sloper and the Alexion inventors during the prosecution of the five follow-on patents were directly material to patentability. The examiner consistently rejected the three 2017 patents, until being repeatedly misled by Attorney Sloper and Dr. Bell concerning the public disclosure of eculizumab prior to March 2007. Had they not repeatedly (and falsely) responded with the calculated misrepresentation of fact that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, supported by the omission of key pieces of prior art, the three 2017 patents and subsequent 2020 child patents, would never have issued.

230. Alexion and Attorney Sloper's withholding of Tacken 2005 and Mueller PCT 1997—Alexion's *own* prior art--from the examiner during the entirety of the prosecution proceedings for the 2017 patents can only be explained by a deliberate intent to deceive the examiner. Alexion and Attorney Sloper all had specific knowledge of Tacken 2005 and Mueller PCT 1997, and they knew that disclosing them would offer a clear and straightforward path to the full sequence of eculizumab. And this clear path was fatal to their quest for additional patents. But for these and other omissions, the three 2017 patents and the two 2020 patents would not have issued.

231. The examiner--already deprived of key pieces of prior art Tacken 2005 and Mueller PCT 1997 due to Alexion's omissions--consistently rejected the three 2017 patents, until Attorney Sloper and Dr. Bell's relentless misrepresentations concerning the public disclosure of eculizumab finally convinced him to grant allowances. Had they not repeatedly (and falsely) responded with the calculated misrepresentation of fact—including through a declaration by Alexion's Leonard Bell himself-- that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, the examiner would not have allowed any of the '504, '149, and '880 patents to be issued.

232. Likewise, failing to disclose the express statements it had made concerning Soliris and the '245 patent when obtaining the PTE, withholding the CAS submission, and 2002 press release can only be explained by a deliberate intent to conceal and deceive.

233. Eventually, Tacken 2005 and Mueller PCT 1997 were submitted during the '189 patent proceedings in a flood of documents that were much less relevant. Alexion and Attorney Sloper made sure *not* to bring those pieces of prior art to the attention of the examiner, who, having been directed over and over again to Thomas and the misrepresentations about the

IgG4 constant domain was convinced to only look at Thomas as his starting point. Tacken 2005 and Mueller PCT 1997 were *never* discussed by Alexion, Sloper, or the examiner.

234. Similarly, while during the '189 patent proceedings, the examiner, also finally became aware of Bowdish, Alexion also made intentional factual misrepresentations to ensure the examiner did not appreciate the reference. Alexion and Sloper falsely represented that Evans, which is incorporated by Bowdish, only applies to mice antibody constructs, and not to humans. This lie, about Alexion's *own* prior art, convinced the examiner to rely on Alexion's misrepresentation. The examiner was once again deceived into allowing two more patents to issue. But for Alexion and Sloper's lie and misrepresentation of Evans, the examiner could have understood that Bowdish disclosed the full sequence of eculizumab, and would not have issued either the '189 patent or the subsequent '809 patent.

235. Deceptive intent is the single most reasonable inference to be drawn when assessing Alexion and Sloper's conduct in all five patent prosecutions. The clear intent was to counter the Examiner's rejections and falsely represent that the sequence of eculizumab was not in the public domain as of March 15, 2007.

236. Alexion, Attorney Sloper and co-inventor Bell each made these omissions and misrepresentations knowingly and intentionally. For example, Attorney Sloper, as a patent attorney representing Alexion and Alexion's agent, would have been aware of the ongoing prosecution of Alexion's patent portfolio pertaining to equivalent subject matter to the PNH patents in other patent jurisdictions, such as the EPO. And she would have been aware of the 1999 admission made to the EPO, which was not disclosed during the prosecution of the 2017 patents.

237. In making these statements, Alexion and Attorney Sloper were making false statements of fact about what Thomas and other relevant art disclosed. They were not making

any legal argument as to the import of those (partial) facts. Indeed, the record is clear that the examiner knew full well what the law was – that is why he continually rejected Alexion's applications; it was not until he was misled by Alexion and Sloper as to the factual record that he granted allowance. By making these factual misrepresentations, Alexion and Attorney Sloper affirmatively misled the examiner and caused the examiner to fail to appreciate the importance of Tacken and Mueller PCT.

238. Misrepresentations such as this have been found by courts to be material *even if* the information itself is before (and in some cases even if it were actually considered by) the examiner. And courts have rejected arguments that an examiner is "on notice" regarding everything that may be contained in information before it, particularly where the patent applicant leaves the impression with the examiner that no further investigation is necessary, as was done here.

239. The duty at issue in a patent prosecution is not the examiner's duty to read and fully comprehend every word of every document that may be put before it; rather it is the *duty of candor* that is owed by the patent applicant and its attorneys to the PTO and examiner. And that duty of candor prohibits the patent applicant and its attorney from masking the materiality of references by affirmatively misleading the examiner away from the reference.

240. Given the indisputable knowledge that Alexion and Attorney Sloper had with respect to Tacken 2005, Mueller PCT 1997, and Bowdish 2003, the only logical inference to draw from their intentional omissions and misrepresentations is that they were acting to deceive to examiner. In fact, they succeeded in doing so.

241. Alexion obtained these patents to delay competition for Soliris beyond March 2021, and that is what they were successfully used for.

I. Alexion used its fraudulently obtained patents to delay competition from would-be eculizumab biosimilar competitors.

242. Alexion and the marketplace expected Soliris to lose exclusivity by March 2021, upon expiration of the '245 patent.

243. And Alexion recognized that "approval of a biologic product biosimilar to one of our products, including Soliris, could have a material impact on our business because it may be significantly less costly to bring to market, may be priced significantly lower than our products, and result in a reduction in the pricing and reimbursement of our products."

244. Analysts projected that Amgen, who had initiated Phase II trials by 2018, would be able to launch its biosimilar by 2022.

245. But by obtaining additional patents by fraud, Alexion extended its ostensible patent protection beyond expiration of its compound patent in March 2021. Alexion then used these patents to extend biosimilar entry until March 2025. As alleged below, absent the wrongful patent acquisition and enforcement, biosimilar competition for eculizumab could have started as early as March 2022. Absent a court enjoining Alexion's ongoing wrongful prolongation of its monopoly in the U.S. market for eculizumab, Alexion will be able to continue to limit and/or delay additional biosimilar competition in this market.

1. Alexion knowingly used its fraudulently obtained patents to leverage a settlement with Amgen and delay competition.

246. Despite Amgen's strong IPR challenge to Alexion's patents, Alexion and Amgen announced on May 28, 2020—just before the scheduled final oral argument—that they had reached a settlement and licensing agreement that required Amgen to dismiss its IPR challenges before the PTAB made a final determination on the validity of Alexion's 2017 Soliris patents.

247. Under the May 2020 settlement agreement, whose key terms remain largely confidential and publicly unavailable, Amgen agreed to delay marketing its biosimilar eculizumab product until March 1, 2025.

248. The Amgen-Alexion settlement came about as analysts reported that Alexion was a prime target for acquisition by a larger pharmaceutical company. As early as August 2019, days before the PTAB issued its decision to initiate review on all three 2017 Alexion Soliris patents, industry analysts reported speculation that Amgen was looking to acquire Alexion.

249. In October 2019, speculation increased about an Alexion acquisition. A leading pharmaceutical industry blog ranked Alexion as the most likely pharma firm to be acquired, claiming it to head "most lists of biotech takeover prospects in recent years" and linked Alexion to "a number of possible suitors *including Amgen* . . . ." One potential sticking point to the sale was reportedly Alexion's dependency on Soliris, which in 2019 was "approaching the end of its patent life." Extending that patent life, through fraudulently obtained patents, and protecting Soliris against biosimilar competition, including through settlements with would-be biosimilar manufacturers, made Alexion a more attractive acquisition target.

250. In 2020, Soliris was still, by far, Alexion's biggest drug, earning nearly $2.3 billion in U.S. sales that year—far more than any other Alexion product. Alexion admitted that a "significant portion of [its] 2020 revenue was attributable" to Soliris, and thus "one or more competitive novel products or biosimilars could have a significant impact on [its] entire business." In fact, Alexion had recognized for years that if it was "not able to maintain revenues from sales of Soliris…. [its] results of operations and stock price could be adversely affected."

251. In May 2020, investors criticized Alexion's leadership in a public letter, detailing the company's "underperformance" and recommending that the board explore acquisition options, urging that "an acquisition would be very financially attractive."

252. In December 2020, Alexion announced it was indeed merging with a major pharmaceutical company, AstraZeneca. At the time the merger was announced, Alexion's chairman was David Brennan, former CEO of AstraZeneca.

253. On information and belief, the May 2020 settlement of the Amgen IPR challenges helped make Alexion a more attractive target for acquisition by addressing a major concern reported in the industry: that the impending end of its monopoly over Soliris negatively impacted its attractiveness to potential acquirers like AstraZeneca.

2. Alexion knowingly used its fraudulently obtained patents to delay competition from Samsung Bioepis.

254. While settling with Amgen eliminated a first threat of biosimilar competition until March 2025, Samsung remained to be dealt with.

255. Samsung's position as a leader in the biosimilar market positioned it as a key competitor to Alexion's Soliris product.

256. And in August 2019, Samsung had announced that it had initiated a Phase III study of its eculizumab biosimilar, which was completed on October 21, 2021.

a) Samsung challenges Alexion's 2017 and 2020 patents with the PTO.

257. In June 2023, Samsung filed five IPR petitions, one for each of the three 2017 patents and two 2020 patents, supported by declarations from Drs. Jeffrey Ravetch and Cindy Ippoliti. After reviewing Samsung's allegations and evidence, the PTAB instituted review, often on multiple grounds, of all five patents. It found that Samsung demonstrated a reasonable likelihood of success in showing that the challenged claims were invalid. In each, the panel

concluded that the prior art had been incorrectly presented to the PTO examiner and that, for at least the '809 patent, Alexion had misled the PTO.

258. *The '149 patent.* Samsung's IPR petition regarding Alexion's '149 patent was filed on May 18, 2023. On December 8, 2023, the PTAB issued its decision to institute a proceeding, agreeing with Samsung on *four independent grounds* for invalidity, two for anticipation and two for obviousness, and rejecting Alexion's evidence of non-obviousness. Throughout its opinion, the PTAB panel rejected Alexion's arguments, finding at times that they "mischaracterize[d]" the prior art and ignored the "close association between Alexion" and the prior arts' authors. The panel also credited Samsung's argument that Alexion had misled the PTO with an incorrect characterization of Alexion's own '245 Patent.

259. *The '880 patent.* Samsung's IPR petition for review of claims 1-3 (all claims) of the '880 patent was filed on May 31, 2023. On December 8, 2023, the PTAB issued its decision to institute a proceeding, finding that Samsung demonstrated a reasonable likelihood of prevailing on its invalidity arguments as to all the challenged claims of the '880 patent on all *six, independent grounds* of unpatentability—four for obviousness and two for anticipation—and again noted that Alexion had likely misled the PTO about its '245 Patent.

260. *The '504 patent.* Samsung's IPR petition for review of claims 1-10 (all claims) of the '504 patent was filed on May 31, 2023. On December 8, 2023, the PTAB issued its decision to institute a proceeding, finding that Samsung demonstrated a reasonable likelihood of prevailing on its invalidity arguments as to all the challenged claims of the '504 patent on all *five independent grounds* of unpatentability—four for obviousness and one for anticipation. Once again, the PTAB noted that Alexion had likely misled the PTO about its '245 Patent.

261. *The '189 patent.* Samsung's IPR petition for review of all claims of the '189 patent was filed on June 16, 2023. On December 20, 2023, the PTAB issued its decision to institute a

proceeding, finding that Samsung demonstrated a reasonable likelihood of prevailing on at least one of its invalidity arguments and instituted a review as to all challenged claims. The PTAB initiated review on three independent grounds of obviousness, and again credited Samsung's argument that Alexion had misled the PTO about its own patent. The PTAB rejected Alexion's interpretation of the prior art, "particularly in view of what appears to be a close association between Alexion" and the prior arts' authors. The PTAB was incredulous at Alexion's arguments that the listed inventors of the '189 patent, who often times are the authors of the prior art, would not understand the prior art, its implications, how the research was developing, or the logical next steps.

262. *The* '809 patent. Samsung's IPR petition for review of all claims of the '809 patent was filed on June 16, 2023. On December 19, 2023 the PTAB issued its decision to institute a proceeding, finding that Samsung demonstrated a reasonable likelihood of prevailing on at least one of its invalidity arguments and instituted a review as to all challenged claims.

263. Samsung and Alexion jointly requested to synchronize the proceedings for all five IPRs and briefing was scheduled to conclude by summer 2024.

b) Alexion sues Samsung in federal court.

264. On or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval to market its biosimilar in the United States. That same month, the FDA accepted Samsung's aBLA for review.

265. Also in July 2023, Samsung provided Alexion with notice that it expected to receive FDA approval of its Soliris biosimilar product in the first half of 2024 for the treatment of PNH and aHUS. In that same letter, Samsung notified Alexion that it would launch its product after January 3, 2024.

266. On January 3, 2024, Alexion filed suit against Samsung in Delaware federal court. Alexion alleged that Samsung's biosimilar eculizumab product would infringe the '149 patent, '880 patent, '504 patent, '189 patent, '809 patent, and U.S. Patent No. 9,447,176 (the '176 patent).

267. Given the manner in which Alexion had obtained each of those patents, no reasonable company would have expected to prevail on the merits as to any claims based on those patents. Indeed, the only reasonably foreseeable outcome of that litigation on its merits was dismissal on patent invalidity grounds.

268. Alexion's misconduct concerning the 2017 patents and the 2020 patents is detailed above. No reasonable company in Alexion's position would have reasonably expected to prevail on any claim based on infringement of the asserted patents.

269. The facts surrounding the '176 patent, and what was known about its claimed inventions before the relevant priority date, also make clear that no reasonable company in Alexion's position would have reasonably expected the patent to be determined valid, and thus would not have expected to prevail on any claims alleging infringement of that patent.

270. The '176 patent claims a method of using eculizumab to treat aHUS. Specifically, claim 1 claims a dosing schedule for treating aHUS. This same dosing schedule was known and approved by 2007 to treat PNH. Both aHUS and PNH cause the same hyperactivation of the same complement system; the reality that treating both diseases with an antibody (eculizumab) that blocks that complement system from activating and thus prevents the resulting hyperactivation in PNH *and* aHUS is not surprising. Indeed, a 2005 publication teaches that eculizumab should be investigated as a treatment for aHUS due to its effectiveness in blocking the relevant complement system in other diseases, such as PNH. The knowledge that eculizumab would be effective in treating a similar disease activated by identical cleaving in the

same complement (C5) combined with the publicly-known dosing schedule for using eculizumab in a highly-analogous disease would lead a person of skill in the art, during the relevant time period, to the exact claims of the '176 patent—rendering them invalid for obviousness.

271. In short, two references that pre-date the '176 patent's priority date – Noris (2005) and the 2007 SOLIRIS label – show that a person of ordinary skill in the art would have known that Soliris was clinically safe and possessed a reasonable likelihood of successfully treating aHUS by inhibiting the c5 pathway.

272. The '176 patent is also invalid for the independent reason that it is anticipated by, *inter alia*, a 2008 public abstract that discloses each of the patent's claims. The Chatelet (2008) abstract[63] predates the proper priority date for the '176 patent and describes a study using eculizumab off-label to treat aHUS with the same dosing regimen claimed in the '176 patent. It was published online in November 2008 and presented at a public meeting in 2008. Alexion was fully aware of the Chatelet abstract: In a 2008 press release, Alexion pointed to Chatelet when referencing public data "regarding initial experience with eculizumab in patients with two other rare diseases (Atypical Hemolytic Uremic Syndrome [aHUS] and Cold Agglutinin Disease)."[64]

273. Chatelet (2008) discloses each and every limitation of claim 1 of the '176 patent.

274. When it obtained the '176 patent, Alexion convinced the examiner that its patent application was entitled to a priority date of November 11, 2008, based on the date that

[63] Valerie Chatelet et. al, *Efficacy of Eculizumab in a Plasmatherapy-Dependent Patient with Atypical Hemolytic Uremic Syndrome with C3 Mutation Following Plasmatherapy Withdrawal*, 112 Blood 4579 (2008).

[64] Alexion, *Researchers to Present Additional Data on Soliris(R) (eculizumab) for the Treatment of PNH at the ASH Annual Meeting* (Nov. 10, 2008), https://media.alexion.com/news-releases/news-release-details/researchers-present-additional-data-solirisr-eculizumab (last accessed February 11, 2025).

the provisional '803 application was filed. But none of the provisional applications filed by Alexion, for which it could seek a priority date, provide any support for the claimed maintenance dosing limitation of "at least 900mg" contained in the '176 patent.

275. The earliest effective filing date of the aHUS claim is the filing date of the PCT application, November 10, 2009.

276. Samsung answered Alexion's complaint on February 8, 2024, denying that its biosimilar product would infringe any valid or enforceable patents. Samsung also lodged multiple counterclaims, including a central counterclaim that was unavailable to Amgen or Samsung during the IPR challenges: that the '149 patent, '880 patent, '504 patent, '189 patent, and '809 patent (the patents obtained by Alexion in 2017 and 2020) are all unenforceable due to inequitable conduct. Specifically, Samsung alleged that Alexion and its employees—including its patent attorney Ms. Sloper and founder Dr. Bell—had materially misled the PTO and withheld and misrepresented at least two material pieces of prior art which would have impacted the examiner's decision to issue the five patents. Samsung further alleged that the one additional patent asserted by Alexion, the '176 patent, was invalid due to obviousness and anticipation.

277. In its sham lawsuit against Samsung, Alexion asserted patents that it had obtained by fraud against Samsung without even an arguable basis for their validity. It did so to interfere with its would-be competitor's business through the use of government processes, not to seek a valid outcome from those processes.

278. By filing suit against Samsung, Alexion tied its competitor up in litigation for the purpose of delaying its biosimilar launch. The District Court for the District of Delaware's median time from filing to trial is roughly 38 months, so no trial was to be expected until March 2027.

279. On February 12, 2024, Alexion filed a motion for preliminary injunction to prevent Samsung from launching its biosimilar until a final decision on the merits of the case. This attempt to further delay Samsung's launch was denied by court order on May 6, 2024.

280. Nevertheless, Alexion filed for an immediate appeal of the court's denial and sought an injunction or temporary restraining order while that appeal *and* its emergency motion was pending. The request reflects an apparent fear from Alexion that Samsung was preparing for an immediate launch of its Soliris biosimilar, even as the litigation was ongoing.

281. In seeking an injunction, Alexion stressed the immediate and significant price impact that biosimilar competition brings to the market, arguing that "[i]f Samsung launches its biosimilar product, Alexion will lose significant dollar sales and market share" and "suffer net price erosion[.]"As Alexion concedes, "The direct competition between Alexion and Samsung will drive down the price of both companies' products, which will, in turn, lead to irreversible price erosion of Alexion's SOLIRIS® product." Once biosimilar entry occurs and the price drops, purchasers like plaintiff is often resistant to "any attempts to return to pre-entry prices[.]"Additionally, Alexion expressed concern that decreased prices for Soliris would also lead to price decreases for its follow-on product, Ultomiris—a telling admission that the supracompetitive price for Soliris has *also* led to supracompetitive prices for Ultomiris.

282. Alexion's motion was denied in full on June 17, 2024, with Judge Williams holding, "[s]pecifically, the Court finds that the well-reasoned IPR institution decision raises a substantial question of validity. Injunctions are an equitable remedy, and the Court *will not grant an injunction on a patent likely to be invalid*." Alexion sought an appeal.

283. Meanwhile, In May 2024, the FDA gave final approval to Amgen's biosimilar eculizumab product—Bkemv—an approval delayed by the settlement agreement. Not only did Amgen secure approval, but it secured interchangeable status for both the PNH and aHUS

indications—meaning it will be far easier for patients to switch to Amgen's biosimilar product from Alexion's Soliris product.

284. Samsung was also pushing forward with the necessary regulatory approvals for launch. On July 19, 2024, the FDA approved Samsung's biosimilar eculizumab, Epysqli, approximately one year after Samsung announced the FDA's acceptance of its aBLA. Not only did the FDA approve Samsung's product, but it also approved it as interchangeable—making it much easier for pharmacists to switch Soliris prescriptions for the interchangeable biosimilar Epysqli and thereby increasing competition (and the threat Samsung's product poses to Alexion).

c) Samsung and Alexion enter a settlement agreement.

285. By this time, briefing in the Samsung IPR proceedings were drawing to a close and oral argument was scheduled for September 17, 2024. Rather than face a determination on the merits before the IPR, Alexion settled with Samsung.

286. On August 30, 2024, Alexion and Samsung filed voluntary dismissals in all their pending patent proceedings related to Soliris, including the Delaware patent litigation (Case No. 1:24-cv-00005) and all pending IPRs. The Delaware court entered the dismissal on September 3, 2024. The PTAB granted the motion to terminate each of the pending IPRs on September 4, 2024.

287. No terms of their settlement agreement have been made public.

J. Competition finally arrives in the marketplace.

288. In early March 2025, Amgen announced that it had finally launched Bkemv, its Soliris biosimilar product. Had Amgen not had to face Alexion's enforcement of the fraudulently acquired patents, Amgen would have been ready, willing, and able to launch its biosimilar eculizumab product by as early as March 2022.

289. In early April 2025, Samsung announced it had launched Epysqli, its Soliris biosimilar product. Had Samsung not had to face Alexion's enforcement of the fraudulently acquired patents, Samsung would have been ready, willing, and able to launch its biosimilar eculizumab product earlier.

290. Delaying Amgen's entry until March 2025 also helped Alexion achieve another one of its core strategic goals: converting the market off Soliris and onto its follow-on product, Ultomiris, before Soliris faced competition—thereby protecting its franchise. Shortly after the Amgen settlement was announced, Alexion told its investors how the settlement fit into its long-term strategy:

> I think where the Amgen settlement, the 2025, what it does is give us enough time for all our current SOLIRIS indications, which is PNH, atypical HUS, MG and NMO. It gives us plenty of time to convert all of those indications. PNH, obviously, we're already established. ULTOMIRIS is a leader there. Atypical HUS and MG and NMO will follow sort of starting in 2023. And by the time 2025 -- mid of 2025 comes around, most patients would be -- would have been on ULTOMIRIS for 2, 3, 5 years. And remember, it is a biosimilar to SOLIRIS. It's not a biosimilar to ULTOMIRIS.

K. Alexion's use of its fraudulent patents has harmed the plaintiff and the class.

291. Alexion's use of its fraudulently obtained patents to delay the entry of biosimilar eculizumab has cost, and continues to cost, purchasers like Emblem billions of dollars.

292. Alexion wrongfully acquired the 2017 and 2020 eculizumab patents and then intentionally enforced them—as well as the sham '176 patent—against would-be competitors in IPRs and baseless litigation to delay the entry of competing biosimilar eculizumab products, to the detriment of U.S. purchasers of eculizumab.

293. Alexion executives explicitly touted their new patents as a strategy against competition.

294. For example, in a call with investors, former CEO and Director David L. Hallal touted the skill of Alexion's *patent attorneys* in creating a "last line of defense" for its key biologic—not any new inventive discoveries relating to eculizumab.

295. That Alexion was highly motivated to delay competition to Soliris is no surprise. Since its approval in 2007, Soliris has played a central role as Alexion's most important and highest grossing product. As detailed above, Alexion's expectation, as of 2016 (before it engaged in its unlawful patent scheme), was that it would lose exclusivity over eculizumab by no later than March 2021. And it knew that the loss of such exclusivity would lead to a decrease in sales, disclosing starting in 2016 that "when market exclusivity expires and biosimilar or generic versions of the product are approved and marketed, there can be *substantial decline* in the innovative product's sales."

296. By 2016, Alexion knew that Amgen, a serious competitive threat, was working on its own Soliris biosimilar. By 2019, the threat was significantly heightened as (i) Amgen entered Phase III studies to establish pharmacokinetic (PK) and pharmacodynamic (PD) equivalence between Amgen's biosimilar and Soliris, and (ii) the PTAB found that Amgen was likely to succeed on its validity challenge (on multiple grounds) to all three then-existing patents which stood in Amgen's way before launch. Alexion was only able to neutralize the threat Amgen presented by entering into a settlement agreement delaying entry until 2025—a date Alexion never would have been able to obtain from Amgen had it not fraudulently obtained new eculizumab patents.

297. By the time Samsung emerged as the next major competitive threat, Alexion had acquired even more fraudulent eculizumab patents. By filing sham litigation in federal court and seeking to enforce these fraudulent and/or invalid patents—and filing to prevent any

launch while the litigation was pending—Alexion subjected its would-be competitor Samsung to lengthy and costly litigation. The terms of their settlement have not been made public.

298. Alexion used its wrongfully-obtained patents to unlawfully delay the entry of eculizumab biosimilars and, therefore, the entry of any competition into the eculizumab market in the United States. And it made repeated misrepresentations to deceive the public, its investors, and consumers by both misrepresentations and by withholding material information.

299. Alexion's wrongful actions in improperly maintaining its monopoly over the eculizumab market in the United States has allowed it to make billions in additional profit at the expense of purchasers of eculizumab in the United States, including the plaintiff and class members, who have paid, and will continue to pay, supracompetitive prices.

VI. CLASS ALLEGATIONS

300. The plaintiff, on behalf of itself and all class members, seeks damages, measures as overcharges, trebled, against Alexion based on allegations of anticompetitive conduct in the market for eculizumab in the United States.

301. The plaintiff brings this action on behalf of itself and, pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2) and 23(b)(3), as representative of the class defined as:

> All end payors (including any assignees of such end payors) in the United States and its territories who purchased and/or paid all or part of the purchase price of Soliris from March 2022 until the anticompetitive effects of Alexion's conduct cease (the class period).

302. Excluded from the class are Alexion and any of its officers, directors, management, employees, subsidiaries, and affiliates.

303. Also excluded from the class are: (1) the government of the United States and all agencies thereof, and (2) all state or local governments and all agencies thereof.

304. Class members are so numerous and geographically dispersed that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together.

305. The plaintiff's claims are typical of those of the class members. The same wrongful conduct of Alexion damaged the plaintiff and all class members—i.e., they paid and will pay artificially inflated prices for eculizumab and were deprived of earlier and more robust competition from cheaper biosimilar versions of eculizumab because of Alexion's wrongful conduct.

306. The plaintiff will fairly and adequately protect and represent the class's interests. The plaintiff's interests are coincident with, and not antagonistic to, those of the other class members.

307. Counsel representing the plaintiff is experienced in the prosecution of class action antitrust litigation and have robust experience with class action antitrust litigation involving pharmaceutical products.

308. Questions of law and fact common to the class members predominate over questions that might affect only individual class members because Alexion has acted on grounds generally applicable to the entire class. This conduct renders appropriate overcharge damages with respect to the class as a whole. Such generally applicable conduct is inherent to Alexion's wrongful actions.

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

a. whether Alexion willfully and improperly maintained monopoly power over eculizumab in the United States;

b. whether Alexion or its employees, agents, or counsel, on behalf of Alexion, made material misrepresentations and/or omissions to the PTO with the specific intent to deceive the PTO;

c. whether Alexion or its employees, agents, or counsel, on behalf of Alexion, obtained the '149 patent, '880 patent, '504 patent, '189 patent, and/or '809 patent by fraud on the PTO;

d. whether Alexion intentionally acquired the patents to unlawfully delay competition and to unlawfully maintain its monopoly over eculizumab;

e. whether Alexion knowingly and unlawfully enforced the fraudulently obtained '149 patent, '880 patent, '504 patent, '189 patent, and '809 patent against would-be biosimilar competitor, Amgen;

f. whether Alexion knowingly and unlawfully enforced the fraudulently obtained the '149 patent, '880 patent, '504 patent, '189 patent, and '809 patent against would-be biosimilar competitor, Samsung;

g. whether the '176 patent is valid and enforceable and would be infringed by a biosimilar Soliris product, including the products made by Amgen and Samsung;

h. whether Alexion unlawfully used the '149 patent, '880 patent, '504 patent, '189 patent, '809 patent, and '176 patent to delay eculizumab biosimilar competition;

i. whether Alexion unlawfully excluded competitors and potential competitors from the market for eculizumab;

j. whether Alexion unlawfully delayed or prevented manufacturers of eculizumab biosimilars from coming to market in the United States;

k. whether Alexion improperly maintained monopoly power by delaying biosimilar entry;

l. whether the law requires a definition of a relevant market when direct proof of monopoly power is available, and if so, the definition of the relevant market;

m. whether Alexion's activities as alleged herein have substantially affected interstate commerce;

n. whether, and if so to what extent, Alexion's conduct caused antitrust injury (i.e., overcharges) to the plaintiff and the class members; and

o. the quantum of aggregate overcharge damages to the plaintiff and class members.

310. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such 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, or expense that numerous individual actions would require. The benefits of proceeding through the class mechanism—including providing injured persons or entities with a method for obtaining redress on claims that they could not practicably pursue on an individual basis—substantially outweigh potential difficulties in management of this class action.

311. Alexion's anticompetitive conduct has imposed and will continue to impose (unless the plaintiff obtains equitable relief) a common antitrust injury on the plaintiff and all class members. Alexion's anticompetitive conduct and its relationships with the class members have been substantially uniform. Alexion has acted and refused to act on grounds that apply to the class generally, and injunctive and other equitable relief is appropriate respecting the class as a whole.

312. The plaintiff knows of no special difficulty in litigating this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND MARKET DEFINITION

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

314. The relevant product market is eculizumab.

315. Since 2007, Alexion has had, and continues to have, monopoly power in the market for eculizumab in the United States.

316. As Alexion publicly touted, it has "no competitors for the patient segments [Alexion] target[s]."

A. Direct evidence demonstrates Alexion's market power.

317. *Supracompetitive prices.* At all times relevant to this civil action, Alexion charged supracompetitive prices for Soliris—i.e., prices that were and are markedly higher than it could

have been charged had there been biosimilar competition for eculizumab in the United States. Alexion also steadily *increased* the price of Soliris over the years without losing market share to other pharmaceutical products.

318. From 2007—the entry of Soliris into the U.S. marketplace—until 2021, Alexion did not have to compete with *any other pharmaceutical company* for FDA-approved PNH drugs.

319. From 2007 to date, Alexion has not had to compete with *any other pharmaceutical company* for FDA-approved aHUS drugs.

320. Soliris is one of the top ten most expensive drugs in the world, indicating that its sales are not constrained by any other products. Indeed, in response to criticism over its Soliris pricing, Alexion stated that its drug pricing strategy depends on a number of factors, but did not list among them the price of any other drug, instead claiming it takes into account "the rarity and severity of the disease, *the absence of effective alternative treatments*, indirect medical and social costs, and clinical data that demonstrate the impact of the drug on patients who desperately need it."

321. In 2020, Alexion told its investors that there was very little "price sensitivity" to Soliris, thus allowing Alexion to charge sky-high prices:

> And one also has to remember, we're talking about a rare ultra-orphan to orphan market. This is not Humira where there are millions and millions of patients, and therefore, there may be some price sensitivity. We're talking for every payer or every country, there may be 20, 30, 50 patients on these therapies. So it's a very different dynamic versus very large primary care or even specialty markets, which may have price sensitivity.

322. *Supracompetitive profits margins.* At all times relevant to this civil action, Alexion enjoyed extraordinarily high profit margins from the sale of Soliris.

323. *Combination patent protection and other barriers.* From 2007 (product launch) through March 2021 (expiration of original patent), Alexion enjoyed legitimate patent protection for eculizumab. As a result, Alexion had the power to exclude competition from

eculizumab biosimilars and thereby restrict output. From and after March 2021, Alexion used ostensible patent protection from its fraudulently acquired patents to exclude competition from eculizumab biosimilars and thereby restrict output. In addition, the FDA approval processes for the marketing of biosimilars in the U.S. presented barriers to biosimilar entry.

324. *Lack of interchangeability.* Eculizumab is not readily interchangeable with other treatments for PNH or aHUS. Eculizumab is a unique treatment for these diseases, ostensibly offering advantages over other available treatment for these conditions.

325. *Biosimilar competition.* Recent reports regarding biosimilars confirm that biosimilar competition has a significant effect in lowering price among equally effective therapies.

326. Recent biosimilars have achieved high market volume share, reaching more than 60% of a given biologic's volume within the first three years. The introduction of biosimilars frequently leads to higher utilization of the treatment as lower costs improve patient access.

327. Introduction of lower cost biosimilars precipitates reductions in overall drug costs per unit at invoice prices over time. Indeed, such competition typically lowers the per unit cost of both the brand and biosimilar drug. Costs are down between 18% and 50% per unit for drugs with biosimilars.

328. One of Alexion's would-be competitors, Amgen, commented in its 2022 Biosimilar Trends report that biosimilar entrants, typically, are successful at taking market share from the reference biologic drug. Amgen's report states: "Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced." Amgen further remarked "[f]or therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%," and "[f]or therapeutic areas with biosimilars launched prior to 2019, the average share after 3 years was 39%."

329. A 2022 study published in the Journal of the American Medical Association (JAMA) found that "[b]iosimilars in the US that entered the market more recently were estimated to experience a faster uptake (as measured by the market share 1 year after launch). . . ." Alexion has endorsed the accuracy of this report.

330. *Alexion admissions.* The effects of biosimilar competition in the U.S. market for eculizumab would also have substantial downward pressure on the price of eculizumab, as Alexion conceded, and cause a "substantial decline" in Soliris sales. Indeed, Alexion cited such an irreversible decline in sales and price as a reason the court should grant its motion for a preliminary injunction in its litigation against Samsung (a motion the court twice denied due to the likely invalidity of Alexion's patents).

331. Direct evidence shows that Alexion has monopoly power over the sale of eculizumab in the United States and that entry of a biosimilar eculizumab would cause significant downward pressure on price, resulting in more affordable and accessible eculizumab products.

B. Indirect evidence demonstrates Alexion's market power.

332. To the extent the plaintiff is legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, indirect evidence shows that Alexion had monopoly power in an antitrust market of the sale of eculizumab in the United States.

333. The relevant product market is the sale of eculizumab in the United States and has, thus far, consisted solely of Soliris. Biosimilar versions of eculizumab will also be in the relevant market once they are available. At all relevant times, Alexion's market share in the market was and remains 100%.

334. Alexion, at all relevant times, enjoyed high barriers to entry with respect to competition in the product market of eculizumab due, in large part, to legally and illegally created patent protections.

335. Soliris does not exhibit significant, positive cross-elasticity of demand with any other medication. Until 2021, there were no non-Alexion FDA-approved treatments for PNH, and there remain none for aHUS. The eventual existence of non-eculizumab products that may be used to treat similar indications as eculizumab did not constrain Alexion's ability to raise or maintain Soliris prices without losing substantial sales. As a result, those other drug products do not occupy the same relevant antitrust market as Soliris.

336. Alexion needed to control only eculizumab, and no other products, to maintain a supracompetitive price for Soliris while preserving all or virtually all its sales. Only market entry of a competing, biosimilar eculizumab would undermine Alexion's ability to keep Soliris prices high without losing substantial sales.

337. Alexion has admitted that competition from a biosimilar to Soliris is the level of competition that would force Alexion to compete based on price or, if it did not, lose significant market share. As Alexion had conceded in 2016, "In our industry, much of an innovative product's commercial value is realized while it has market exclusivity. *When market exclusivity expires and biosimilar or generic versions of the product are approved and marketed, there can be substantial decline in the innovative product's sales.*"

338. Competition from Amgen was particularly threatening to Alexion. Amgen had made it clear, publicly, that it intended to seek approval of its biosimilar product to compete with Soliris. For example, Amgen reported that it was beginning the studies to support approval and in 2019 announced that Phase I data showed pharmacokinetic (PK) and pharmacodynamic (PD) equivalence between Amgen's biosimilar and Soliris. An

interchangeability designation—which Amgen ultimately obtained—will allow Amgen's biosimilar to be substituted for Soliris at the pharmacy level, without physician authorization, enabling Amgen's biosimilar to compete with Alexion's Soliris based on price alone.

VIII. MARKET EFFECTS AND CLASS DAMAGES

339. In the absence of the anticompetitive conduct alleged above, multiple manufacturers would have entered the market with eculizumab biosimilars starting as early as March 2022.

340. Instead, Alexion willfully and unlawfully maintained its monopoly power in the market for eculizumab through the following anticompetitive scheme: (i) Alexion fraudulently obtained five eculizumab patents in 2017 and 2020; and (ii) Alexion used those patents, along with another later-wrongfully-obtained patent to delay competition from would-be eculizumab biosimilar competitors—including through the pursuit of sham litigation. These acts, individually and in combination, were anticompetitive.

341. Alexion's scheme had the purpose and effect of preventing any biosimilar competition, and continues to prevent full biosimilar competition, permitting Alexion to maintain supracompetitive monopoly prices for Soliris and enabling Alexion to sell Soliris without competition for far longer than it was lawfully entitled. Absent Alexion's conduct, biosimilar versions of eculizumab would have been available sooner.

342. Competition among drug manufacturers enables all purchasers of their drugs to buy biosimilar versions of the drugs at substantially lower prices and/or to buy the reference biologic products at reduced prices. Consequently, reference (i.e., brand) biologic manufacturers have a strong incentive to delay biosimilar competition. Purchasers experience substantial cost inflation from that delay. In this manner, Alexion's acts and practices hamred the public at

large and were consumer-oriented in that they exerted an impact broadly on purchasers of prescription drugs.

343. If competition from biosimilar manufacturers had not been restrained and forestalled in the case of eculizumab, end payers like the plaintiff and class members would have paid less for eculizumab by: (i) purchasing, and providing reimbursement for, biosimilar versions of eculizumab instead of the more expensive Soliris, and (ii) purchasing, and providing reimbursement for, Soliris at lower prices.

344. Alexion's conduct has forced and will continue to force the plaintiff and class members to pay more for Soliris and biosimilar eculizumab than they would have paid absent Alexion's misconduct.

345. Emblem has purchased Soliris for its members in at least nine states: Arizona, Connecticut, Florida, North Carolina, New Jersey, New York, Pennsylvania, South Carolina, and Tennessee.

IX. ANTITRUST IMPACT

346. The effect of Alexion's misconduct is to net Alexion billions of dollars in revenue at the expense of end payers, including the plaintiff and the class members, who will pay hundreds of millions, if not billions, of dollars in unlawful overcharges.

347. During the relevant period, the plaintiff and the class members purchased Soliris indirectly from Alexion.

348. As a direct and proximate result of Alexion's anticompetitive conduct, the plaintiff and the class members have paid and will continue to pay supracompetitive prices for eculizumab because (1) the price of Soliris was and is artificially inflated by Alexion's anticompetitive conduct, and (2) the plaintiff and the class members were and are deprived of the opportunity to purchase lower-priced biosimilar versions of eculizumab.

349. As a result, the plaintiff and class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

350. The overcharges resulting from Alexion's conduct occurred in each state and are directly traceable through the pharmaceutical distribution chain to the plaintiff and other class members. Alexion sells eculizumab to a group of authorized distributors, who in turn sell to specialty pharmacies, hospitals, health care providers, infusion therapy providers, who then provide it to patients (who typically pay for the drug using third-party payers—also known as end payers—and other forms of payment). In this short chain of distribution, drug products are not altered or incorporated into other products. Each drug purchase is documented and closely tracked by pharmacies, pharmacy benefit managers, and third-party payers (such as insurers and health and welfare funds). The products and their prices are thus directly traceable from manufacturer to consumer.

X. IMPACT ON INTERSTATE AND INTRASTATE COMMERCE

351. Alexion's efforts to monopolize and restrain competition in the market for eculizumab have substantially affected both interstate and intrastate commerce and the people of each State.

352. At all material times, Alexion manufactured, sold, and shipped substantial amounts of Soliris across state lines in an uninterrupted flow of commerce across state and national lines throughout the United States.

353. At all material times, Alexion transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Soliris.

354. To further its monopolization and restraint on competition in the market for eculizumab, Alexion used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. Alexion engaged in illegal activities, as charged herein, within the flow of—and substantially affecting—interstate commerce, including in this district.

XI. FEDERAL CLAIMS FOR RELIEF

COUNT ONE

MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2) SEEKING DECLARATORY AND INJUNCTIVE RELIEF

355. The plaintiff repeats and incorporates the above paragraphs as though fully set forth herein.

356. At all relevant times, Alexion possessed and continues to possess substantial market power (i.e., monopoly power) in the market for eculizumab in the United States. Alexion possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for eculizumab.

357. Alexion's market power is coupled with strong regulatory and contractual barriers to entry.

358. At all relevant times, Alexion knowingly, willfully, and improperly maintained its monopoly power in the U.S. market for eculizumab after March 2022 through restrictive and exclusionary conduct, rather than through growth or development resulting from a superior product, business acumen, or historic accident, and thereby injured the plaintiff and class members. Alexion's conscious objective was to further its dominance and monopoly power in the market for eculizumab in the United States.

359. Alexion knowingly, willfully, and improperly maintained its monopoly power and substantially reduced and harmed competition in the market for eculizumab in the United States by:

- fraudulently obtaining five eculizumab patents in 2017 and 2020 by withholding material information from, and deliberating misrepresenting material information provided to, the patent examiner regarding the state of the art regarding eculizumab; and
- using and/or enforcing the fraudulently obtained eculizumab patents, which Alexion knew it had obtained by fraud on the PTO, as well as asserting objectively meritless infringement claims concerning the '176 patent, to unlawfully delay competition from would-be eculizumab biosimilar competitors, including Amgen and Samsung.

360. Alexion's monopoly power over eculizumab should have ended by no later than March 2022 (by which time Alexion's eculizumab composition patent was expired and Amgen's product should have entered the market). Instead, due to its fraudulently obtained patents and use of all five patents—as well as its meritless assertion of the '176 patent—Alexion was able to unlawfully delay biosimilar competition. As a result, Alexion's monopoly power will extend by approximately four years—potentially until Amgen's licensed entry date of March 1, 2025. As a result of Alexion's unlawful anticompetitive scheme, no other entity currently sells biosimilar eculizumab in the United States, despite their current availability overseas.

361. The goal, purpose, and effect of Alexion's overarching anticompetitive scheme was to delay and/or block eculizumab biosimilars from entering the market, maintain its monopoly in that market, and maintain its supracompetitive prices for Soliris.

362. Alexion's anticompetitive scheme substantially reduced and harmed competition in the relevant market and was an unreasonable restraint on trade.

363. Had Alexion competed on the merits, instead of unlawfully maintaining its monopoly in the market for eculizumab, one or more eculizumab biosimilars would have been available by no later than March 2022. The plaintiff and class members would have substituted the lower-priced eculizumab biosimilar products for the higher-priced brand Soliris (or purchased Soliris at lower prices) for some or all their eculizumab requirements. As a result, they would have paid substantially lower prices for eculizumab.

364. To the extent that Alexion is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable justifications that Alexion were permitted to assert, Alexion's conduct is and was broader than necessary to achieve such a purpose.

365. Alexion's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiff and class members throughout the United States. The plaintiff's and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Soliris from Alexion; (b) paying higher prices for eculizumab than they would have paid in the absence of Alexion's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar eculizumab at a price substantially lower than what they were forced to pay for Soliris. These injuries are of the type that the antitrust laws were designed to prevent, and they flow from that which makes Alexion's conduct unlawful.

366. The plaintiff and the class members are the proper entities to bring a case concerning Alexion's unlawful anticompetitive scheme.

367. The plaintiff and class members have been injured—and unless Alexion's unlawful conduct is enjoined, the plaintiff and class members will continue to be injured—in

their businesses and property, as a direct and proximate result of Alexion's continuing monopolization in violation of Section 2 of the Sherman Act.

368. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a), the plaintiff and the class members seek a declaratory judgment that Alexion's conduct in seeking to prevent competition, as described in the preceding paragraphs, violates Section 2 of the Sherman Act.

369. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, the plaintiff and class members further seek equitable and injunctive relief to correct for the anticompetitive market effects Alexion's unlawful conduct caused and to ensure that similar anticompetitive conduct does not occur in the future.

COUNT TWO

ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2) SEEKING DECLARATORY AND INJUNCTIVE RELIEF

370. The plaintiff repeats and incorporates the above paragraphs as though fully set forth herein.

371. At all relevant times, Alexion possessed and continues to possess substantial market power (i.e., monopoly power) in the U.S. market for eculizumab. Alexion possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for eculizumab.

372. Alternatively, if Alexion does not already have a monopoly in the market for eculizumab in the United States, it has attempted to monopolize this market.

373. Alexion engaged in predatory or anticompetitive conduct by:

- fraudulently obtaining five eculizumab patents in 2017 and 2020 by withholding material information from, and deliberating misrepresenting material information provided to, the patent examiner regarding the state of the art regarding eculizumab; and

- using and/or enforcing the fraudulently obtained eculizumab patents, which Alexion knew it had obtained by fraud on the PTO, as well as asserting objectively meritless infringement claims concerning the '176 patent, to unlawfully delay competition from would-be eculizumab biosimilar competitors, including Amgen and Samsung.

374. Through its anticompetitive scheme, as alleged above, Alexion specifically intended to monopolize the market for eculizumab in the United States. Alexion's goal, purpose, and effect was to delay and/or block eculizumab biosimilars from entering the market, maintain its monopoly in that market, and maintain its supracompetitive prices for Soliris.

375. Based on its current market power in the market for eculizumab in the United States, there is a dangerous probability that Alexion will achieve monopoly power.

376. Alexion's attempted monopolization directly, foreseeably, and proximately caused injury to the plaintiff and class members throughout the United States. The plaintiff's and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Soliris from Alexion; (b) paying higher prices for eculizumab than they would have paid in the absence of Alexion's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar eculizumab at substantially lower prices than what they were forced to pay for Alexion's Soliris. These injuries are of the type that the laws of the jurisdictions below were designed to prevent, and they flow from that which makes Alexion's conduct unlawful. The plaintiff and class members are the proper entities to bring a case concerning Alexion's unlawful anticompetitive scheme.

377. The plaintiff's and class members' allegations comprise a violation of Section 2 of the Sherman Act.

378. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a), the plaintiff and the class members seek a declaratory judgment that Alexion's conduct in seeking

to prevent competition, as described in the preceding paragraphs, violates Section 2 of the Sherman Act.

379. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, the plaintiff and class members further seek equitable and injunctive relief to ensure Alexion's attempted monopolization does not occur in the future.

XII. STATE CLAIMS FOR RELIEF

COUNT THREE

MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW

380. The plaintiff repeats and incorporates the above paragraphs as though fully set forth herein.

381. Count Three is pled on behalf of the plaintiff and class members under the antitrust laws of each jurisdiction identified below.

382. Count Three arises from Alexion's exclusionary, anticompetitive scheme that was designed to create and maintain Alexion's improper monopoly over eculizumab and exclude or substantially exclude its biosimilars from the market.

383. The essential elements of each antitrust claim in Count Three are the same. The above-alleged conduct that violates the Sherman Act will, if proven, establish a claim under each of the laws cited below.

384. At all relevant times, Alexion possessed and continues to possess substantial market power (i.e., monopoly power) in the market for eculizumab. Alexion possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for eculizumab.

385. Through its overarching anticompetitive scheme, as alleged above, Alexion willfully maintained its monopoly power in the market for eculizumab in the United States after

March 2022 using restrictive or exclusionary conduct, rather than by means of a superior product, business acumen, or historic accident, and thereby injured the plaintiff and the class members. Alexion engaged in its anticompetitive scheme with the specific intent to maintain its monopoly in the market for eculizumab in the United States.

386. Alexion accomplished its anticompetitive scheme by: (i) fraudulently obtaining five eculizumab patents in 2017 and 2020 by withholding material information from, and deliberately misrepresenting material information provided to, the patent examiner regarding the state of the art as to eculizumab; and (ii) using and/or enforcing the fraudulently obtained eculizumab patents, which Alexion knew it had obtained by fraud on the PTO, as well as asserting objectively meritless infringement claims concerning the '176 patent, to unlawfully delay competition from would-be eculizumab biosimilar competitors, including Amgen and Samsung.

387. The goal, purpose, and effect of Alexion's overarching anticompetitive scheme was to delay and/or block eculizumab biosimilars from entering the market, extend Alexion's monopoly in that market, and maintain its supracompetitive prices for Soliris.

388. Alexion's anticompetitive scheme substantially reduced and harmed competition in the relevant market and was an unreasonable restraint on trade.

389. Alexion's anticompetitive scheme directly impacts and disrupts commerce within each jurisdiction below.

390. Had Alexion competed on the merits, instead of unlawfully maintaining its monopoly in the market for eculizumab, one or more eculizumab biosimilars would have been available no later than March 2022. The plaintiff and class members would have substituted the lower-priced eculizumab biosimilars for the higher-priced brand Soliris (or paid less for Soliris)

for some or all their eculizumab requirements. As a result, they would have paid substantially lower prices for eculizumab.

391. During the class period, Soliris, manufactured and sold by Alexion, was shipped into each state and was sold to or paid for by the plaintiff and the members of the class.

392. During the class period, in connection with the purchase and sale of Soliris, money changed hands and business communications and transactions occurred in each state.

393. Alexion's conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Soliris to end payors purchasing inside each respective state. This impairment of competition directly impacts and disrupts commerce within each state.

394. Alexion's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiff and class members throughout the United States. The plaintiff's and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Soliris from Alexion; (b) paying higher prices for eculizumab than they would have paid in the absence of Alexion's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar eculizumab at prices substantially lower than what they were forced to pay for Soliris. These injuries are of the type that the laws of the jurisdictions below were designed to prevent, and they flow from that which makes Alexion's conduct unlawful.

395. The plaintiff and class members are the proper entities to bring a case concerning Alexion's unlawful anticompetitive scheme.

396. The defendants are jointly and severally liable for all damages suffered by the plaintiff and the class members.

397. By engaging in the foregoing conduct, Alexion intentionally and flagrantly maintained its monopoly power over eculizumab in the United States in violation of the following state laws:

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to the plaintiff's and class members' purchases in Alabama.

b. Ariz. Arizona Rev. Stat. §§ 44-1401, *et seq.*, including Ariz. Rev. Stat. § 44-1403, with respect to the plaintiff's and class members' purchases in Arizona.

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to the plaintiff's and class members' purchases in California.

d. Col. Rev. Stat. Ann. §§ 6-4-105, *et seq.*, with respect to the plaintiff's and class members' purchases in Colorado.

e. Conn. Gen. Stat. §§ 35-24, *et seq.*, with respect to the plaintiff's and class members' purchases in Connecticut.

f. D.C. Code §§ 28-4501, *et seq.*, with respect to the plaintiff's and class members' purchases in the District of Columbia.

g. Fla. Stat. §§ 501.201, *et seq.*, with respect to the plaintiff's and class members' purchases in Florida.

h. Haw. Rev. Stat. §§ 480-13.3, *et seq.*, with respect to the plaintiff's and class members' purchases in Hawaii.

i. 740 Ill. Comp. Stat. 10/1, *et seq.*, including 740 Ill. Comp. Stat. 10/3, with respect to the plaintiff's and class members' purchases in Illinois.

j. Iowa Code §§ 553.1, *et seq.*, including Iowa Code § 553.5, with respect to the plaintiff's and class members' purchases in Iowa.

k. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, including Me. Rev. Stat. Ann. tit. 10, §1102, with respect to the plaintiff's and class members' purchases in Maine;

l. Md. Code Com. Law § 11-201, *et seq.*, including Md. Code Com. Law § 11-204, with respect to the plaintiff's and class members' purchases in Maryland.

m. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiff's and class members' purchases in Michigan.

n. Minn. Stat. Ann. §§ 325D.49, *et seq.*, including Minn. Stat. Ann. § 325D.52 and Minn. Stat. Ann. § 8.31, *et seq.*, with respect to the plaintiff's and class members' purchases in Minnesota.

o. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiff's and class members' purchases in Mississippi.

p. Neb. Code Ann. §§ 59-801, *et seq.*, including Neb. Code Ann. § 59-802, with respect to the plaintiff's and class members' purchases in Nebraska.

q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, including Nev. Rev. Stat. Ann. § 598A.060, with respect to the plaintiff's and class members' purchases in Nevada.

r. N.H. Rev Stat. Ann. §§ 356.1, *et seq.*, including N.H. Rev. Stat. Ann. § 356.3, with respect to the plaintiff's and class members' purchases in New Hampshire.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, including N.M. Stat. Ann. § 57-1-2, with respect to the plaintiff's and class members' purchases in New Mexico.

t. N.C. Gen. Stat. Ann. §§ 75-1, *et seq.*, including N.C. Gen. Stat. Ann. § 75-2.1, with respect to the plaintiff's and class members' purchases in North Carolina.

u. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, including N.D. Cent. Code § 51-08.1-03, with respect to class members' purchases in North Dakota.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, including Or. Rev. Stat. § 646.730, with respect to the plaintiff's and class members' purchases in Oregon.

w. 10 L.P.R.A. §§ 257, *et seq.*, with respect to class members' purchases in Puerto Rico.

x. R.I. Gen. Laws §§ 6-36-1, *et seq.*, including R.I. Gen. Laws § 6-36-5, with respect to class members' purchases in Rhode Island.

y. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, including S.D. Codified Laws § 37-1-3.2, with respect to class members' purchases in South Dakota.

z. Utah Code Ann. §§ 76-10-3101, *et seq.*, including Utah Code Ann. § 76-10-3104, with respect to purchases in Utah by class members that are Utah residents or citizens.

aa. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*, with respect to the plaintiff's and class members' purchases in Vermont.

bb. W.Va. Code §§ 47-18-1, *et seq.*, including § 47-18-4, with respect to the plaintiff's and class members' purchases in West Virginia.

cc. Wis. Stat. §§ 133.01, *et seq.*, including Wis. Stat. § 133.04, with respect to the plaintiff's and class members' purchases in Wisconsin.

398. As a result of the unlawful and anticompetitive conduct described above, the plaintiff and/or members of the class paid artificially inflated prices for Soliris, in each of these listed jurisdictions.

COUNT FOUR

ATTEMPTED MONOPOLIZATION UNDER STATE LAW

399. The plaintiff repeats and incorporates the above paragraphs as though fully set forth herein.

400. Count Four is pled on behalf of the plaintiff and class members under the antitrust laws of each jurisdiction identified below.

401. Count Four arises from Alexion's exclusionary, anticompetitive scheme that was designed to create and maintain Alexion's improper monopoly over eculizumab and exclude or substantially exclude its biosimilars from the market.

402. The essential elements of each antitrust claim in Count Four are the same. The above-alleged conduct that violates the Sherman Act will, if proven, establish a claim under each of the laws cited below.

403. At all relevant times, Alexion possessed and continues to possess substantial market power (i.e., monopoly power) in the market for eculizumab. Alexion possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for eculizumab.

404. Alternatively, if Alexion does not already have a monopoly in the market for eculizumab in the United States, it has attempted to monopolize this market.

405. Alexion engaged in predatory or anticompetitive conduct by: (i) fraudulently obtaining five eculizumab patents in 2017 and 2020 by withholding material information from, and deliberating misrepresenting material information provided to, the patent examiner regarding the state of the art regarding eculizumab; and (ii) using and/or enforcing the fraudulently-obtained eculizumab patents, which Alexion knew it had obtained by fraud on the PTO, as well as asserting objectively meritless infringement claims concerning the '176 patent, to unlawfully delay competition from would-be eculizumab biosimilar competitors, including Amgen and Samsung.

406. Through its anticompetitive scheme, Alexion specifically intended to monopolize the market for eculizumab in the United States after March 2022 using restrictive or exclusionary conduct, rather than by means of a superior product, business acumen, or historic accident.

407. The goal, purpose, and effect of Alexion anticompetitive scheme was to delay and/or block eculizumab biosimilars from entering the market, extend Alexion's monopoly in that market, and maintain its supracompetitive prices for Soliris.

408. Based on its current market power in the market for eculizumab in the United States, there is a dangerous probability that Alexion will achieve monopoly power.

409. During the class period, Soliris, manufactured and sold by Alexion, was shipped into each state, and was sold to or paid for by the plaintiff and the class.

410. During the class period, in connection with the purchase and sale of Soliris, money changed hands and business communications and transactions occurred in each state.

411. Alexion's conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering

cheaper biosimilar Soliris to end payors purchasing inside each respective state. This impairment of competition directly impacts and disrupts commerce within each state.

412. Alexion's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiff and class members throughout the United States. The plaintiff's and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Soliris from Alexion; (b) paying higher prices for eculizumab than they would have paid in the absence of Alexion's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar eculizumab at prices substantially lower than what they were forced to pay for Soliris. These injuries are of the type that the laws of the jurisdictions below were designed to prevent, and they flow from that which makes Alexion's conduct unlawful.

413. The plaintiff and class members are the proper entities to bring a case concerning Alexion's unlawful anticompetitive scheme.

414. The defendants are jointly and severally liable for all damages suffered by the plaintiff and the class members.

415. By engaging in the foregoing conduct, Alexion intentionally, wrongfully, and flagrantly attempted to monopolize the market for eculizumab in the United States in violation of the following state laws:

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to the plaintiff's and class members' purchases in Alabama.

b. Ariz. Rev. Stat. Ann. §§ 44-1401, *et seq.*, including Ariz. Rev. Stat. § 44-1403, with respect to the plaintiff's and class members' purchases in Arizona.

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to the plaintiff's and class members' purchases in California.

d. Col. Rev. Stat. Ann. §§ 6-4-105, *et seq.*, with respect to the plaintiff's and class members' purchases in Colorado.

e. Conn. Gen. Stat. §§ 35-24, *et seq.*, with respect to the plaintiff's and class members' purchases in Connecticut.

f. D.C. Code §§ 28-4501, *et seq.*, with respect to the plaintiff's and class members' purchases in the District of Columbia.

g. Fla. Stat. §§ 501.201, *et seq.*, with respect to the plaintiff's and class members' purchases in Florida.

h. Haw. Rev. Stat. §§ 480-13.3, *et seq.*, with respect to the plaintiff's and class members' purchases in Hawaii.

i. 740 Ill. Comp. Stat. 10/1, *et seq.*, including 740 Ill. Comp. Stat. 10/3, with respect to the plaintiff's and class members' purchases in Illinois.

j. Iowa Code §§ 553.1, *et seq.*, including Iowa Code § 553.5, with respect to the plaintiff's and class members' purchases in Iowa.

k. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, including Me. Rev. Stat. Ann. tit. 10, §1102, with respect to the plaintiff's and class members' purchases in Maine;

l. Md. Code Com. Law § 11-201, *et seq.*, including Md. Code Com. Law § 11-204, with respect to the plaintiff's and class members' purchases in Maryland.

m. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiff's and class members' purchases in Michigan.

n. Minn. Stat. Ann. §§ 325D.49, *et seq.*, including Minn. Stat. Ann. § 325D.52 and Minn. Stat. Ann. § 8.31, *et seq.*, with respect to the plaintiff's and class members' purchases in Minnesota.

o. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiff's and class members' purchases in Mississippi.

p. Neb. Code Ann. §§ 59-801, *et seq.*, including Neb. Code Ann. § 59-802, with respect to the plaintiff's and class members' purchases in Nebraska.

q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, including Nev. Rev. Stat. Ann. § 598A.060, with respect to the plaintiff's and class members' purchases in Nevada.

r. N.H. Rev Stat. Ann. §§ 356.1, *et seq.*, including N.H. Rev. Stat. Ann. § 356.3, with respect to the plaintiff's and class members' purchases in New Hampshire.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, including N.M. Stat. Ann. § 57-1-2, with respect to the plaintiff's and class members' purchases New Mexico.

t. N.C. Gen. Stat. Ann. §§ 75-1, *et seq.*, including N.C. Gen. Stat. Ann. § 75-2.1, with respect to the plaintiff's and class members' purchases in North Carolina.

u. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, including N.D. Cent. Code § 51-08.1-03, with respect to class members' purchases in North Dakota.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, including Or. Rev. Stat. § 646.730, with respect to the plaintiff's and class members' purchases in Oregon.

w. 10 L.P.R.A. §§ 257, *et seq.*, with respect to class members' purchases in Puerto Rico.

x. R.I. Gen. Laws §§ 6-36-1, *et seq.*, including R.I. Gen. Laws § 6-36-5, with respect to class members' purchases in Rhode Island.

y. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, including S.D. Codified Laws § 37-1-3.2, with respect to class members' purchases in South Dakota.

z. Utah Code Ann. §§ 76-10-3101, *et seq.*, including Utah Code Ann. § 76-10-3104, with respect to purchases in Utah by class members that are residents or citizens of Utah.

aa. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*, with respect to the plaintiff's and class members' purchases in Vermont.

bb. W.Va. Code §§ 47-18-1, *et seq.*, including § 47-18-4, with respect to the plaintiff's and class members' purchases in West Virginia.

cc. Wis. Stat. §§ 133.01, *et seq.*, including Wis. Stat. § 133.04, with respect to the plaintiff's and class members' purchases in Wisconsin.

416. As a result of the unlawful and anticompetitive conduct described above, the plaintiff and/or members of the class paid artificially inflated prices for Soliris, in each of these listed jurisdictions.

COUNT FIVE

VIOLATIONS OF STATE CONSUMER PROTECTION LAWS

417. The plaintiff repeats and incorporates the above paragraphs as though fully set forth herein.

418. As described above, Alexion engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent conduct, acts, or practices in violation of the consumer

protection statutes set forth below. As a direct and proximate result of Alexion's anticompetitive, deceptive, unfair, unconscionable, and/or fraudulent conduct, the plaintiff has been and continue to be deprived of the opportunity to purchase lower-priced eculizumab.

419. Alexion established, maintained, and/or used a monopoly, or attempted to establish a monopoly, and to restrain trade or commerce in the U.S. market for eculizumab. A substantial part of this conduct occurred within each jurisdiction identified below. Alexion intended to injure competitors and exclude or substantially lessen competition. Alexion intended to injure consumers by unlawfully reaping supracompetitive profits.

420. By unlawfully delaying the entry of eculizumab biosimilars, Alexion, as a supplier, engaged in a fraudulent or deceptive act or practice in connection with a consumer transaction.

421. Alexion's conduct constitutes consumer-oriented deceptive acts or practices that resulted in consumer injury and broad adverse impact on the public at large. Alexion's conduct thereby harmed consumers' interest in an honest marketplace where economic activity is conducted in a competitive manner.

422. Alexion withheld material facts and information from the plaintiff and class members, including that Alexion was unlawfully excluding manufacturers of biosimilar eculizumab from the market and monopolizing the market for eculizumab (and thereby profiting from the resulting supracompetitive prices that the plaintiff and class members who purchased or reimbursed purchases of Soliris paid).

423. Alexion's conduct was willful and knowing. Alexion intended to deceive the plaintiff and class members regarding the nature of its actions within the stream of commerce in each jurisdiction below.

424. Alexion's acts, omissions, misrepresentations, practices, and/or non-disclosures constituted a common, continuous, and continuing course of conduct of unfair competition by means of unfair, unlawful, and/or fraudulent business acts or practices.

425. The plaintiff and class members purchased (or reimbursed their members for their purchases of) eculizumab primarily for personal, family, or household purposes.

426. The plaintiff and class include, and the plaintiff administer benefits for, non-profit health and welfare plans whose core mission includes providing health benefits, including prescription drug benefits, to their members and members' spouses and dependents. In carrying out that core mission, those health and welfare plans purchase or provide reimbursement for eculizumab.

427. The plaintiff and class members who do not profit from purchasing eculizumab or from reimbursing their members for purchases of eculizumab are "consumers" under the consumer protection laws of the jurisdictions below.

428. There was and is a gross disparity between the price that the plaintiff and class members paid for eculizumab and the value they received, given that less expensive biosimilar versions of eculizumab should have been available and would have been but for Alexion's unlawful conduct.

429. As a direct and proximate result of Alexion's unlawful conduct, the plaintiff and class members have been injured and are threatened with continued injury.

430. As a direct and proximate result of Alexion's unfair, unconscionable, deceptive, and fraudulent conduct in violation of the state consumer protection statutes listed below, the plaintiff and class members were denied the opportunity to purchase lower-priced eculizumab biosimilars and paid higher prices for Soliris than they would otherwise have paid.

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

432. Alexion's unlawful conduct substantially affected the trade and commerce of each jurisdiction in which eculizumab was sold.

433. Alexion's unfair and deceptive acts described above were knowing and willful and constitute violations or flagrant violations of the following unfair trade practices and consumer protection statutes. As a result of Alexion's unfair and deceptive conduct, as described above, the plaintiff and members of the class paid artificially inflated prices in each of the following jurisdictions. [65]

[65] Upon completion of the requisite statutory notices, the plaintiff intends to amend this complaint to add claims under the following state statutes:

a. Ala. Code §§ 8-19-10(e), *et seq.*, with respect to the plaintiff's and class members' purchases in Alabama.

b. Alaska Stat. §§ 45.50.471, *et seq.*, with respect to class members' purchases in Alaska.

c. California Consumer Legal Remedies Act - Cal. Civ. Code §§ 1750, *et seq.*, with respect to the plaintiff's and class members' purchases in California.

d. Ga. Stat. §§ 10-1-390, *et seq.*, with respect to the plaintiff's and class members' purchases in Georgia.

e. Ind. Code Ann. §§ 24-5-0.5-3, *et seq.*, with respect to the plaintiff's and class members' purchases in Indiana.

f. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the plaintiff's and class members' purchases in Maine.

g. Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*, with respect to the plaintiff's and class members' purchases in Massachusetts.

h. Tex. Bus. & Com. Code §§ 17.41, *et seq.*, with respect to the plaintiff's and class members' purchases in Texas.

i. West Va. Code §§ 46A-6-101, *et seq.*, with respect to the plaintiff's and class members' purchases in West Virginia.

j. Wyo. Stat. §§ 40-12-100, *et seq.*, with respect to class members' purchases in Wyoming.

1. Ariz. Rev. Stat. §§ 44-1521, *et seq.* (with respect to the plaintiff's and class members' purchases of eculizumab in Arizona)

434. Section 44-1522 of the Arizona Revised Statutes provides:

> The act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

435. As set forth in detail above, Alexion violated § 44-1522 of the Arizona Revised Statutes by fraudulently obtaining five eculizumab patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

436. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

437. The plaintiff's and class members' injuries are of the type that § 44-1522 of the Arizona Revised Statutes was intended to prevent.

438. The plaintiff is entitled to bring this action for damages pursuant to § 44-1533 of the Arizona Revised Statutes.

439. The plaintiff is entitled to recover actual damages and punitive damages because Alexion's conduct was wanton, was reckless, shows spite or ill will, and demonstrates a reckless indifference to the interests of others.

2. Ark. Code Ann. §§ 4-88-101, *et seq.* (with respect to class members' purchases in Arkansas)

440. Section 4-88-107 of the Arkansas Code provides as follows:

> (a) Deceptive and unconscionable trade practices made unlawful and prohibited by this chapter include, but are not limited to, the following: . . .
>
> (10) Engaging in any . . . unconscionable, false, or deceptive act or practice in business, commerce, or trade; . . .
>
> (b) The deceptive and unconscionable trade practices listed in this section are in addition to and do not limit the types of unfair trade practices actionable at common law or under other statutes of this state.

441. As set forth in detail above, Alexion violated § 4-88-107 of the Arkansas Code by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

442. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

443. The plaintiff's and class members' injuries are of the type that § 4-88-107 of the Arkansas Code was intended to prevent.

444. The plaintiff is entitled to bring this action for damages pursuant to § 4-88-113 of the Arkansas Code.

445. The plaintiff is entitled to recover its actual damages, along with reasonable attorneys' fees, pursuant to § 4-88-113(f) of the Arkansas Code.

3. Colo. Rev. Stat. §§ 6-1-105, *et seq.* (with respect to the plaintiff's and class members' purchases in Colorado)

446. Colorado Revised Stature § 6-1-105 (as amended and effective as of August 7, 2024) provides that "a person engages in a deceptive trade practice when, in the course of the person's business, vocation, or occupation, the person… [e]ither knowingly or recklessly engages in any unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practice…." Colo. Rev. Stat. § 6-1-105(1)(rrr).

447. The Colorado Revised Statute is clear that the "deceptive trade practices listed in this section are in addition to *and do not limit the types of unfair trade practices actionable at common law or under other statutes of this state.*" Colo. Rev. Stat. § 6-1-105(3)(emphasis added).

448. As alleged above in Count Four, Colorado Revised Statute § 6-4-105 provides that it is "illegal for any person to monopolize, attempt to monopolize, or combine or conspire with any other person to monopolize any part of trade or commerce."

449. As set forth in detail above, Alexion violated § 6-1-105 *et seq.* of the Colorado Revised Statute (as well as § 6-4-105) by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

450. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's wrongful conduct.

451. The plaintiff's and class members' injuries are of the type that § 6-1-105 *et seq.* was intended to prevent.

452. The plaintiff is entitled to bring this action for damages pursuant to § 6-1-105 of the Colorado Revised Code.

453. The plaintiff is entitled to recover its actual damages and injunctive relief, along with reasonable attorneys' fees and costs, pursuant to § 6-1-113 of the Colorado Revised Code.

4. D.C. Code §§ 28-3901, *et seq.* (with respect to the plaintiff's and class members' purchases in the District of Columbia)

454. District of Columbia Code § 28-3904 provides that "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice. . . ."

455. District of Columbia Code § 28-4502 provides that every contract or conspiracy "in restraint of trade or commerce all or any part of which is within the District of Columbia is declared to be illegal."

456. District of Columbia Code § 28-4503 provides that it shall be unlawful for any person "to monopolize, attempt to monopolize, or combine or conspire with any other person or persons to monopolize any part of trade or commerce, all or any part of which is within the District of Columbia."

457. As set forth in detail above, Alexion violated §§ 28-3901, *et seq.*, of the District of Columbia Code by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

458. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

459. The plaintiff's and class members' injuries are of the type that §§ 28-3901, *et seq.*, of the District of Columbia Code was intended to prevent.

460. The plaintiff is entitled to bring this action for damages pursuant to § 28-3905 of the District of Columbia Code.

461. The plaintiff is entitled to recover its actual damages, treble damages, and punitive damages, along with reasonable attorneys' fees as expenses, pursuant to § 28-3905(k) of the District of Columbia Code.

5. Fla. Stat. §§ 501.201, *et seq.* (with respect to the plaintiff's and class members' purchases in Florida)

462. Section 501.204(1) of the Florida Statutes declares unlawful "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce."

463. As set forth in detail above, Alexion violated §§ 501.201, *et seq.*, of the Florida Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

464. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's unlawful conduct.

465. The plaintiff's and class members' injuries are of the type that §§ 501.201, *et seq.*, of the Florida Statutes was intended to prevent.

466. The plaintiff is entitled to bring this action for damages pursuant to § 501.211 of the Florida Statutes.

467. The plaintiff is entitled to recover its actual damages, along with reasonable attorneys' fees and expenses, pursuant to §§ 501.211 & 501.2015 of the Florida Statutes.

6. 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.* (with respect to the plaintiff's and class members' purchases in Illinois)

468. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Illinois Compiled Statutes § 505/2, makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . . in the conduct of any trade or commerce."

469. As set forth in detail above, Alexion violated §§ 505/1, *et seq.*, of the Illinois Compiled Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

470. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

471. The plaintiff's and class members' injuries are of the type that §§ 505/1, *et seq.*, of the Illinois Compiled Statutes was intended to prevent.

472. The plaintiff is entitled to bring this action for damages pursuant to § 505/10a of the Illinois Compiled Statutes.

473. The plaintiff is entitled to recover its actual damages and punitive damages, along with reasonable attorneys' fees and costs, pursuant to §§ 505/10a(a) & 505/10a(c) of the Illinois Compiled Statutes.

7. La. Rev. Stat. Ann. §§ 51:1401, *et seq.* (with respect to the plaintiff's and class members' purchasers in Louisiana)

474. The Louisiana Unfair Trade Practices and Consumer Protection Law, §§ 51:1401 *et seq.*, of the Louisiana Revised Statutes, declares unlawful "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

475. As set forth in detail above, Alexion violated the Louisiana Unfair Trade Practices and Consumer Protection Law by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

476. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

477. The plaintiff's and class members' injuries are of the type that Louisiana Unfair Trade Practices and Consumer Protection Law was intended to prevent.

478. The plaintiff is entitled to bring this action for damages pursuant to § 51:1409 of the Louisiana Revised Statutes.

8. 5 Md. Code, Com. Law §§ 13-301, *et seq.* (with respect to the plaintiff's and class members' purchasers in Maryland)

479. Section 13-303 of the Maryland Code provides that "[a] person may not engage in any unfair, abusive, or deceptive trade practice, as defined in this subtitle or as further defined by the Division, in . . . [t]he sale, lease, rental, loan, or bailment of any consumer goods, consumer realty, or consumer services . . . ."

480. As set forth in detail above, Alexion violated the §§ 13-301, *et seq.*, of the Maryland Code by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

481. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

482. The plaintiff's and class members' injuries are of the type that §§ 13-301, *et seq.*, of the Maryland Code was intended to prevent.

483. The plaintiff is entitled to bring this action for damages pursuant to § 13-408 of the Maryland Code.

9. Mich. Comp. Laws Ann. §§ 445.901, *et seq.* (with respect to the plaintiff's and class members' purchasers in Michigan)

484. Section 445.903 of the Michigan Compiled Laws provides that "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful."

485. As set forth in detail above, Alexion violated §§ 445.901, *et seq.*, of the Michigan Compiled Laws by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair, unconscionable, and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

486. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

487. The plaintiff's and class members' injuries are of the type that §§ 445.901, *et seq.*, of the Michigan Compiled Laws was intended to prevent.

488. The plaintiff is entitled to bring this action for damages pursuant to § 445.911 of the Michigan Compiled Statutes.

489. The plaintiff is entitled to recover its actual damages and punitive damages, along with reasonable attorneys' fees, pursuant to § 445.911 of the Michigan Compiled Statutes.

10. Minn. Stat. §§ 325F.68, *et seq.*, with respect to the plaintiff's and class members' purchases in Minnesota.

490. Section 325D.44 of the Minnesota Statutes provides that "[a] person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person . . . engages in (i) unfair methods of competition, or (ii) unfair or unconscionable acts or practices."

491. Section 325F.69 of the Minnesota Statutes provides:

> The act, use, or employment by any person of any fraud, unfair or unconscionable practice, false pretense, false promise, misrepresentation, misleading statement or deceptive practice,

> with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable . . . .

492. As set forth in detail above, Alexion violated §§ 325D.43, *et seq.*, of the Minnesota Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

493. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

494. The plaintiff's and class members' injuries are of the type that §§ 325D.43, *et seq.*, of the Minnesota Statutes was intended to prevent.

495. The plaintiff is entitled to bring this action for damages pursuant to § 8.31 of the Minnesota Statutes.

496. The plaintiff is entitled to recover its actual damages, along with reasonable attorneys' fees and costs, pursuant to § 8.31 of the Minnesota Statutes.

11. Miss. Code Ann. §§ 75-24-5, *et seq.* (with respect to the plaintiff's and class members' purchases in Mississippi)

497. Section 75-24-5 of the Mississippi Code prohibits "unfair methods of competition affecting commerce and unfair or deceptive trade practices in or affecting commerce."

498. As set forth in detail above, Alexion violated §§ 75-24-5, *et seq.*, of the Mississippi Code by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO

and then using those patents to unlawfully delay and/or block competition—unfair and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

499. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

500. The plaintiff's and class members' injuries are of the type that §§ 75-24-5, *et seq.*, of the Mississippi Code was intended to prevent.

501. The plaintiff is entitled to bring this action for damages pursuant to § 75-24-15 of the Mississippi Code

12. Mo. Rev. Stat. §§ 407.010, *et seq.* (with respect to the plaintiff's and class members' purchases in Missouri)

502. Section 407.020 of the Missouri Statutes provides:

> [T]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose, as defined in section 407.453, in or from the state of Missouri, is declared to be an unlawful practice.

503. As set forth in detail above, Alexion violated §§ 407.010, *et seq.*, of the Missouri Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

504. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

505. The plaintiff's and class members' injuries are of the type that §§ 407.20, *et seq.*, of the Missouri Statutes was intended to prevent.

506. The plaintiff is entitled to bring this action for damages pursuant to § 407.025 of the Missouri Statutes.

13. Neb. Rev. Stat. §§ 59-1601, *et seq.* (with respect to the plaintiff's and class members' purchases in Nebraska)

507. Nebraska's Consumer Protection Act, Nebraska Revised Statutes §§ 59-1602, provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce shall be unlawful."

508. Section 59-1603 of the Nebraska Revised Statutes provides that "any contract, combination, in the form of trust or otherwise, or conspiracy in restraint of trade or commerce shall be unlawful."

509. Section 59-1604 of the Nebraska Revised Statutes provides that "it shall be unlawful for any person to monopolize, or attempt to monopolize or combine or conspire with any other person or persons to monopolize, any part of trade or commerce."

510. As set forth in detail above, Alexion violated §§ 59-1602, 59-1603 & 59-1604 of the Nebraska Revised Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

511. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

512. The plaintiff's and class members' injuries are of the type that §§ 59-1601, *et seq.*, of the Nebraska Revised Statutes was intended to prevent.

513. The plaintiff is entitled to bring this action for damages pursuant to § 59-1609 of the Nebraska Revised Statutes.

14. Nev. Rev. Stat. §§ 598.0903, *et seq.* (with respect to class members' purchases in Nevada)

514. Section 41.600 of the Nevada Revised Statutes provides that "an action may be brought by any person who is a victim of consumer fraud. "Consumer fraud" means "a deceptive trade practice as defined in NRS 598.0915 to 598.0925, inclusive."

515. Section 598.015 of the Nevada Revised Statutes provides:

> A person engages in a "deceptive trade practice" if, in the course of his or her business or occupation, he or she . . . [m]akes false or misleading statements of fact concerning the price of goods or services for sale or lease, or the reasons for, existence of or amounts of price reductions.

516. Section 598.0923 of the Nevada Revised Statutes provides that "[a] person engages in a 'deceptive trade practice' when in the course of his or her business or occupation he or she knowingly . . . uses an unconscionable practice in a transaction."

517. As set forth in detail above, Alexion violated §§ 598.0903, *et seq.*, of the Nevada Revised Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or

blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

518. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

519. The plaintiff's and class members' injuries are of the type that §§ 598.0903, *et seq.*, of the Nevada Revised Statutes was intended to prevent.

520. The plaintiff is entitled to bring this action for damages pursuant to § 41.600 of the Nevada Revised Statutes.

521. The plaintiff is entitled to recover actual damages, along with costs and reasonable attorneys' fees, pursuant to § 41.600 of the Nevada Revised Statutes.

15. N.H. Rev. Stat. §§ 358-A:1, *et seq.* (with respect to the plaintiff's and class members' purchases in New Hampshire)

522. Section 358-A:2 of the New Hampshire Revised Statutes provides:

> It shall be unlawful for any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state. Such unfair method of competition or unfair or deceptive act or practice shall include, but is not limited to, the following:
>
> . . .
>
> XIV. Pricing of goods or services in a manner that tends to create or maintain a monopoly, or otherwise harm competition, including the pricing of generic prescription drugs.

523. As set forth in detail above, Alexion violated §§ 358-A:1, *et seq.*, of the New Hampshire Revised Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying

and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

524. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

525. The plaintiff's and class members' injuries are of the type that §§ 358-A:1, *et seq.*, of the New Hampshire Revised Statutes was intended to prevent.

526. The plaintiff is entitled to bring this action for damages pursuant to § 358-A:10 of the New Hampshire Revised Statutes.

527. Because Alexion's conduct constitutes a willful or knowing violation of § 358-A:2 of the New Hampshire Revised Statutes, the plaintiff is entitled to recover a damages award up to three times the amount of its actual damages, along with the costs of suit and reasonable attorneys' fees, pursuant to § 358-A:10 of the New Hampshire Revised Statutes.

16. N.M. Stat. Ann. §§ 57-12-1, *et seq.* (with respect to the plaintiff's and class members' purchases in New Mexico)

528. Section 57-12-3 of the New Mexico Statutes provides that "[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce are unlawful."

529. As set forth in detail above, Alexion violated §§ 57-12-1, *et seq.*, of the New Mexico Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair, deceptive acts, and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

530. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

531. The plaintiff's and class members' injuries are of the type that §§ 57-12-1, *et seq.*, of the New Mexico Statutes was intended to prevent.

532. The plaintiff is entitled to bring this action for damages pursuant to § 57-12-10 of the New Mexico Statutes.

533. Because Alexion's conduct constitutes a willful violation of § 57-12-10 of the New Mexico Statutes, the plaintiff is entitled to recover a damages award up to three times the amount of its actual damages, along with the costs of suit and reasonable attorneys' fees, pursuant to § 57-12-10 of the New Mexico Statutes.

17. N. Y. Gen. Bus. Law §§ 349, *et seq.* (with respect to the plaintiff's and class members' purchases in New York)

534. Section 349(a) of the New York General Business Law provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful."

535. As set forth in detail above, Alexion violated §§ 349, *et seq.*, of the New York General Business Law by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair, deceptive acts, and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

536. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

537. The plaintiff's and class members' injuries are of the type that §§ 349, *et seq.*, of the New York General Business Law was intended to prevent.

538. The plaintiff is entitled to bring this action for damages pursuant to § 349(h) of the New York General Business Law.

539. Because Alexion's conduct constitutes a willful or knowing violation of § 349(a) of the New York General Business Law, the plaintiff is entitled to recover a damages award up to three times the amount of its actual damages up to one thousand dollars, along reasonable attorneys' fees, pursuant to § 349(h) of the New York General Business Law.

18. N.C. Gen. Stat. §§ 75-1.1, *et seq.* (with respect to the plaintiff's and class members' purchases in North Carolina)

540. Section 75-1.1(a) of the North Carolina General Statutes provides that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful."

541. As set forth in detail above, Alexion violated §§ 75-1.1, *et seq.*, of the North Carolina General Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

542. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Amgen's conduct.

543. The plaintiff's and class members' injuries are of the type that §§ 75-1.1, *et seq.*, of the North Carolina General Statutes was intended to prevent.

544. The plaintiff is entitled to bring this action for damages pursuant to § 75-16 of the North Carolina General Statutes.

545. The plaintiff is entitled to recover a damages award up to three times the amount of its actual damages pursuant to § 75-16.1 of the North Carolina General Statutes. Because Alexion's conduct constitutes a willful violation of § 75-1.1(a) of the North Carolina General Statutes, the plaintiff is also entitled to recover costs of suit and reasonable attorneys' fees.

19. Or. Rev. Stat. §§ 646.605, *et seq.* (with respect to the plaintiff's and class members' purchases in Oregon)

546. Section 646.608 of the Oregon Revised Statutes provides that "[a] person engages in an unlawful practice if in the course of the person's business, vocation or occupation the person . . . [e]ngages in any other unfair or deceptive conduct in trade or commerce."

547. As set forth in detail above, Alexion violated §§ 646.605, *et seq.*, of the Oregon Revised Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

548. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

549. The plaintiff's and class members' injuries are of the type that §§ 646.605, *et seq.*, of the Oregon Revised Statutes was intended to prevent.

550. The plaintiff is entitled to bring this action for damages pursuant to § 646.648 of the Oregon Revised Statutes.

551. The plaintiff is entitled to its actual damages and punitive damages, along with reasonable attorneys' fees and costs, pursuant to § 646.638 of the Oregon Revised Statutes.

20. 73 Pa. Stat. Ann. §§ 201-1, *et seq.* (with respect to the plaintiff's and class members' purchases in Pennsylvania)

552. Section 201-3 of the Pennsylvania Statutes declares unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

553. As set forth in detail above, Alexion violated §§ 201-1, *et seq.*, of the Pennsylvania Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

554. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

555. The plaintiff's and class members' injuries are of the type that §§ 201-1, *et seq.*, of the Pennsylvania Statutes was intended to prevent.

556. The plaintiff is entitled to bring this action for damages pursuant to § 201-9.2 of the Pennsylvania Statutes.

557. The plaintiff is entitled to a damages award of up to three times the amount of its actual damages, along with reasonable attorneys' fees and costs, pursuant to § 201-9.2 of the Pennsylvania Statutes.

21. S.C. Stat. §§ 39-5-10, *et seq.* (with respect to the plaintiff's and class members' purchases in South Carolina)

558. Section 39-50-20 of the Code of Laws of South Carolina provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

559. As set forth in detail above, Alexion violated §§ 39-50-10, *et seq.*, of the Code of Laws of South Carolina by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

560. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

561. The plaintiff's and class members' injuries are of the type that §§ 39-50-10, *et seq.*, of the Code of Laws of South Carolina was intended to prevent.

562. The plaintiff is entitled to bring this action for damages pursuant to § 39-5-140 of the Code of Laws of South Carolina.

563. Because Alexion's conduct constitutes a willful or knowing violation of § 39-5-20, the plaintiff is entitled to a damages award of up to three times the amount of its actual damages, along with reasonable attorneys' fees, pursuant to § 39-5-140 of the Code of Laws of South Carolina.

22. S.D. Codified Laws §§ 37-24-1, *et seq.* (with respect to class members' purchases in South Dakota)

564. Section 37-24-6 of the South Dakota Codified Laws provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." It further provides:

> It is a deceptive act or practice for any person to . . . [k]nowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise or the solicitation of contributions for charitable purposes, regardless of whether any person has in fact been misled, deceived, or damaged thereby . . . .

565. As set forth in detail above, Alexion violated §§ 37-24-1, *et seq.*, of the South Dakota Codified Laws by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

566. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

567. The plaintiff's and class members' injuries are of the type that §§ 37-24-1, *et seq.*, of the South Dakota Codified Laws was intended to prevent.

568. The plaintiff is entitled to bring this action for damages pursuant to § 37-24-31 of the South Dakota Codified Laws.

23. Utah Code Ann. §§ 13-11-1, *et seq.* (with respect to the plaintiff's and class members' purchases in Utah)

569. Section 13-11-5 of the Utah Code provides that "[a]n unconscionable act or practice by a supplier in connection with a consumer transaction violates this act whether it occurs before, during, or after the transaction."

570. As set forth in detail above, Alexion violated §§ 13-11-1, *et seq.*, of the Utah Code by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

571. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

572. The plaintiff's and class members' injuries are of the type that §§ 13-11-1, *et seq.*, of the Utah Code was intended to prevent.

573. The plaintiff is entitled to bring this action for damages pursuant to § 13-1119 of the Utah Code.

574. The plaintiff is entitled to recover its actual damages, along with reasonable attorneys' fees and court costs, pursuant to § 13-11-19 of the Utah Code.

24. Vt. Stat. Ann. tit. 9, §§ 2453, et seq. (with respect to the plaintiff's and class members' purchases in Vermont)

575. Section 2453 of the Vermont Statutes provides that "[a]n unconscionable act or practice by a supplier in connection with a consumer transaction violates this act whether it occurs before, during, or after the transaction."

576. As set forth in detail above, Alexion violated §§ 2453, *et seq.*, of the Vermont Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

577. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

578. The plaintiff's and class members' injuries are of the type that §§ 2453, *et seq.*, of the Vermont Statutes was intended to prevent.

579. The plaintiff is entitled to bring this action for damages pursuant to § 2453 of the Vermont Statutes.

25. Va. Code Ann. §§ 59.1-196, *et seq.* (with respect to the plaintiff's and class members' purchases in Virginia)

580. Section 59-1-200 of the Virginia Code provides:

> A. The following fraudulent acts or practices committed by a supplier in connection with a consumer transaction are hereby declared unlawful:
>
> . . .

> 14. Using any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

581. As set forth in detail above, Alexion violated §§ 59-1-196, *et seq.*, of the Virginia Code by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

582. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

583. The plaintiff's and class members' injuries are of the type that §§ 59-1-196, *et seq.*, of the Virginia Code was intended to prevent.

584. The plaintiff is entitled to bring this action for damages pursuant to § 59-1.204 of the Virginia Code.

585. Because Alexion's conduct was willful, the plaintiff is entitled to a damages award of up to three times the amount of its actual damages, along with reasonable attorneys' fees and court costs, pursuant to § 59.1-204 of the Virginia Code.

26. W. Va. Code §§ 46A-6-101, *et seq.* (with respect to the plaintiff's and class members' purchases in West Virginia)

586. Section 46A-6-104 of the West Virginia Code declares unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

587. As set forth in detail above, Alexion violated §§ 46A-6-101, *et seq.*, of the West Virginia Code by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

588. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

589. The plaintiff's and class members' injuries are of the type that §§ 46A-6-101, *et seq.*, of the West Virginia Code was intended to prevent.

590. The plaintiff is entitled to bring this action for damages pursuant to § 46A-6-104 of the West Virginia Code.

27. Wis. Stat. §§ 100.20, *et seq.* (with respect to the plaintiff's and class members' purchases in Wisconsin)

591. Section 100-20 of the Wisconsin Statutes prohibits "[u]nfair methods of competition in business and unfair trade practices in business."

592. As set forth in detail above, Alexion violated §§ 100.20, *et seq.*, of the Wisconsin Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

593. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

594. The plaintiff's and class members' injuries are of the type that §§ 100.20, *et seq.*, of the Wisconsin Statutes was intended to prevent.

595. The plaintiff is entitled to bring this action for damages pursuant to § 100.20 of the Wisconsin Statutes.

596. The plaintiff is entitled to a damages award of twice the amount of its actual pecuniary loss, along with reasonable attorneys' fees and court costs, pursuant to § 100.20(5) of the Wisconsin Statutes.

28. Wyo. Stat. Ann. §§ 40-12-101, *et seq.* (with respect to the plaintiff's and class members' purchases in Wyoming)

597. Section 40-12-105 of the Wyoming Statutes provides:

> A person engages in a deceptive trade practice unlawful under this act when, in the course of his business and in connection with a consumer transaction, he knowingly . . . [e]ngages in unfair or deceptive acts or practices[.]

598. As set forth in detail above, Alexion violated §§ 40-12-101, *et seq.*, of the Wyoming Statutes by deceptively, and wrongfully, obtaining the eculizumab patents by withholding material information from, and deliberating misrepresenting material information provided to, the PTO and then using those patents to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of eculizumab biosimilars, extending Alexion's monopoly in the eculizumab market, and maintaining supracompetitive prices for Soliris.

599. As a direct and proximate result of Alexion's conduct, the plaintiff and class members suffered injury and actual damages in the form of paying higher prices for eculizumab than they would have paid but for Alexion's conduct.

600. The plaintiff's and class members' injuries are of the type that §§ 40-12-101, *et seq*., of the Wyoming Statutes was intended to prevent.

601. The plaintiff is entitled to bring this action for damages pursuant to § 40-12-108 of the Wyoming Statutes.

COUNT SIX

UNJUST ENRICHMENT UNDER STATE LAW

602. The plaintiff repeats and incorporates the above paragraphs as though fully set forth herein.

603. To the extent required, this claim is pled in the alternative to the other claims in this complaint.

604. As a result of its unlawful conduct described above, Alexion has and will continue to be unjustly enriched by the receipt of unlawfully inflated prices and unlawful profits from sales of eculizumab. Alexion's financial benefits are traceable to the plaintiff's and class members' overpayments for eculizumab. Alexion has received a benefit from the class in the form of revenue resulting from unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class. Alexion has benefited from its unlawful acts, and it would be inequitable for Alexion to retain any of the ill-gotten gains resulting from the plaintiff's and class members' overpayments for eculizumab during the class period.

605. It would be futile for the plaintiff and class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they

indirectly purchased Soliris, as those intermediaries are not liable for, and would not compensate the plaintiff and class members for, Alexion's unlawful conduct.

606. The economic benefit Alexion derived from the plaintiff's and class members' purchases of eculizumab is a direct and proximate result of Alexion's unlawful and anticompetitive practices.

607. The financial benefits Alexion derived are ill-gotten gains that rightfully belong to the plaintiff and class members who paid and continue to pay artificially inflated prices that inured to Alexion's benefit.

608. It would be inequitable under unjust enrichment principles under the laws of the jurisdictions identified below for Alexion to retain any of the benefits Alexion derived from its unfair, anticompetitive, and unlawful methods, acts, and trade practices.

609. Alexion is aware of and appreciates the benefits that the plaintiff and class members have bestowed upon it.

610. Alexion should be ordered to disgorge all unlawful or inequitable proceeds it received to a common fund for the benefit of the plaintiff and class members who collectively have no adequate remedy at law.

611. A constructive trust should be imposed upon all unlawful or inequitable sums Alexion received that are traceable to the plaintiff and class members.

612. By engaging in the unlawful or inequitable conduct described above, which deprived the plaintiff and class members of the opportunity to purchase lower-priced biosimilar versions of eculizumab and forced them to pay higher prices for Soliris, Alexion has been unjustly enriched in violation of the common law of the following jurisdictions:

1. Alabama

613. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Alabama. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

614. Alexion received money from the plaintiff and class members as a direct result of the unlawful overcharges and has retained this money.

615. Alexion has benefitted at the expense of the plaintiff and class members from revenue resulting from unlawful overcharges for eculizumab.

616. It is inequitable for Alexion to accept and retain the benefits received without compensating the plaintiff and class members.

2. Alaska

617. Alexion unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for eculizumab in Alaska. Class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

618. Alexion has received a benefit from class members in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion, to the economic detriment of class members.

619. Alexion appreciated the benefits bestowed upon it by class members.

620. Alexion accepted and retained the benefits bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to class members.

621. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating class members.

3. Arizona

622. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Arizona. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

623. Alexion has been enriched by revenue resulting from unlawful overcharges for eculizumab.

624. The plaintiff and class members have been impoverished by the overcharges for eculizumab resulting from Alexion's unlawful conduct.

625. Alexion's enrichment and the impoverishment of the plaintiff and class members are connected. Alexion has paid no consideration to any other person for any benefits it received from the plaintiff and class members.

626. There is no justification for Alexion's receipt of the benefits causing its enrichment and the impoverishment of the plaintiff and class members because the plaintiff and class members paid supracompetitive prices that inured to Alexion's benefit, and it would be inequitable for Alexion to retain any revenue gained from its unlawful overcharges.

627. The plaintiff and class members have no adequate remedy at law.

4. Arkansas

628. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Arkansas. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

629. Alexion received money from the plaintiff and class members as a direct result of the unlawful overcharges and have retained this money.

630. Alexion has paid no consideration to any other person in exchange for this money.

631. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the plaintiff and the class.

5. California

632. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in California.[66] The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

633. Alexion has received a benefit from the plaintiff and the class as a direct result of Alexion's fraudulent and misleading conduct and the resulting unlawful overcharges to the class.

634. Alexion retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the plaintiff and the class.

635. Plaintiff and members of the class are entitled to restitution from Alexion.

6. Colorado

636. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Colorado. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

637. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

[66] Affidavit pursuant to CAL. CIV. CODE § 1780(d) attached hereto.

638. Alexion retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the plaintiff and the class.

639. Under the circumstances, it would be inequitable and unjust for Alexion to retain such benefits without compensating the plaintiff and class members.

7. Connecticut

640. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Connecticut. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

641. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

642. Alexion has paid no consideration to any other person in exchange for this benefit.

643. Alexion retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the plaintiff and class members.

644. Under the circumstances, it would be inequitable and unjust for Alexion to retain such benefits.

8. Delaware

645. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Delaware. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

646. Alexion has been enriched by revenue resulting from unlawful overcharges for eculizumab.

647. The plaintiff and the class have been impoverished by the overcharges for eculizumab resulting from Alexion's unlawful conduct.

648. Alexion's enrichment and the impoverishment of the plaintiff and the class are connected. Alexion has paid no consideration to any other person for any benefits they received from the plaintiff and class members.

649. There is no justification for Alexion's receipt of the benefits causing its enrichment and the impoverishment of the plaintiff and the class because the plaintiff and the class paid supracompetitive prices that inured to Alexion's benefit, and it would be inequitable for Alexion to retain any revenue gained from its unlawful overcharges.

650. The plaintiff and the class have no remedy at law.

9. District of Columbia

651. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in the District of Columba. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

652. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion, to the economic detriment of the plaintiff and the class.

653. Alexion accepted and retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the class.

654. Under the circumstances, it would be inequitable and unjust for Alexion to retain such benefits.

10. Florida

655. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Florida. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

656. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

657. Alexion appreciated and retained the benefit bestowed upon it by the plaintiff and class members.

658. It is inequitable and unjust for Alexion to accept and retain such benefits without compensating the plaintiff and class members.

11. Georgia

659. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Georgia. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

660. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

661. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the plaintiff and the class.

12. Hawaii

662. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Hawaii. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

663. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

664. It is unjust for Alexion to retain such benefits without compensating the plaintiff and the class.

13. Idaho

665. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Idaho. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

666. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

667. Alexion appreciated the benefit conferred upon it by the class.

668. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

14. Illinois

669. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Illinois. The plaintiff

and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

670. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

671. Alexion retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

672. It is against equity, justice, and good conscience for Alexion to be permitted to retain the revenue resulting from its unlawful overcharges without compensating the plaintiff and class members.

15. Iowa

673. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Iowa. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

674. Alexion has been enriched by revenue resulting from unlawful overcharges for eculizumab, which revenue resulted from anticompetitive prices paid by the class, which inured to Alexion's benefit.

675. Alexion's enrichment has occurred at the expense of the class.

676. It is against equity and good conscience for Alexion to retain such benefits without compensating the class.

16. Kansas

677. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Kansas. The plaintiff

and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

678. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

679. Alexion retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

680. Alexion was unjustly enriched at the expense of the plaintiff and the class members.

17. Kentucky

681. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Kentucky. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

682. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

683. Alexion appreciated the benefit bestowed upon it by the class.

684. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

18. Louisiana

685. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Louisiana. The plaintiff

and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

686. Alexion has been enriched by revenue resulting from unlawful overcharges for brand and eculizumab.

687. The plaintiff and class members have been impoverished by the overcharges for eculizumab resulting from Alexion's unlawful conduct.

688. Alexion's enrichment and the impoverishment of the plaintiff and the class are connected.

689. There is no justification for Alexion's receipt of the benefits causing its enrichment and the class's impoverishment because the plaintiff and the class paid supracompetitive prices that inured to Alexion's benefit, and it would be inequitable for Alexion to retain any revenue gained from its unlawful overcharges.

690. The plaintiff and the class have no other remedy at law.

19. Maine

691. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Maine. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

692. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

693. Alexion was aware of or appreciated the benefit bestowed upon it by the plaintiff and the class.

694. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

20. Maryland

695. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Maryland. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

696. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion, to the economic detriment of the plaintiff and the class.

697. Alexion was aware of or appreciated the benefit bestowed upon it by the class.

698. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

21. Massachusetts

699. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Massachusetts. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

700. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

701. Alexion was aware of and/or appreciated the benefit conferred upon it by the class.

702. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class. Fairness and good conscience require Alexion not be permitted to retain the revenue resulting from its unlawful overcharges at the expense of the plaintiff and class members.

22. Michigan

703. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Michigan. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

704. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion.

705. Alexion retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

706. Alexion was unjustly enriched at the expense of the plaintiff and the class members.

23. Minnesota

707. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Minnesota. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

708. Alexion appreciated and knowingly accepted the benefits bestowed upon it by the plaintiff and class members. Alexion has paid no consideration to any other person for any of the benefits they have received from the plaintiff and class members.

709. It would be inequitable for Alexion to accept and retain such benefits without compensating the class.

24. Mississippi

710. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Mississippi. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

711. Alexion received money from the class as a direct result of the unlawful overcharges. Alexion retains the benefit of overcharges received on the sales of brand eculizumab, which in equity and good conscience belong to the class on account of Alexion's anticompetitive conduct.

712. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

25. Missouri

713. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Missouri. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

714. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

715. Alexion appreciated the benefit bestowed upon it by the class.

716. Alexion accepted and retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the class.

26. Montana

717. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Montana. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

718. The plaintiff and the class have conferred an economic benefit upon Alexion in the form of revenue resulting from unlawful overcharges to the economic detriment of the plaintiff and the class.

719. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

27. Nebraska

720. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Nebraska. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

721. Alexion received money from the class as a direct result of the unlawful overcharges and have retained this money. Alexion has paid no consideration to any other person in exchange for this money.

722. In justice and fairness, Alexion should disgorge such money and remit the overcharged payments back to the class.

28. Nevada

723. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Nevada. The plaintiff

and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

724. The plaintiff and the class have conferred an economic benefit upon Alexion in the form of revenue resulting from unlawful overcharges.

725. Alexion appreciated the benefits bestowed upon it by the class, for which it has paid no consideration to any other person.

726. Alexion has knowingly accepted and retained the benefits bestowed upon it by the plaintiff and class members.

727. The circumstance under which Alexion has accepted and retained the benefits bestowed on it by the plaintiff and the class are inequitable in that they result from Alexion's unlawful overcharges.

29. New Hampshire

728. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in New Hampshire. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

729. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

730. Under the circumstances, it would be unconscionable for Alexion to retain such benefits.

30. New Jersey

731. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in New Jersey. The

plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

732. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

733. The benefits conferred upon defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the plaintiff and class members.

734. Alexion has paid no consideration to any other person for any of the unlawful benefits they received from the plaintiff and class members with respect to Alexion's sales of brand eculizumab.

735. Under the circumstances, it would be unjust for defendants to retain such benefits without compensating the plaintiff and class members.

31. New Mexico

736. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in New Mexico. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

737. Alexion has knowingly benefitted at the expense of the class from revenue resulting from unlawful overcharges for eculizumab.

738. To allow Alexion to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Alexion's benefit and because Alexion has paid no consideration to any other person for any of the benefits it received.

32. New York

739. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in New York. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

740. Alexion has been enriched by revenue resulting from unlawful overcharges for brand eculizumab, which revenue resulted from anticompetitive prices paid by the class, which inured to Alexion's benefit.

741. Alexion's enrichment has occurred at the expense of the class.

742. It is against equity and good conscience for Alexion to be permitted to retain the revenue resulting from its unlawful overcharges.

33. North Carolina

743. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in North Carolina. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

744. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

745. The class did not interfere with Alexion's affairs in any manner that conferred these benefits upon Alexion.

746. The benefits conferred upon Alexion were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Alexion's actions in delaying entry of

generic versions of eculizumab to the market and preventing fulsome generic competition in the market for eculizumab.

747. The benefits conferred on Alexion are measurable, in that the revenue Alexion has earned due to unlawful overcharges are ascertainable by review of sales records.

748. Alexion consciously accepted the benefits conferred upon it and continues to do so as of the date of this filing.

34. North Dakota

749. Alexion unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for eculizumab in North Dakota. Class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

750. Alexion has been enriched by revenue resulting from unlawful overcharges paid by plaintiff and members of the class.

751. The class has been impoverished by the overcharges for eculizumab resulting from Alexion's unlawful conduct.

752. Alexion's enrichment and the class's impoverishment are connected. Alexion has paid no consideration to any other person for any benefits it received directly or indirectly from class members.

753. There is no justification for Alexion's receipt of the benefits causing its enrichment because the class paid supracompetitive prices that inured to Alexion's benefit, and it would be inequitable for Alexion to retain any revenue gained from its unlawful overcharges.

754. The class has no remedy at law.

35. Oklahoma

755. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Oklahoma. The plaintiff

and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

756. Alexion received money from the plaintiff and class members as a direct result of the unlawful overcharges and have retained this money.

757. Alexion has paid no consideration to any other person in exchange for this money.

758. The plaintiff and class members have no remedy at law.

759. It is against equity and good conscience for Alexion to be permitted to retain the revenue resulting from its unlawful overcharges.

36. Oregon

760. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Oregon. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

761. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

762. Alexion was aware of the benefit bestowed upon it by the class.

763. Under the circumstances, it would be unjust for Alexion to retain any of the overcharges derived from its unfair conduct without compensating the plaintiff and the class.

37. Pennsylvania

764. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Pennsylvania. The

plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

765. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

766. Alexion was aware of and/or appreciated the benefit bestowed upon it by the class.

767. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

38. Puerto Rico

768. Alexion unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for eculizumab in Puerto Rico. Class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

769. Alexion has been enriched by revenue resulting from unlawful overcharges.

770. The class has been impoverished by the overcharges for eculizumab resulting from Alexion's unlawful conduct.

771. Alexion's enrichment and the class's impoverishment are connected.

772. There is no justification for Alexion's receipt of the benefits causing its enrichment and the class's impoverishment because the class paid supracompetitive prices that inured to Alexion's benefit, and it would be inequitable for Alexion to retain any revenue gained from its unlawful overcharges.

773. The class has no remedy at law.

39. Rhode Island

774. Alexion unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for eculizumab in Rhode Island. Class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

775. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the class.

776. Alexion was aware of and/or recognized the benefit bestowed upon it by the class.

777. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

40. South Carolina

778. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in South Carolina. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

779. The benefits conferred upon Alexion were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the class.

780. Alexion realized value from the benefit bestowed upon it by the class.

781. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

41. South Dakota

782. Alexion unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for eculizumab in South Dakota. Class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

783. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the class.

784. Alexion was aware of the benefit bestowed upon it by the class.

785. Under the circumstances, it would be inequitable and unjust for Alexion to retain such benefits without reimbursing the class.

42. Tennessee

786. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Tennessee. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

787. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

788. Alexion was aware of or appreciated the benefit bestowed upon it by the class.

789. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

790. It would be futile for the class to seek a remedy from any party with whom they have privity of contract. Alexion has paid no consideration to any other person for any of the unlawful benefits they received indirectly from the class with respect to Alexion's sale of

eculizumab. It would be futile for the class to exhaust all remedies against the entities with which the class has privity of contract because the class did not purchase eculizumab directly from any defendant.

43. Texas

791. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Texas. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

792. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion, to the economic detriment of the plaintiff and class members.

793. Alexion was aware of and/or appreciated the benefit bestowed upon it by the plaintiff and class members.

794. The circumstances under which Alexion has retained the benefits bestowed upon it by the plaintiff and class members are inequitable in that they result from Alexion's unlawful conduct.

795. The plaintiff and class members have no remedy at law.

44. Utah

796. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Utah. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

797. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

798. Alexion was aware of and/or appreciated the benefit bestowed upon it by the class.

799. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

45. Vermont

800. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Vermont. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

801. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

802. Alexion accepted the benefit bestowed upon it by the class.

803. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

46. Virginia

804. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Virginia. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

805. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

806. Alexion was aware of the benefit bestowed upon it.

807. Alexion should reasonably have expected to repay the class.

808. The benefits conferred upon Alexion were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from the Alexion's illegal and unfair actions to inflate the prices of eculizumab.

809. Alexion has paid no consideration to any other person for any of the benefits it has received from the class.

47. Washington

810. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Washington. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

811. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

812. Alexion was aware of and/or appreciated the benefit bestowed upon it by the class.

813. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

48. West Virginia

814. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in West Virginia. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

815. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

816. Alexion was aware of and/or appreciated the benefit bestowed upon it by the class.

817. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

49. Wisconsin

818. Alexion unlawfully profited from overcharges paid by the plaintiff and class members who made purchases of or reimbursements for eculizumab in Wisconsin. The plaintiff and class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

819. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the plaintiff and the class.

820. Alexion was aware of and/or appreciated the benefit bestowed upon it by the class.

821. Under the circumstances, it would be inequitable for Alexion to retain such benefits without compensating the class.

50. Wyoming

822. Alexion unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for eculizumab in Wyoming. Class members paid higher prices for eculizumab than they would have paid but for Alexion's actions.

823. Alexion has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Alexion and to the economic detriment of the class.

824. Alexion accepted, used, and enjoyed the benefits bestowed upon it by the class under inequitable and unjust circumstances arising from unlawful overcharges to class members.

825. Under the circumstances, it would be inequitable for Alexion to retain such benefits.

DEMAND FOR RELIEF

WHEREFORE, the plaintiff, on behalf of itself and the class members, respectfully demands that this Court:

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

B. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy the ongoing anticompetitive effects of Alexion's unlawful monopolization in the market for eculizumab in the United States;

C. Grant declaratory judgment pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) that Alexion's conduct in seeking to prevent competition violates Section 2 of the Sherman Act;

D. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy Alexion's attempted monopolization in the market for eculizumab in the United States;

E. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

F. Enter judgment against Alexion and in favor of the plaintiff and the class;

G. Award the class damages (including double or treble damages, where appropriate) in an amount to be determined at trial, plus interest in accordance with law;

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

I. Award such further and additional relief as is necessary to correct for the anticompetitive market effects Alexion's unlawful conduct caused and as the Court may deem just and proper under the circumstances.

JURY DEMAND

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

Dated: April 16, 2025

Respectfully submitted,

/s/ DRAFT
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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: April 16, 2025

/s/ Thomas M. Sobol
Thomas M. Sobol