COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP
PETER S. PEARLMAN
psp@njlawfirm.com
Park 80 West-Plaza One
250 Pehle Avenue | Suite 401
Saddle Brook, NJ 07663
Telephone: 201/845-9600
201/845-9423 (fax)

*Attorneys for Plaintiffs*

[Additional counsel appear on signature page.]

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| SELF-INSURED SCHOOLS OF CALIFORNIA, on behalf of itself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED,<br><br>Defendants. | Civil Action No.<br><br>**CLASS ACTION COMPLAINT**<br><br>**JURY TRIAL DEMANDED** |

## CLASS ACTION COMPLAINT

Plaintiff Self Insured Schools of California ("SISC"), maintaining its principal place of business at 2000 K Street Bakersfield, CA 93301, on behalf of itself and all others similarly situated, files this Class Action Complaint ("Complaint") against Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, Johnson & Johnson, and BTG International Limited (collectively, "Defendants"), based upon personal knowledge and upon information and belief, and alleges as follows:

## I. INTRODUCTION

1. This civil antitrust action is an action to recover damages arising from Defendants' unlawful scheme to prolong their monopoly in the market for abiraterone acetate, which is used to treat patients with prostate cancer. Plaintiff seeks an award of damages for itself and for the proposed class of end-payors that purchased Zytiga (Defendants' branded abiraterone acetate) indirectly from Defendants at supracompetitive prices.

2. Federal law rewards inventors with a fixed period of patent protection for their novel and non-obvious inventions. But once their legally sanctioned monopoly ends, the law prohibits patent holders from unlawfully prolonging their monopoly through fraudulent patents, sham proceedings, and collusion. A patent holder may not extend its monopoly by misrepresenting facts to the Patent and Trademark Office ("PTO") to obtain additional blocking patents.

3. The patent covering the chemical compound in Zytiga—U.S. Patent No. 5,604,213 (the '213 Patent)—expired on December 13, 2016.

4. Prior to the expiration of the '213 Patent, Defendants knew that roughly a dozen generic manufacturers were ready, willing, and able to introduce generic versions of Zytiga as soon as Defendants' patent on the chemical compound expired. Such generic competition would have reduced the price of abiraterone acetate by at least 80%, and Defendants would have reasonably expected to lose 90% or more of Zytiga's market share.

5. To extend their supracompetitive profits for abiraterone acetate beyond the legitimate exclusivity period secured by the '213 Patent, Defendants fraudulently obtained and asserted a second patent to block generic entry after the expiration of the '213 Patent. The fraudulently obtained patent, U.S. Patent 8,822,438 (the '438 Patent), covers the use of

abiraterone acetate in combination with prednisone to treat prostate cancer. Prednisone is one of the most commonly prescribed corticosteroids, which are man-made drugs that closely resemble cortisol.

6. Defendants had previously tried to patent this method in an earlier application to the United States Patent and Trademark Office ("Patent Office"). But, as the Patent Office stated in five separate rejections of Defendants' submissions, the method of using abiraterone acetate in combination with prednisone to treat prostate cancer was obvious and thus not patentable.

7. More specifically, before Defendants submitted their patent applications on the method of combining abiraterone acetate with prednisone, it was already well known that:

a. both drugs could be used to treat prostate cancer;

b. abiraterone has a side effect of reducing patients' cortisol levels, which is associated with certain adverse health risks;

c. prednisone is a corticosteroid—a man-made drug that closely resembles cortisol—and is one of the most widely prescribed drugs in this class; and

d. combining abiraterone acetate with a corticosteroid such as prednisone therefore reduces the risk or severity of certain adverse side effects associated with treating prostate cancer with abiraterone acetate alone.

Thus, the method of using abiraterone acetate in conjunction with prednisone was obvious.

8. But even if a use appears obvious, a patent applicant may still obtain a patent if the applicant essentially rebuts the Patent Office's obviousness finding by demonstrating "commercial success" of the use.

9. After five failed attempts to prove that the combination of the two drugs was not obvious, Defendants took the "commercial success" approach in their sixth submission to the Patent Office. Defendants argued that the combination of Zytiga and prednisone had been a commercial success, and that Zytiga would not have had that success in the market had the combination of abiraterone acetate and prednisone been obvious. Had the latter been true, Defendants argued, practitioners would have already been prescribing prednisone alongside abiraterone acetate, and Zytiga would not have enjoyed such commercial success.

10. But Defendants omitted a central fact that would have explained the commercial success of Zytiga: The '213 Patent was a "blocking patent" that prevented any other manufacturer from making any drug product containing abiraterone acetate. During the term of that patent, no other manufacturer could make or sell an abiraterone acetate product, whether in conjunction with prednisone or not. Thus, the '213 Patent was the central explanatory factor underlying Zytiga's commercial success—not the use of Zytiga in combination with prednisone. In other words, the commercial success argument that Defendants presented to the Patent Office was patently false.

11. Defendants' material omission of the '213 Patent in its application to the Patent Office, however, was successful, and the Patent Office examiner, left unaware of the '213 Patent, issued the '438 Patent based on Defendants' commercial success argument.

12. After its issuance, Defendants initiated patent infringement litigation based on the '438 Patent even though they knew the '438 Patent would be invalidated as soon as anyone raised the '213 Patent in litigation. Though they knew they would eventually lose the meritless lawsuits, Defendants pursued the litigation because they also understood that the lawsuits would serve to delay the entry of generic alternatives to Zytiga.

13. Defendants' '438 Patent litigation was successful in the sense that the lawsuits did in fact delay all generic entry by nearly two years—from the expiration of the '213 Patent until November 2018. During that period, Defendants were able to charge artificially inflated prices for Zytiga and to continue selling units of Zytiga that would otherwise have been filled with a generic alternative. Defendants' revenue from United States sales of Zytiga grew from $1.1 billion in 2016 to $1.2 billion in 2017 and to over $1.7 billion in 2018.

14. In the absence of Defendants' anticompetitive scheme to extend their monopoly on abiraterone acetate beyond the term of the '213 Patent, generic abiraterone acetate would have been available by December 2016, and Plaintiff and the proposed class would have paid less for abiraterone acetate products. Instead, Plaintiff and the proposed class have paid hundreds of millions of dollars in overcharges as a result of Defendants' anticompetitive scheme.

## II. PARTIES

15. Plaintiff Self-Insured Schools of California ("SISC"), is a Joint Powers Authority under California law that serves the interests of California public school district members. It is headquartered in Bakersfield, California. SISC provides health benefit plans to approximately 300,000 members who reside in numerous locations in the United States. During the Class Period, SISC indirectly purchased and paid for some or all of the purchase price for Zytiga, other than for resale, manufactured by the Defendants. During the Class Period, SISC paid and reimbursed more for Zytiga than it would have absent Defendants' anticompetitive conduct. As a result of the wrongful conduct alleged herein, SISC has been injured in its business or property by reason of the violations of law alleged herein.

16. Defendant Janssen Biotech, Inc., is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044. Janssen Biotech is a wholly owned subsidiary of Johnson & Johnson ("J&J").

17. Defendant Janssen Oncology, Inc., is a corporation organized and existing under the laws of Delaware, with its principal place of business at 10990 Wilshire Boulevard, Los Angeles, CA 90024. Janssen Oncology is a wholly owned subsidiary of J&J.

18. Defendant Janssen Research & Development, LLC ("Janssen R&D") is a limited liability company organized and existing under the laws of the State of New Jersey, with its principal place of business at 920 Route 202 South, Raritan, New Jersey 08869. Janssen R&D is a wholly owned subsidiary of J&J.

19. Defendant Johnson & Johnson ("J&J") is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business of One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J is the parent corporation of the Janssen entities and filed false, misleading, and fraudulent documents with the USPTO in connection with the '438 Patent in concert with the other Defendants and in furtherance of Defendants' collective efforts improperly to exclude generic competitors through the scheme alleged herein. Through its wholly owned subsidiary Cougar Biotechnology, J&J also holds the rights to the '213 Patent, which originally protected Zytiga's chemical compound and expired in December 2016.

20. Defendant BTG International Ltd. ("BTG") is a company organized and existing under the laws of the United Kingdom, with its principal place of business at 5 Fleet Place,

London, EC4M 7RD United Kingdom. BTG was formerly known as British Technology Group Limited.

21. The ’213 Patent was assigned to BTG. BTG exclusively licensed the worldwide rights to abiraterone acetate to Cougar Biotechnology (now J&J). Under the license agreement, BTG receives milestone payments and royalties.

22. Defendants sell Zytiga in the United States pursuant to New Drug Application (“NDA”) No. 202379, which was approved by the United States Food and Drug Administration (“FDA”). Janssen Biotech is the holder of NDA No. 202379. Janssen R&D works in collaboration with Janssen Biotech with respect to NDA No. 202379.

23. Janssen Oncology owns all rights, title, and interest in the ’438 Patent, entitled “Methods and Composition for Treatment of Cancer,” as issued by the United States Patent and Trademark Office on September 2, 2014.

## III. JURISDICTION AND VENUE

24. This court has jurisdiction over this action pursuant to 28 U.S.C. section 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred members of the Class, and at least one member of the proposed Class is a citizen of a state different from that of one of the Defendants. The court has subject matter jurisdiction under 28 U.S.C. section 1332(d).

25. Venue is proper in this District under 28 U.S.C. section 1391 because: Defendants transact business in this District; J&J was incorporated in and Janssen R&D was formed under the laws of the State of New Jersey; both J&J and Janssen R&D maintain their

principal places of business in this District; a substantial portion of the wrongful conduct alleged herein occurred in and was directed from this District; and a substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. The acts complained of have and will continue to have substantial effects in this District.

## IV. THE REGULATORY STRUCTURE THAT DEFENDANTS MANIPULATED TO BLOCK GENERIC COMPETITORS TO ZYTIGA

### A. United States Patent Law

26. United States patents grant the patent owner or assignee the exclusive right to exclude others from practicing the patent product for a fixed period of time from the patent's priority date.

#### 1. Only novel, non-obvious inventions are patentable.

27. The protections afforded by patents must strike a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might spur invention.

28. Accordingly, under applicable patent law, an application for a patent will be rejected by the Patent Office examiner reviewing the application if the claimed invention is not novel because it was already "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." 35 U.S.C. § 102. Even if the invention was not disclosed in detail as set forth in § 102, a claim is unpatentable if the claimed innovation would have been obvious based on the prior art to a person with ordinary skill in the art. 35 U.S.C. § 103.

29. If the patent application reveals prior art that satisfies section 103, it establishes a *prima facie* case of obviousness. To overcome a *prima facie* case of obviousness, the patent

applicant has a number of options, including: (i) narrowing the invention to distinguish over the prior art; (ii) arguing the prior art does not render the claim obvious; or (iii) submitting objective evidence of secondary considerations.

30. Secondary considerations of non-obviousness can come in many different forms. The most common forms are, *inter alia*: (i) the invention has achieved commercial success resulting from the supposedly patentable subject matter; (ii) the invention satisfies a long-felt but unsolved need; or (iii) the invention yields unexpected and surprising results. In each case, the patent applicant argues that even if a *prima facie* case of obviousness exists, the patent nevertheless should be allowed based on a secondary consideration of non-obviousness.

31. The commercial success argument is relatively straightforward: If an idea were obvious, normal market forces would already have caused a product or use embodying the idea to be available in the market.

32. But evidence of commercial success is significant only if there is a causal relationship, or "nexus," between the claimed invention and the commercial success. If the feature creating the commercial success is not due to the claimed invention, then the success is not pertinent to the application. This is well-known by practitioners in the field, particularly Defendants, who have large and well-funded internal legal departments with access to significant and highly qualified outside patent counsel.

33. For example, existing patents can serve to legally bar other manufacturers from commercially testing the idea or invention at issue in a new patent application. This is commonly the case in the pharmaceutical industry, where the initial patents on the active ingredient or compound in a drug frequently block other innovators from creating or even testing any products that incorporate the patented compound for the term of the initial patent. These initial patents are

commonly known as "blocking patents" because they have the effect of blocking others from utilizing the active ingredient in *any* form. Thus, other innovators have very little incentive to come up with new formulations or methods of use of the active ingredient, as they will not be able to market any innovations that incorporate the patented ingredient during the term of the blocking patent. While others are deterred from innovating, the blocking patent does not hinder the patent holder from developing and seeking patents on new formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings.

34. The existence of a blocking patent is therefore highly relevant to the evaluation of a commercial success argument related to the patent holder's application for a new, narrower patent relating to the same drug. When there is a blocking patent, commercial success is of "minimal probative value" and does not, by itself, justify a finding of non-obviousness.

**2. Because patent prosecutions are non-adversarial, patent applicants are subject to special oaths and duties.**

35. Because patents often enable a brand manufacturer to exclude competition and charge supracompetitive prices, it is crucial as a policy matter that any patent underlying a branded drug be valid and lawfully obtained.

36. Patent prosecutions are non-adversarial. The patent applicant submits information to the Patent Office, and an examiner at the Patent Office relies on the materials submitted to determine whether the patent should issue. Only *after* issuance can another person or entity challenge the validity of a patent by filing a lawsuit in district court or a petition for *inter partes* review with the Patent and Trademark Appellate Board ("PTAB"). 35 U.S.C. § 311.

37. Thus, in order to help assure that the public interest is best served through the Patent Office's issuance of patents that are valid and lawfully obtained, patent applicants are

subject to various special oaths and duties. These duties include an affirmative duty of candor and good faith when prosecuting a patent application and an affirmative duty to disclose "all information known . . . to be material to patentability." 37 C.F.R. § 1.56. These duties extend not only to each and every named inventor on the patent application, but also to each and every "attorney or agent who prepares or prosecutes the application" and "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id.* § 1.56(c).

38. No patent may lawfully be granted where fraud on the PTO "was practiced or attempted" or where the duty of disclosure, candor, and good faith "was violated through bad faith or intentional misconduct." *Id.* § 1.56(a). Thus, failure to disclose material facts can render a patent unenforceable. *See e.g.*, *C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d 1340, 1367 (Fed. Cir. 1998) ("Fraud in obtaining a United States patent is a classical ground of invalidity or unenforceability of the patent."). Moreover, concealing a material fact in a matter within the jurisdiction of a federal executive agency is a criminal offense punishable by fine and imprisonment. 18 U.S.C. § 1001.

**B. The Regulatory Structure for Approval of Brand and Generic Drugs**

**1. New drugs must receive FDA approval before they may be marketed.**

39. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer must obtain FDA approval to sell a new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug.

40. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA then publishes a list of those patents in its publicly available publication *Approved Drug Products with Therapeutic*

*Equivalence Evaluations*, commonly known as the "Orange Book." 21 U.S.C. § 355(a), (b). Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. § 355(b)(1), (c)(2).

41. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand name drug.

42. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, because the agency does not have the resources or authority to verify the manufacturer's patents were not procured through fraud. In listing patents in the Orange Book, the FDA merely performs a ministerial act. Therefore, pharmaceutical companies that list patents in the Orange Book that they claim protect a particular drug have a duty to list only those patents they believe in good faith restrict generic entry.

**2. Generic versions of approved brand drugs may submit an abbreviated application and rely on the brand drug's NDA.**

43. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. (1984). A generic manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA.

44. To rely on the brand drug's original NDA, an ANDA applicant must demonstrate that the proposed generic drug is "therapeutically equivalent" to the brand drug. *See generally* 21 U.S.C. § 355(j) *et seq.* To do so, an applicant must show two types of equivalence. First, the ANDA applicant must prove the generic drug and the brand drug are

pharmaceutically equivalent, which requires showing that the drugs have the same active ingredient(s), dosage form, route of administration, and strength. Second, an applicant must prove that the generic and brand drugs are bioequivalent, which requires showing that the generic drug is absorbed at the same rate and to the same extent as the brand drug.

45. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, allowing their substitution for the brand when a patient presents a prescription for the brand product.

46. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors and to thereby reduce healthcare expenses nationwide. As a result, generic drugs became an increasingly large part of prescription drug revenues and a growing threat to brand name drug profits. For example, since 1998, generic versions have been available for nearly all top-selling brand drugs with expired patents. But in 1983, before the Hatch-Waxman Amendments, generic alternatives were available for only 35% of the top-selling drugs with expired patents. Moreover, in 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of total prescriptions. By 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 84% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine and Shifting Costs of Healthcare* 30, 51 (2014). By 2017, prescriptions for generic drugs accounted for about 90% of all prescriptions. *See* https://www.fdanews.com/articles/186526-generics-spending-declined-in-2017-iqvia-reports. For drugs subject to generic competition, a recent report puts the generic share at around 97% in 2017. *See* IVQIA Institute, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018, p. 14.

**3. Generic manufacturers must certify that their drug product will not infringe on any patents.**

47. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications for each Orange Book-listed patent:

a. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

48. Because ANDAs with Paragraph I, II, or III certifications face no potential patent challenge, FDA approval of these ANDAs is relatively quick and expeditious.

49. On the other hand, when a generic manufacturer is forced to file a Paragraph IV certification because the Orange Book lists a drug that has not or will not expire by the time of the planned generic entry, the brand manufacturer is able to trigger extensive regulatory delays that will block FDA approval of generic entry—potentially for many years—simply by instituting a patent infringement action against the ANDA filer.

**4. When an ANDA includes a Paragraph IV certification, brand manufacturers can delay generic entry by instituting infringement litigation.**

50. The filing of an ANDA with a Paragraph IV certification can give rise to a cause of action for patent infringement, even though the generic is not yet on the market. The ANDA filer's stated intent to market its product prior to patent expiry is considered a technical act of constructive infringement. The Federal Rules of Civil Procedure and general principles of standing still apply, however, and the patent holder may bring suit only if it has a legitimate basis to claim infringement.

51. When a generic manufacturer files a Paragraph IV certification, it must promptly notify the brand manufacturer. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA generally will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months from the notification date, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. This period is commonly referred to as the "30-month stay."

52. Until a court issues a decision finding the patent invalid or not infringed or until 30 months has passed, the FDA may grant "tentative approval" to the ANDA filer, recognizing that the ANDA is approvable. Tentative approval means the ANDA would be ready for final approval but for the 30-month stay.

53. As a practical matter, the initiation of a patent infringement action provides the brand manufacturer with the equivalent of an automatic injunction that prevents the generic manufacturer from releasing a competing generic product, regardless of the merits of the infringement action, for up to two and a half years.

54. Once a district court rules that a generic drug does not infringe on the brand drug patent or that the brand drug patent is invalid or unenforceable, the manufacturer of that

generic drug may rely on its tentative approval from the FDA and begin marketing the generic product. Such a launch is considered "at risk" because the generic manufacturer may be subject to damages if the district court's ruling is later reversed.

**C. The Economic Benefits of Blocking Generic Entry, Even When Frivolous**

55. Therapeutically equivalent (or AB-rated) generic drugs contain the same active ingredient—and are determined by the FDA to be just as safe and effective—as their branded counterparts. The only material difference between generic drugs and branded drugs is their price.

56. When multiple generic drug manufacturer competitors enter the market for a given branded drug, competition among the generic drug manufacturers drives drug prices down toward marginal manufacturing costs. As a result, the price of generic drugs is, on average, 80%-85% less than the price of the branded drug prior to generic entry.

57. In addition to driving down prices, generics in the market displace a large portion of brand sales. In the majority of states, pharmacists are either required or allowed by statute or regulation to substitute a therapeutically equivalent generic drug for a brand-name drug—even when a prescription lists a brand-name drug—unless the prescription specifically prohibits such substitution. As a result, the Federal Trade Commission (FTC) estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales. The Office of Inspector General of the Department of Health and Human Services has similarly determined that generic drugs are dispensed 89% of the time when generic substitutes are available. The degree to which generic drugs take market share away from brand drugs increases for drugs with high annual sales. One study found that brand drugs with annual sales

of over $250 million that experienced generic entry in 2013-2014 retained a share of just 7% after one year.

58. Defendants prevented these shifts in the market from happening with Zytiga by fraudulently obtaining and litigating the ’438 Patent.

## V. DEFENDANTS’ SCHEME TO UNLAWFULLY MAINTAIN ITS MONOPOLY ON ABIRATERONE ACETATE

### A. Defendants’ Patent Exclusivity for Zytiga Should Have Ended in December 2016

59. Zytiga (abiraterone acetate) is indicated in combination with prednisone for the treatment of patients with prostate cancer. Abiraterone acetate works by suppressing the synthesis of testosterone and thereby slowing the growth of malignant tumors. Co-administration with prednisone counters abiraterone acetate’s side-effects, such as increased risk of hypertension.

60. Defendants have jointly collaborated in the development, manufacture, sale and distribution of Zytiga.

61. In the 1990s, scientists at the Institute of Cancer Research studied the use of several steroids including abiraterone in the treatment of androgen-dependent disorders, with particular emphasis on prostate cancer. They applied for a patent in September 1994.

62. In February 1997, the Patent Office granted the application and issued the ’213 Patent. The patent was then assigned to BTG.

63. In 2004, Cougar Biotechnology acquired the exclusive license to the ’213 Patent. J&J acquired Cougar Biotechnology in May 2009.

64. On December 13, 2016, the ’213 Patent, which protected the chemical compound for Zytiga (abiraterone acetate), expired.

65. In the meantime, Cougar Biotechnology initiated patent application number 11/844,440 (the ’440 Application) in August 2007.

66. In 2010, after J&J had acquired Cougar Biotechnology, BTG and Janssen Oncology reframed the claims stated in the ’440 Application.

67. The revised Application contained two principal claims, which related to a “method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone,” and a “method for the treatment of a refractory prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.”

68. Patent Office examiner San-ming Hui rejected Defendants’ ’440 Application twice in 2010 based on obviousness. After the second rejection, Defendants did not respond with additional submissions in support of its application, and the Patent Office issued a notice of abandonment of the application.

**B. Defendants’ Fraudulent Prosecution of the ’438 Patent**

69. In February 2011, Janssen Oncology and BTG filed patent application number 13/034,340 (the ’340 Application), which it identified as a continuation of the ’440 Application that reasserted the same claims. The main claim asserted was for “[a] method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.”

70. The proposed invention claimed a method for treating prostate cancer through co-administration of abiraterone acetate and prednisone (a corticosteroid).

71. As a continuation of the ’440 Application, the ’340 Application was reviewed by the prior examiner—San-ming Hui.

72. As with the prior application, examiner Hui repeatedly rejected Defendants’ ’340 Application on the ground that co-administering abiraterone acetate with prednisone to treat prostate cancer was obvious in light of the prior art.

73. Nonetheless, as a result of Defendants’ fraudulent submissions to the Patent Office during the patent prosecution, the ’340 Application eventually led to the grant of the ’438 Patent.

74. On July 3, 2012, in an attempt to overcome the previous obviousness rejections, J&J, on behalf of Defendants, made several submissions to the Patent Office to show that Zytiga—a commercial embodiment to the claimed invention—was a commercial success.

75. Defendants’ July 3 submissions asserted that Zytiga enjoyed commercial success because, within the first year of its release, “worldwide sales were over $400 million.” Defendants, however, did not attempt to demonstrate that the purportedly high sales amount were related, or had the requisite nexus, to the claimed patentable subject matter of the ’340 Application.

76. On or about September 11, 2012, the Patent Office once again rejected Defendants’ submission and reaffirmed that the claims in the ’340 Application were obvious in light of the prior art: “It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and abiraterone acetate, in the dosage

herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer." This rejection was a "final action."

77. Nevertheless, on January 11, 2013, Defendants asked the examiner to reconsider her final action. Examiner Hui issued another final rejection on March 4, 2013.

78. Notwithstanding the five prior rejections, Defendants tried once more on June 4, 2013, to obtain the '438 Patent based on the commercial success of Zytiga. On behalf of the Defendants, J&J represented to the Patent Office that the materials it submitted truthfully evidenced Zytiga's commercial success *as a result of* the invention claimed in the '340 Application.

79. But in all of Defendants' submissions to the Patent Office regarding Zytiga's commercial success, Defendants omitted a key material fact: the existence of the '213 Patent, a blocking patent that precluded *any* competing drug manufacturers from introducing or even conducting research related to *any* abiraterone acetate product until December 2016. Thus, no other abiraterone acetate drug products could have been marketed—whether for use in combination with prednisone or in any other form—during the period in which Defendants had commercial success in marketing Zytiga for use in combination with prednisone.

80. The '213 Patent makes clear that Zytiga's high sales revenues after launch were of limited probative value to the claimed innovation in the '438 Patent. Defendants knew of this fact and its materiality to their commercial success argument. Defendants further knew that the fact of the '213 Patent should have been disclosed to the Patent Office, particularly since the Patent Office and the courts have repeatedly stressed the importance of a blocking patent when determining whether a drug's commercial success obviates a finding of obviousness. *See, e.g.*, *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) ("Because

market entry by others was precluded [due to patent protection and statutory exclusivity], the inference of non-obviousness . . . from evidence of commercial success . . . is weak"); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740-41 (Fed. Cir. 2013) (same). But Defendants deliberately refrained from mentioning the '213 Patent.

81. Moreover, the '438 Patent is not a continuation of the '213 Patent, and thus different Patent Office examiners considered the two patent applications. The examiner for the '438 Patent was San-Ming Hui, whereas the examiner for the '213 Patent was Anthony Bottino. The examiner for the '438 Patent appropriately reviewed the record submitted in relation to the '340 Application. The examiner cannot therefore be presumed to have been aware of the earlier blocking '213 Patent.

82. On July 3, 2013, examiner Hui allowed the application, providing a single justification: "The unexpected commercial success of the launch of the drug obviates the rejection under 35 U.S.C. § 103(a) [for obviousness]."

83. Over the following year, Defendants followed up on examiner Hui's allowance by submitting five additional information disclosure statements with dozens of references. Most references were categorized as relating to "Other Prior Art – Non Patent Literature Documents." However, Defendants did disclose the existence of several prior patent applications, including the '440 Application, the European counterpart to the '340 application, and two others. Defendants omitted any mention of the '213 Patent in these five additional submissions.

84. Based on Defendants' false and misleading representations and reliance thereon, the Patent Office allowed the claims in the '340 Application and the '438 Patent issued on September 2, 2014.

85. Defendants thus fraudulently procured the ‘438 Patent by failing to disclose the existence of the ’213 Patent as a blocking patent to the Patent Office when pursing the ’438 Patent, even though Defendants’ duties of candor and good faith required such disclosure.

### C. Defendants Used the Fraudulently Obtained ’438 Patent to Block Generic Competition

86. After fraudulently obtaining the ’438 Patent, Defendants listed the patent in the Orange Book along with the ’213 Patent. During all relevant times, Defendants listed in the Orange Book only two patents covering Zytiga: the ’213 Patent, and the ’438 Patent.

87. The ’213 Patent (which is directed to the compound, abiraterone acetate) expired on December 13, 2016, and the ’438 Patent—until it was invalidated—was set to expire in 2027. Thus, after December 13, 2016, only the ’438 Patent blocked generic competition for abiraterone acetate.

#### 1. One or more ANDA applicants would have been ready, willing, and able to manufacture and distribute commercial quantities of generic Zytiga in December 2016 upon expiration of the ’213 Patent.

88. Prior to December 2016, numerous generic companies filed ANDAs with the FDA seeking approval to distribute a generic version of Zytiga.

89. In fact, several generic manufacturers filed ANDAs on April 28, 2015, the very first day that ANDAs could be filed for generic Zytiga. Other manufacturers quickly followed suit. These early ANDA filers included Actavis Laboratories, FL, Inc.; Amneal Pharmaceuticals, LLC, and Amneal Pharmaceuticals of New York, LLC; Apotex Inc. and Apotex Corp.; Amerigen Pharmaceuticals Limited; Citron Pharma LLC; Dr. Reddy’s Laboratories, Ltd., and Dr. Reddy’s Laboratories, Inc.; Glenmark Pharmaceuticals Inc. and

related entities;[1] Mylan Pharmaceuticals Inc. and Mylan Inc.; Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc.; Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc.; Teva Pharmaceuticals USA, Inc.; Wockhardt Bio A.G., Wockhardt USA LLC and Wockhardt Ltd.; and West-Ward Pharmaceutical Corp. and Hikma Pharmaceuticals, LLC (collectively, the "ANDA Filers").

90. Ten of the ANDA Filers—the Amneal, Apotex, Citron, Dr. Reddy's, Mylan, Par, Sun, Teva, Hikma/West Ward, and Wockhardt entities—filed Paragraph III certifications regarding the '213 Patent (meaning they would not launch until it expired in December 2016) and Paragraph IV certifications regarding the '438 Patent.[2]

91. But for Defendants' wrongful listing of the fraudulently obtained '438 Patent in the Orange Book, these generic manufacturers would have been able to file their ANDAs with only Paragraph I, II, or III certifications and gain approval to introduce generic alternatives to Zytiga by December 2016, when the '213 Patent expired.

92. Instead, because Defendants fraudulently obtained the '438 Patent and improperly listed it in the Orange Book, Defendants forced the ANDA Filers to file Paragraph IV certifications as to the '438 Patent.

**2. Defendants instituted sham patent infringement litigation.**

93. In June and July 2015, at least 11 ANDA Filers promptly sent notice of their Paragraph IV certifications to Defendants, as required by statute.

[1] Glenmark filed its ANDA on March 31, 2016.
[2] Actavis initially notified Defendants that it had filed Paragraph IV certifications as to both the '213 Patent and the '438 Patent. However, Actavis revised its certification and stipulated with Defendants that it would not seek to sell abiraterone acetate until after the '213 Patent expired.

94. In response, on July 31, 2015, Defendants instituted objectively baseless litigation against these 11 ANDA Filers, alleging infringement of Defendants' invalid, unenforceable, and fraudulently-obtained '438 Patent.[3] Defendants instituted a single lawsuit against the 11 ANDA Filers in the District of New Jersey.

95. On May 2, 2016, Defendants filed an additional infringement lawsuit against Amerigen after Amerigen filed a Paragraph IV certification regarding the '438 Patent.

96. On August 25, 2017, Defendants filed yet another infringement suit regarding the '438 Patent against Teva.

97. All three of the meritless infringement actions were consolidated before Judge McNulty in the District of New Jersey.

98. On October 18, 2017, the FDA granted tentative approval of Wockhardt's ANDA. On October 27, 2017, the FDA granted tentative approval of Amneal's ANDA. Had Defendants not initiated sham patent litigation against Amneal and Wockhardt that was still pending at this time, the FDA would have granted final approval rather than tentative approval.

99. By filing the infringement claims, Defendants triggered the 30-month stays on FDA approval of the ANDA Filers' applications to market generic alternatives to Zytiga. Defendants commenced these sham litigations for the anticompetitive and unlawful purpose of delaying or preventing generic entry into the relevant market. But Defendants also knew that

[3] Initially, Defendants' claims against Actavis included infringement of the '213 Patent, on which Actavis had initially filed a Paragraph IV certification. On August 30, 2016, however, after Actavis changed its certification to a Paragraph III certification, Actavis, Janssen, and BTG filed a joint stipulation in the infringement action dismissing "all claims, counterclaims, and affirmative defenses relating to the '213 patent . . . for lack of subject matter jurisdiction" as no case or controversy existed as to that patent. From that point forward, every claim that Defendants pursued in the infringement litigation concerned solely the fraudulently obtained '438 Patent, which they knew was invalid and unenforceable.

the mere filing of patent infringement suits (however baseless) would immediately trigger the automatic 30-month stays of FDA final approval of any generic abiraterone acetate product. For a $1.2 billion to $1.7 billion a year franchise, every extra month Defendants could postpone generic competition would add another $100 million to $140 million to its revenues.

### 3. Generic manufacturers sought *inter partes* review of the validity of the '438 Patent.

100. In parallel to the sham infringement actions that triggered the 30-month stay of FDA approval for the ANDA Filers, several generics manufacturers turned to the PTAB's *inter partes* review process for a ruling on the invalidity of the '438 Patent. Amerigen Pharmaceuticals Ltd. was the first to petition for *inter partes* review in December 2015. Amerigen pointed out the obviousness of the use in light of prior art and further attacked the lack of a nexus between Zytiga's commercial success and the claimed invention in the '438 Patent. Among other things, Amerigen highlighted that the '213 Patent was a "blocking patent" that limited the ability of any would-be competitors to develop or market any abiraterone acetate product.

101. The PTAB granted Amerigen's petition on May 31, 2016, and instituted a formal proceeding to examine the '438 Patent. Several other generics manufacturers including Argentum, Mylan, Actavis, Amneal, Dr. Reddy's, Sun, Teva, West Ward, Hikma, and Wockhardt followed suit by filing additional petitions for *inter partes* review on the same grounds as Amerigen. All of the petitions were granted.

102. In January 2018, the PTAB invalidated the '438 Patent in several decisions stemming from the *inter partes* reviews. *Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (P.T.A.B. Jan. 17, 2018); *Mylan Pharms., Inc. v. Janssen Oncology, Inc.*, IPR2016-01332 (P.T.A.B. Jan. 17, 2018); *Wockhardt Bio AG v. Janssen Oncology, Inc.*,

IPR2016-01582 (P.T.A.B. Jan. 17, 2018). The PTAB rejected all of Defendants' arguments regarding non-obviousness as well as their secondary consideration arguments, including their commercial success argument. In particular, the PTAB was persuaded by the generic manufacturers' "argument that the blocking patent would have deterred others from exploring the commercial potential of abiraterone acetate, and thus, that blocking patent to abiraterone acetate limits the applicability of other evidence of commercial success."

103. By statute, however, the invalidation of the '438 Patent by the PTAB did not lift the 30-month stays on FDA final approval. Only entry of judgment by a district court could do so.

**4. Defendants attempted to use the invalidity rulings by the PTAB to delay or derail the district court's decision**

104. After losing before the PTAB, Defendants attempted to twist their loss into a mechanism to prevent the district court from considering or ruling on the ANDA Filers' invalidity arguments that had been successful in the *inter partes* review process. Defendants pointed to an estoppel provision codified at 35 U.S.C. § 315(e)(2), which provides that a party that receives a written decision from the PTAB after seeking review of a patent claim may not present the same invalidity argument in a district court action. Defendants argued that the ANDA Filers could no longer pursue an invalidity argument in the district court action on the same grounds presented to the PTAB because they had received a favorable ruling from the PTAB.

105. Whether the estoppel provision applies to successful PTAB petitioners was a matter of first impression. Under Defendants' proposed reading of the provision, the district court was required to ignore the generic manufacturers' invalidity arguments and the PTAB's invalidity determinations, and instead enforce the '438 without regard to the merits.

106. After a nine-day trial on the merits and post-trial briefing, the district court issued an opinion in favor of the generic manufacturers on October 26, 2018. Judge McNulty decided the ’438 Patent was invalid based on its obviousness. Judge McNulty also ruled that the interpretation of 35 U.S.C. § 315(e)(2) proposed by Defendants would fly in the face of the statute’s intent “to prevent parties from using multiple, possibly inconsistent and wasteful means of attacking a patent.” Defendants’ reading, the court reasoned, would lead to a perverse result of requiring a court “to enter an injunction against infringement based on a patent already found invalid” and to do so without consideration of legally relevant facts and issues.

107. As for the merits, the district court—like the PTAB—rejected all of Defendants’ obviousness arguments and their secondary consideration arguments, including commercial success. The ’213 Patent, in particular, indicated that the commercial success of Zytiga was likely not attributable to the combination therapy claimed in the ’438 Patent.

108. On October 31, 2018, the district court entered final judgment declaring the ’438 Patent to be invalid.

109. On the same day that the district court entered final judgment, the FDA finally approved four ANDA Filers’ applications—those of Apotex, Hikma, Mylan, and Teva.

110. Defendants, however, attempted to pursue a host of procedural mechanisms to stay the district court’s order invalidating the ’438 Patent and thereby delay the inevitable launch of generic competition. First, on or about October 30, 2018, Defendants convinced the district court to enter a preliminary injunction enjoining all of the generic manufacturers that were party to the suits from marketing an abiraterone acetate product until November 9, 2018, or until the Federal Circuit rendered a decision on a stay pending appeal, whichever came first.

111. On October 31, 2018, Defendants filed a notice of appeal to the Federal Circuit. The following day, Defendants filed an emergency motion for an injunction pending appeal, based on Judge McNulty's "fundamental" error in examining the merits despite the estoppel provision in 35 U.S.C. § 315(e)(2). Had the district court not examined the merits, as Defendants argued was required by the estoppel provision, the FDA would not have been allowed to grant final approval to any of the ANDA filers. Based on this reasoning, Defendants requested the Federal Circuit to "preserve the status quo," *i.e.*, Defendants' unlawfully extended monopoly on abiraterone acetate, while reviewing the appeal. Defendants also requested a temporary injunction be put in place to prohibit the ANDA Filers from marketing any generic abiraterone acetate product until the Federal Circuit ruled on the emergency motion. The Federal Circuit granted Defendants' request for a temporary injunction pending a ruling on the motion for an injunction pending appeal.

112. On November 20, 2018, the Federal Circuit denied Defendants' emergency motion for an injunction and vacated the temporary injunction put in place pending its decision.

113. Defendants immediately filed another emergency motion requesting the Federal Circuit to reinstate the temporary injunction pending a forthcoming appeal to the Supreme Court. The Federal Circuit denied that motion the next day, on November 21, 2018.

114. On November 21, 2018, Defendants also filed an application to the Supreme Court requesting it to institute an injunction pending appeal. The Supreme Court also denied Defendants' motion.

115. On or about November 21, 2018—as soon as the temporary injunction pending adjudication of Defendants' motions for a preliminary injunction was vacated—generic competition for Zytiga began. Within two days, four generic competitors had entered the market.

And within a few months, J&J launched its own authorized generic version of Zytiga, and Amneal, Wockhardt, and Rising Pharms also entered the market with generic products.

116. The Federal Circuit later consolidated the appeals from the district court with Defendants' appeals from the three PTAB decisions. The court heard oral argument on the consolidated appeals on March 14, 2019.

117. On May 14, 2019, the Federal Circuit affirmed the *Wockhardt* PTAB ruling and dismissed the appeals from the district court and the two other PTAB decisions as moot. The Federal Circuit held—as expected—that the '438 patent was invalid and that the blocking patent precluded Defendants from using a commercial success argument to rebut the *prima facie* obviousness of the claim.

### D. Defendants' Fraudulent Scheme Delayed Generic Entry and Caused Plaintiff and Other End-Payors to Pay Overcharges for Zytiga

118. Because of Defendants' false and misleading statements to the Patent Office in procuring the '438 Patent, consumers were deprived of any lower-cost generic form of Zytiga.

119. Defendants initiated the fraudulent scheme alleged herein to allow them to continue selling Zytiga at supracompetitive prices after the expiration of the '213 Patent. Defendants knew and intended unlawfully to sell Zytiga at supracompetitive prices during the 30-month stays triggered by the Hatch-Waxman litigations Defendants instituted on the basis of their improperly listed '438 Patent in the Orange Book.

120. Defendants' fraudulent scheme erected significant barriers to the introduction of generic alternatives to Zytiga in interstate commerce and constitutes a willful attempt to exclude generic alternatives.

121. Defendants' wrongful conduct has enabled Defendants to charge Plaintiff and the class unlawfully inflated prices for abiraterone acetate. Defendants' wrongful conduct has

also enabled Defendants to charge Plaintiff and the class for Zytiga prescriptions that would have otherwise been filled by much lower-cost generic alternatives.

122. But for Defendants' misrepresentations and fraudulent conduct, the vast majority of Zytiga purchases during the relevant time period would have instead been for significantly lower-priced generic abiraterone acetate.

## VI. CLASS ACTION ALLEGATIONS

123. Plaintiff also brings this action under Federal Rules of Civil Procedure 23(a) and (b)(3), as a representative of a class seeking damages defined as follows:

All persons or entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Zytiga, other than for resale, in Arizona, Arkansas, California, Colorado, the District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin from December 13, 2016, through and until the anticompetitive effects of the Defendants' challenged conduct cease, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries.

124. The following persons and entities are excluded from the proposed class:

(a) Defendants, their officers, directors, employees, subsidiaries, and affiliates;

(b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans;

(c) all persons or entities who purchased Zytiga for purposes of resale or directly from Defendants or their affiliates;

(d) fully insured health plans, *i.e.*, plans that purchased insurance covering 100% of their reimbursement obligation to members;

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

(f) pharmacy benefit managers;

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

125. The class members are so numerous that joinder is impracticable. Members of the class are widely dispersed throughout the country. The class includes many thousands of consumers and third-party payors.

126. Plaintiff's claims are typical of the claims of all class members. Plaintiff's claims arise out of the same common course of conduct that gives rise to the claims of the other class members. Plaintiff and all class members were damaged by the same wrongful conduct, *i.e.*, they paid artificially inflated prices for Zytiga, and were deprived of the benefits of competition, as a result of Defendants' conduct.

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

128. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation and have particular expertise with class action antitrust litigation in the pharmaceutical industry.

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

a. whether Defendants willfully maintained monopoly power in the market for Zytiga and its generic equivalents;

b. whether Defendants procured the ’438 Patent by fraud;

c. whether Defendants fraudulently listed the ’438 Patent in the Orange Book;

d. whether Defendants initiated and prosecuted baseless litigation against generic competitors;

e. whether Defendants’ overall course of conduct unlawfully delayed or prevented generic Zytiga from entering the market;

f. whether, and to what extent, Defendants’ conduct caused injury to Plaintiff and the class;

g. whether the alleged conduct violated state laws as alleged in the First through Third Claims for Relief; and

h. what classwide measure of damages is appropriate.

130. Questions of law and fact common to the class members predominate over any questions that may affect only individual class members, because Defendants have acted on grounds generally applicable to the entire class.

131. Class treatment is a superior method for the fair and efficient adjudication of the controversy, because, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a similar forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons and entities with a means of obtaining redress on claims that

might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

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

## VII. MARKET POWER AND RELEVANT MARKET

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

134. Direct evidence demonstrates Defendants' market power. It shows that (a) but for Defendants' conduct, generic versions of Zytiga would have entered the market at substantially lower prices than branded Zytiga; (b) Defendants' gross margin on Zytiga was at all times at least 60%; and (c) Defendants never lowered Zytiga prices in response to the pricing of other branded or generic drugs.

135. Defendants drastically increased the price of Zytiga over the past decade.

136. During the Class Period, Defendants have sold Zytiga far in excess of marginal costs and far in excess of the competitive price.

137. Defendants have held monopoly power conferred by the '213 Patent since 1997 and have enjoyed substantial financial gain from their Zytiga monopoly since 2011, when Defendants launched Zytiga upon FDA approval.

138. To the extent Plaintiff needs to show market power indirectly, the relevant product market is the sale of abiraterone acetate products and consists of Zytiga and any AB-rated generic equivalents.

139. At all relevant times during the Class Period until November 2018, Defendants' share of the relevant market was 100%.

140. Branded drugs like Zytiga are differentiated based on features and benefits (including safety and efficacy), and not only based upon price. Doctors and patients are generally price-insensitive when prescribing and purchasing prescription drugs like Zytiga, in part because insurers typically bear much of the cost of prescriptions. And generic substitution laws in almost every state prevent pharmacists from filling a prescription with a drug that is not an AB-rated equivalent of the prescribed drug. Even drugs within its same therapeutic class do not constrain the price of Zytiga.

141. Zytiga is not reasonably interchangeable with any products apart from AB-rated generic versions of Zytiga. The attributes of Zytiga significantly differentiate it from other treatments for prostate cancer. The FDA does not regard Zytiga and other prostate cancer treatments as interchangeable. Nor do Defendants.

142. At all relevant times, potential entrants into the relevant product market of abiraterone acetate faced high barriers to entry due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and steep financial costs of entry and expansion.

143. Zytiga does not exhibit significant, positive cross-price elasticity of demand with any other medication used to treat prostate cancer. The existence of non-abiraterone acetate products that may be used to treat similar indications as Zytiga did not constrain Defendants' ability to raise or maintain Zytiga prices without losing substantial sales, and therefore those other drug products do not occupy the same relevant antitrust market as Zytiga. Therapeutic alternatives are not the same as economic alternatives.

144. Defendants needed to control only Zytiga, and no other products, to maintain the price of Zytiga profitably at supracompetitive prices while preserving all or virtually all of its

sales. Only market entry of a competing, AB-rated generic version of Zytiga has caused Defendants to be unable to profitably maintain its Zytiga prices without losing substantial sales.

145. Defendants exercised monopoly power to exclude competition.

## VIII. MARKET EFFECTS AND CLASS DAMAGES

146. But for the conduct alleged above, generic Zytiga would have entered the market as early as December 13, 2016, when the exclusivities associated with ’213 Patent expired.

147. As of 2014, it took the FDA an average of a year and a half to fully approve ANDAs. A dozen manufacturers submitted ANDAs for generic Zytiga in April 2015—more than a year and a half before the expiration of the ’213 Patent in December 2016. The generic manufacturers seeking to sell generic Zytiga have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic drug products, and manufacturing commercial-launch quantities sufficient to meet market demand. They were thus ready, willing, and able to enter the market with generic alternatives to Zytiga as soon as they obtained ANDA approval.

148. With competition from generic manufacturers approaching, Defendants willfully and unlawfully maintained their Zytiga monopoly power through a unified scheme to exclude competition. Defendants’ scheme prevented generic competition and had its intended effect of permitting Defendants to maintain supracompetitive monopoly prices for Zytiga. Defendants implemented their scheme by fraudulently obtaining the ’438 Patent, wrongfully and knowingly submitting this invalid patent for listing in the Orange Book, prosecuting sham patent infringement lawsuits against the putative generic manufacturers, and otherwise abusing the Hatch-Waxman framework. These acts, individually and in combination, were fraudulent, unreasonably anticompetitive, and unlawful.

149. Had Defendants not defrauded the Patent Office, the ’438 Patent would not have issued, Defendants would not have been able to improperly list it in the Orange Book, and Defendants could not have initiated sham litigation based on the patent against would-be makers of generic Zytiga to institute 30-month stays of any ANDA approval. In short, absent the ’438 Patent, no patent-based obstacles would have existed after December 13, 2016.

150. Defendants’ conduct had the purpose and effect of foreclosing generic competition to Zytiga. Defendants’ conduct enabled them to maintain their monopoly, exclude competition in the relevant market, and charge high monopoly prices without losing significant sales.

151. Defendants’ exclusionary conduct unlawfully delayed any generic competition for 23 months and enabled them to sell Zytiga without any generic competition during that time. But for Defendants’ unlawful exclusionary conduct, one or more of the ANDA filers would have begun marketing and selling generic versions of Zytiga by December 13, 2016.

152. Defendants’ conduct has caused and will cause Plaintiff and the class to pay more than they would have paid for Zytiga, absent that conduct.

153. Typically, generic versions of branded drugs are initially priced significantly below the corresponding reference listed drug branded counterpart as to which they are AB-rated. As a result, upon generic entry, end-payors rapidly switch from branded drugs to generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decline even further due to competition among the generic firms, and, correspondingly, the branded drug continues to lose even more market share.

154. Price competition enables all purchasers of the drug to buy generic equivalents of a drug at substantially lower prices or to buy the branded drug at reduced prices. Consequently,

brand manufacturers have a strong incentive to delay generic competition, and purchasers experience substantial cost inflation from that delay.

155. If generic competitors had not been unlawfully prevented from entering the Zytiga market earlier and competing with Defendants, end-payors like Plaintiff would have paid less for abiraterone acetate by (a) purchasing, and providing reimbursement for, AB-rated generic Zytiga instead of more-expensive branded Zytiga, and (b) purchasing, and providing reimbursement for, branded Zytiga at lower prices.

156. Defendants' unlawful conduct deprived Plaintiff and the class of the benefits of competition that the antitrust laws were designed to guarantee.

## IX. ANTITRUST IMPACT

157. The effect of Defendants' course of monopolistic conduct was to net Defendants billions of dollars in revenue at the expense of end-payors, including Plaintiff and the proposed class, who paid hundreds of millions of dollars in unlawful overcharges.

158. During the relevant period, Plaintiff and class members purchased substantial amounts of Zytiga indirectly from Defendants.

159. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff and class members paid monopoly prices for Zytiga that were substantially higher than the prices they would have paid absent Defendants' illegal conduct, because: (1) the price of branded Zytiga was artificially inflated as a result of Defendants' illegal conduct, and (2) the class members were deprived of the opportunity to purchase lower-priced generic versions of Zytiga sooner.

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

161. The overcharges resulting from Defendants' conduct are directly traceable through the pharmaceutical distribution chain to Plaintiff and other end-payors. A manufacturer first sells the drug to direct purchaser wholesalers based on the listed WAC, minus applicable discounts. Wholesalers then sell the drug to pharmacies, which in turn sell the drugs to consumers. 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 payors (such as health and welfare funds). The products and their prices are thus directly traceable from the manufacturer until they reach the hands of the consumer at a pharmacy.

## X. INTERSTATE AND INTRASTATE COMMERCE

162. Defendants' efforts to monopolize and restrain competition for Zytiga have substantially affected interstate commerce.

163. At all material times, Defendants manufactured, marketed, promoted, distributed, and sold substantial amounts of Zytiga in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

164. At all material times, Defendants 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 Zytiga.

165. In furtherance of its efforts to restrain competition in the relevant market, Defendants employed the U.S. mails and interstate and international phone lines, as well as

means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

166. Defendants' conduct also had substantial intrastate effects in that, among other things, retailers within each state were prevented from offering more affordable generic Zytiga to end-payors inside each respective state. Defendants' conduct materially deprived the consuming public—including hundreds, if not thousands, of end-payors in each state—of any choice to purchase more affordable generic Zytiga.

## XI. CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF: VIOLATIONS OF STATE ANTITRUST LAWS (On behalf of Plaintiff and the Class)

167. Plaintiff incorporates the above paragraphs by reference.

168. As described above, from 1997 until at least November 2018 (and with continuing effects hereafter), Defendants possessed monopoly power in the market for Zytiga (abiraterone acetate). During that period, no other manufacturer sold a competing version of any abiraterone acetate product in the United States. Defendants have willfully and unlawfully maintained their monopoly power in the abiraterone acetate product market since December 13, 2016.

169. Beginning at a time currently unknown to Plaintiff, but at least as early as July 2015, and continuing through the present, Defendants entered into continuing agreement(s), understanding(s), and conspiracy(ies) in restraint of trade artificially to fix, raise, stabilize, and peg prices for abiraterone acetate in the United States, in violation of the laws enumerated below.

170. Defendants have executed an unlawful overarching scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident. The overarching scheme includes Defendants' fraud before the Patent

Office when obtaining the ’438 Patent, listing the ’438 Patent in the Orange Book, and filing sham patent infringement litigations based on the ’438 Patent.

171. Defendants knowingly and intentionally engaged in an overarching anticompetitive scheme to maintain their monopoly, the components of which either standing alone or in combination (in whole or part) were designed to and in fact have foreclosed generic competition in violation of state antitrust laws. This scheme included:

a. prosecuting serial baseless patent applications and ultimately obtaining the ’438 Patent by fraud through misleading the Patent Office and failing to exercise the duty of disclosure, candor, and good faith;

b. improperly listing the ’438 Patent in the Orange Book; and

c. asserting the ’438 Patent in multiple sham litigations.

172. Defendants knowingly and intentionally committed fraud under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), to induce the Patent Office to grant the ’438 Patent. Specifically, Defendants—after repeated denials of its applications on the ground of obviousness—submitted materials to demonstrate Zytiga’s commercial success and its nexus to the claimed use of abiraterone in conjunction with prednisone without disclosing the highly relevant ’213 Patent. Had Defendants made clear to the Patent Office examiner that the ’213 Patent and J&J’s exclusive license to it blocked any other entity from marketing any form of abiraterone acetate—as Defendants’ duty of disclosure, candor, and good faith required—the Patent Office examiner would have rejected Defendants’ June 4, 2013 submission for the same reasons it had repeatedly denied every prior submission: the claims presented were all obvious in light of the prior art. Defendants’ omission of the ’213 Patent and misrepresentation of the causes of Zytiga’s commercial success in their submissions

to the Patent Office were fraudulent and material; Defendants made these representations and omissions knowingly and with the intent to deceive, and these purposeful misstatements and omissions in fact induced the Patent Office to issue ’438 Patent.

173. Defendants knew when they submitted the ’438 Patent for listing in the Orange Book that the patent was fraudulently procured and otherwise invalid as obvious in light of prior art, and that it was therefore improper to submit the ’438 Patent for listing. Defendants knew that the listing of the ’438 Patent in the Orange Book would force ANDA applicants to file Paragraph IV certifications, which Defendants knew would allow them to file patent infringement suits against those ANDA applicants. Defendants also knew that the infringement lawsuits, despite their objective baselessness, would trigger an automatic stay of FDA final approval of any pending Paragraph IV-certified ANDA applicant’s generic Zytiga product for a period of at least 30 months.

174. Defendants knowingly and intentionally engaged in multiple sham lawsuits against manufacturers of AB-rated generic equivalents of Zytiga. In these sham suits, Defendants intentionally and deceptively alleged the generic manufacturers’ products infringed its ’438 Patent. Defendants knew at all relevant times including at the time of filing these suits that the ’438 Patent was wrongfully obtained though fraud on the Patent Office and was otherwise invalid as obvious in light of the prior art. Defendants also knew, at the time they filed the multiple sham suits, that it had no realistic likelihood of success in the suits; that is, that there was no realistic likelihood that a court would enforce the fraudulently obtained and otherwise invalid ’438 Patent against a generic company. Defendants knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a chance of succeeding on the merits of these infringement lawsuits. Defendants filed these sham lawsuits to use a government process as

an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly, regardless of the lack of any actual merit in its infringement claims.

175. There is no valid procompetitive justification for Defendants' anticompetitive conduct, and to the extent Defendants assert one, it is pretextual and not cognizable, and any procompetitive benefits of Defendants' conduct do not outweigh its anticompetitive harms.

176. Defendants' conduct has affected interstate commerce by keeping the price of abiraterone acetate products higher than they would be absent the anticompetitive scheme.

177. By means of the overarching anticompetitive scheme described herein, Defendants have intentionally and wrongfully maintained monopoly power with respect to abiraterone acetate in violation of the following state laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1402, 44-1403, *et seq.*, with respect to purchases in Arizona by class members and/or purchases by Arizona residents.

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by class members and/or purchases by Arkansas residents before August 1, 2017.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by class members and/or purchases by California residents.

d. D.C. Code §§ 28-4502, 28-4503, *et seq.*, with respect to purchases in D.C. by class members and/or purchases by D.C. residents.

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

f. Haw. Rev. Stat. §§ 480-2, 480-4, 480-9, *et seq.*, with respect to purchases in Hawaii by class members and/or purchases by Hawaii residents.

g. 740 Ill. Comp. Stat. §§10/3, *et seq*., with respect to purchases in Illinois by class members and/or purchases by Illinois residents.

h. Iowa Code §§ 553.4, 553.5, *et seq.*, with respect to purchases in Iowa by class members and/or purchases by Iowa residents.

i. Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to purchases in Kansas by class members and/or purchases by Kansas residents.

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

k. Mass. Gen. Laws ch. 93A §§ 1, 2, 9, *et seq.*, with respect to purchases in Massachusetts by consumer class members and/or purchases by consumer Massachusetts residents.

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

m. Minn. Stat. §§ 325D.51, 325D.52, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by class members and/or purchases by Minnesota residents.

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

o. Mo. Rev. Stat. §§ 407.020, *et seq.*, with respect to purchases in Missouri by consumer class members and/or purchases by consumer Missouri residents.

p. Mont. Code Ann. §§ 30-14-103, *et seq.*, with respect to purchases in Montana by consumer class members and/or purchases by consumer Montana residents.

q. Neb. Rev. Stat. §§ 59-801, 59-802, *et seq.*, with respect to purchases in Nebraska by class members and/or purchases by Nebraska residents.

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

s. N.H. Rev. Stat. Ann. §§ 356:2, 356:3, *et seq.*, with respect to purchases in New Hampshire by class members and/or purchases by New Hampshire residents.

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

u. N.Y. Gen. Bus. Law § 340 with respect to purchases in New York by class members and/or purchases by New York residents.

v. N.C. Gen. Stat. §§ 75-1, 75-2.1, *et seq.*, with respect to purchases in North Carolina by class members and/or purchases by North Carolina residents.

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

x. Or. Rev. Stat. §§ 646.725, 646.730, *et seq.*, with respect to purchases in Oregon by class members and/or purchases by Oregon residents.

y. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases in Rhode Island by class members and/or purchases by Rhode Island residents.

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

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

bb. Utah Code Ann. §§ 76-10-31041, *et seq.*, with respect to purchases by Utah residents.

cc. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by consumer class members and/or purchases by consumer Vermont residents.

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

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

178. Plaintiff and members of the class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Defendants' conduct. These

injuries are of the type that the foregoing laws are intended to prevent, and flow from that which makes Defendants' conduct unlawful.

179. Plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**SECOND CLAIM FOR RELIEF: UNFAIR AND DECEPTIVE ACTS, IN VIOLATION OF STATE CONSUMER PROTECTION LAW (On behalf of Plaintiff and the Class)**

180. Plaintiff incorporates the above paragraphs by reference.

181. Defendants have engaged in unfair, unconscionable, deceptive and fraudulent acts or practices to wrongfully perpetuate its Zytiga patent monopoly. These fraudulent and deceptive acts included intentionally misleading the Patent Office, the FDA, the courts, and the public about the validity of the claims underlying the '438 Patent.

182. As a direct and proximate result of Defendants' unfair, unconscionable, deceptive, and fraudulent conduct, Plaintiff and members of the class were denied the opportunity to purchase generic Zytiga, were forced to pay higher prices for Defendants' branded Zytiga, and lost money or property as a result.

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

184. There was and is a gross disparity between the price that Plaintiff and class members paid for branded Zytiga and the value they received. Much more affordable, therapeutically equivalent generic versions of Zytiga would have been available sooner and in greater quantity, and prices for branded Zytiga would have been far lower, but for Defendants' unfair, unconscionable, deceptive, and fraudulent conduct.

185. By engaging in such conduct, Defendants violated the following state consumer protection laws:

a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by class members and/or purchases by Arkansas residents before August 1, 2017, by engaging in unconscionable, false, and deceptive acts and practices.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in California by class members and/or purchases by California residents by engaging in conduct that is immoral, unethical, oppressive, unscrupulous, and substantially injurious to end-payors. There are no countervailing benefits to end-payors and any utility of Defendants' conduct is outweighed by the consequences to Plaintiff and other end-payors. Defendants' conduct also constitutes an unlawful business practice in that it violates Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2.

c. Colo. Rev. Stat. §§ 6-1-101, *et seq.*, with respect to purchases in Colorado by class members and/or purchases by Colorado residents by engaging in deceptive acts and practices.

d. Idaho Code Ann. §§ 48-601, *et seq.*, with respect to purchases in Idaho by class members and/or purchases by Idaho residents by engaging in deceptive and unconscionable conduct.

e. Mont. Code Ann. §§ 30-14-103, *et seq.*, with respect to purchases in Montana by consumer class members and/or purchases by consumer Montana residents by engaging in unfair or deceptive acts and practices.

f. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by consumer class members and/or purchases by consumer Vermont residents for personal use by engaging in unfair and deceptive acts and practices.

186. On behalf of themselves and the class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

**THIRD CLAIM FOR RELIEF: UNJUST ENRICHMENT UNDER CALIFORNIA LAW (On behalf of Plaintiff and the Class Members residing in, or who paid and/or provide reimbursement in, California)**

187. Plaintiff incorporates the above paragraphs by reference.

188. This claim is pleaded in the alternative to the other claims in this Complaint.

189. Defendants have reaped and retained substantial benefits in the form of higher profits due to its unjust scheme to monopolize the market for Zytiga.

190. The financial benefits to Defendants from its wrongful conduct are traceable to overpayments for Zytiga by Plaintiff and class members.

191. Plaintiff and class members have conferred upon Defendants an economic benefit—their profits stemming from anticompetitive overcharges. Plaintiff and class members paid those monopoly overcharges to their substantial economic detriment.

192. It would be futile for Plaintiff and the class to seek relief against any party with whom they have privity of contract, including the immediate intermediary in the chain of distribution from which they indirectly purchased Zytiga. Defendants have paid no consideration to any other person for any of the unlawful benefits it received indirectly from Plaintiff and the class with respect to Defendants' sales of Zytiga.

193. The financial benefits that Defendants derived by charging supracompetitive prices for Zytiga directly and proximately resulted from Defendants' unjust practices described herein. Those benefits rightfully belong to Plaintiff and the class.

194. It would be wrong and inequitable for Defendants to be permitted to retain any of the ill-gotten gains from its wrongful monopolization scheme.

195. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to its unlawful overcharges of Zytiga is ascertainable by review of sales records.

196. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the class all proceeds that it inequitably derived from its scheme, and a constructive trust should be imposed upon such sums.

## XII. PRAYER FOR RELIEF

197. WHEREFORE Plaintiff, on behalf of the class, pray for judgment via Court orders:

A. Determining that this action may be maintained as a class action under Fed. R. Civ. P. 23(a), (b)(1), (b)(2) and (b)(3), directing that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and appointing Plaintiff as a named representative of the class;

B. Entering judgment against Defendants and in favor of Plaintiff and the class;

C. Awarding treble damages (three times overcharges paid) in an amount to be determined at trial, plus interest in accordance with law;

D. Awarding Plaintiff and the class their costs of suit, including reasonable attorneys' fees, as permitted by law; and

E. Entering such other and further relief as may be just and proper.

## XIII. DEMAND FOR JURY TRIAL

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

DATED: June 26, 2019

COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP
PETER S. PEARLMAN

*/s/ Peter S. Pearlman*
PETER S. PEARLMAN
Park 80 West-Plaza One
250 Pehle Avenue | Suite 401
Saddle Brook, NJ 07663
Telephone: 201/845-9600
201/845-9423 (fax)

Joseph R. Saveri
Steven N. Williams
Kevin Rayhill
JOSEPH SAVERI LAW FIRM, INC.
601 California Street, Suite 1000
San Francisco, California 94108
Telephone: (415) 500-6800
Facsimile: (415) 395-9940

Dan Drachler
ZWERLING, SCHACHTER & ZWERLING, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Telephone: (206) 223-2053
Facsimile: (206) 343-9636

Robert S. Schachter
Sona R. Shah
ZWERLING, SCHACHTER & ZWERLING, LLP
41 Madison Avenue, 32nd Floor
New York, NY 10010
Telephone: (212) 223-3900
Facsimile: (212) 371-5969

Vincent J. Esades
Renae Steiner
HEINS MILLS & OLSON, P.L.C.
310 Clifton Avenue
Minneapolis, MN 55403

*Attorneys for Plaintiff*