UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA

IONSOUTH-MOBILE, LLC, formerly known as COX NUCLEAR PHARMACY d/b/a IONSOUTH DIAGNOSTIC PHARMACY LLC, on behalf of itself and all others similarly situated, and UPPI, LLC,

Plaintiffs,

v.

JUBILANT DRAXIMAGE INC. d/b/a/ JUBILANT RADIOPHARMA,

Defendant.

Civil Action No. 19-CV-518

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Ionsouth-Mobile, LLC, formerly known as Cox Nuclear Pharmacy d/b/a Ionsouth Diagnostic Pharmacy LLC ("Ionsouth"), on behalf of itself and all others similarly situated, and plaintiff UPPI LLC ("UPPI") (together, "Plaintiffs") file this Complaint against Defendant Jubilant DraxImage Inc. d/b/a Jubilant Radiopharma ("JDI" or "Defendant") for violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2) and common law. The allegations herein are based on Plaintiffs' personal knowledge as to their own acts and on information and belief as to all other matters, such information and belief having been informed by the extensive investigation conducted by and under the supervision of their counsel. Ionsouth, on behalf of itself and the Class it seeks to represent (as defined below), and UPPI allege as follows:

I. NATURE OF THE ACTION

1. This action involves radiopharmaceutical products. Radiopharmaceuticals are a class of low-level radioactive medicines used for both diagnostic and therapeutic purposes. Diagnostic radiopharmaceutical products are typically used in conjunction with imaging devices to scan vital organs; therapeutic radiopharmaceutical products can be used, for example, to treat certain cancers.

2. Many radiopharmaceuticals are compounded products composed of a non-radioactive element, known as a ligand or reagent, combined or "radiolabeled" with a radioisotope, most commonly Technetium ("Tc^{99m}"). A "cold kit" contains the non-radioactive ligand. The kits are referred to as "cold" because when manufactured and sold, they have not yet been radiolabeled or "tagged" with any radioactive material. There are also non-compounded radiopharmaceuticals referred to as "hot" products. Hot products are manufactured and sold already containing radioactive material.

3. Defendant JDI is one of the largest radiopharmaceutical manufacturers in the United States. It manufactures a number of radiopharmaceutical products, including both "cold kits" and "hot" products. At issue here are five such products:

SOLE-SOURCE PRODUCTS (*available in U.S. only from JDI*)	**PRODUCT TYPE**	**USES**
MAA	Cold kit	Used to prepare Tc^{99m} Macroaggregated Albumin Injection, a lung imaging agent
DTPA	Cold kit	Used to prepare Tc^{99m} pentetate injection, a multi-purpose renal and lung imaging agent

MULTI-SOURCE PRODUCTS (*available in U.S. from JDI and other mfrs.)*	**PRODUCT TYPE**	**USES**
MDP-25 ("MDP")	Cold kit	Used to prepare Tc^{99m} Medronate, a bone imaging agent
Sestamibi	Cold kit	Used to prepare Tc^{99m} Sestamibi, a heart imaging agent
HICON® ("Sodium Iodine I-131")	Hot product	Sodium Iodine I-131 solution for treatment of thyroid conditions

4. Ionsouth and members of the Class are nuclear pharmacies. Nuclear pharmacies are specialized pharmacies that prepare patient-ready doses in response to hospital or imaging center orders (prescriptions) for radiopharmaceuticals. Nuclear pharmacies purchase radiopharmaceutical products from JDI, as well as from other radiopharmaceutical manufacturers.

5. Nuclear pharmacies can be either independently owned, such as Ionsouth, or part of a corporate-owned network. Plaintiff UPPI is the largest association of independent and institutional nuclear pharmacies in the United States. Over 70 independent nuclear pharmacies, including Ionsouth, are UPPI members.

6. In May 2017, a JDI affiliate purchased Triad Isotopes, Inc., the second-largest network of nuclear pharmacies in the United States. With this acquisition, it acquired over 50 nuclear pharmacies. These pharmacies directly compete with Ionsouth and members of the Class. On June 17, 2019, JDI's parent company, Jubilant Pharma Limited ("JPL"), announced that Triad Isotope nuclear pharmacy business would be integrated with JDI's radiopharmaceutical manufacturing business as a single company: Jubilant Radiopharma (JDI's nuclear pharmacy division will be referred to herein as "Triad Isotopes").

7. In recent years, JDI has aggressively sought to increase revenue and expand market share. It has done this not by competing vigorously on the merits but instead by engaging in unlawful conduct to monopolize or attempt to monopolize the markets for MAA, DTPA, MDP, Sestamibi, and Sodium Iodine I-131 in the United States.

8. JDI's anticompetitive conduct involved abusing its position as sole supplier in the U.S. of two critical radiopharmaceutical cold kits: MAA and DTPA. Cold kits designed to prepare MAA and cold kits designed to prepare DTPA are referred to herein as JDI's "Sole-Source Products" or "MAA and DTPA cold kits."

9. JDI is not the sole supplier of MDP cold kits, Sestamibi cold kits, or Sodium Iodine I-131 in the United States (collectively, "Multi-Source Products"). Although JDI competes with other manufacturers who sell Multi-Source Products, [redacted]

10. Since JDI became the sole supplier of MAA and DTPA cold kits in the U.S., it has engaged in a deliberate course of conduct designed to illegally maintain its monopoly in the markets for these products and reap significant monopoly rents from its nuclear pharmacy customers.

11. In 2013, JDI acquired two approved new drug applications from Pharmalucence, Inc.: NDA 017776, the new drug application for Pulmolite, a competing cold kit to JDI's MAA and NDA 017714, the new drug application for AN-DTPA, a competing cold kit to JDI's DTPA. JDI acquired the NDAs despite substantial interest from other buyers who sought to launch products to compete with JDI's MAA and DTPA cold kits.

12. After purchasing these approved NDAs, JDI "warehoused" them—refusing to either offer new products that would compete with its MAA and DTPA cold kits or to license or sell the NDAs to another compete that could do so.

13. With these NDAs under its control, JDI had the opportunity to hike the prices of its Sole-Source Products to supra-competitive levels without the threat of competitors coming onto the market and gaining market share by competing on (lowering) price. And so it did. In February 2014, JDI announced significant price increases for its Sole-Source Products. For nuclear pharmacies like Ionsouth and members of the Class, the price of a vial of MAA rose from $22 per vial to $400 per vial, ***a 1718% increase***; the price of a vial of DTPA rose from $22 per vial to $138 per vial, ***a 527% increase***. Since 2014, JDI has continued to raise the price of its Sole-Source Products. [redacted]

14. As the sole supplier of MAA and DTPA cold kits in the U.S., JDI already had monopoly power in the markets for these products. Its monopoly power was kept in check, however, by the threat of potential competition. By acquiring the Pulmolite and AN-DTPA NDAs from Pharmalucence and then warehousing those NDAs, thereby eliminating potential competitors, JDI was able to illegally maintain its monopoly in the markets for MAA and DTPA cold kits.

15. Beginning in 2017, JDI initiated additional anticompetitive practices. These practices were designed for two specific purposes: (1) to maintain or enhance its market power in the markets for the Sole-Source and Multi-Source Products; and (2) to benefit JDI's nuclear pharmacy division, Triad Isotopes. The new anticompetitive practices are rooted in JDI's Master Supply and Distribution Agreement (the "JDI Master Agreement"), which contains several provisions intended to monopolize or attempt to monopolize the markets for various radiopharmaceutical products and/or to restrain trade.

16. First, the JDI Master Agreement imposes tying obligations whereby a nuclear pharmacy's purchase of MAA and DTPA cold kits is conditioned on the pharmacy also purchasing a guaranteed minimum amount of [redacted] Because JDI is the sole supplier of MAA and DTPA and has significant market power, and because these are vital nuclear medicines, nuclear pharmacies have no alternative but to enter into the JDI's anticompetitive tying contracts, [redacted] The tying agreements have significantly foreclosed competition in the markets for [redacted], thus causing purchasers, such as Ionsouth and members of the Class, to pay inflated prices for [redacted] purchased from JDI.

17. Second, the JDI Master Agreement prohibits nuclear pharmacies from [redacted]

18. [redacted] "Fractionating" involves reconstituting the contents of a cold kit with saline and

dividing portions of the reconstituted kit into other containers for storage and subsequent radiolabeling. Because a single cold kit can produce multiple doses of a radiopharmaceutical, fractionating enables a nuclear pharmacist to preserve excess cold kit material for use at a later date. Fractionation is a safe and effective industry standard practice and was recently sanctioned in an update to the United States Pharmacopeia, which is recognized as an official compendium under the Federal Food, Drug and Cosmetic Act. [redacted] Such information is of little relevance to JDI's radiopharmaceutical *manufacturing* business. But to Triad Isotopes, information and knowledge about current or potential competitors and their customers is of great value. [redacted]

[redacted]

21. [redacted]

22. By trying to make its Sole-Source products impossible to acquire outside of the JDI Master Agreement, JDI has forced its unwilling customers to enter into the agreement and thereby imposed onerous and wholly unreasonable restraints on its customers. These contract provisions have allowed JDI to unlawfully monopolize or attempt to monopolize the markets for MDP cold kits, Sestamibi cold kits, and Sodium Iodine I-131 in the U.S and constitute an unreasonable restraint of trade.

23. JDI's multi-faceted anticompetitive scheme has come to the attention of U.S. government law enforcers. On September 24, 2018, JPL disclosed that in May 2017 it was "notified that the United States Federal Trade Commission ('USFTC') had begun a non-public investigation into certain competition law matters relating to our sales and distribution practices in our radiopharmaceuticals business and our then pending acquisition of substantially all of the assets which comprised Triad's radiopharmacy business." Additionally, it disclosed that "[i]n February 2018, our Company and Triad received two civil investigative demands ('CIDs') from

the USFTC requesting certain information about our business and operations."[1] Upon information and belief, the FTC's investigation is ongoing.

24. As a result of JDI's anticompetitive conduct, Ionsouth and members of the Class have been injured in their business and property during the Class Periods (defined below), and their injury is continuing. Both Plaintiffs seek injunctive relief, treble damages, and/or related relief under federal antitrust laws and common law.

II. THE PARTIES

25. Plaintiff Ionsouth-Mobile, LLC is an Alabama company with its principal place of business at 146 South Florida Street, Mobile, Alabama 36609. Ionsouth has nuclear pharmacy locations in Alabama, Mississippi, and Florida. Ionsouth purchased JDI's Sole-Source and Multi-Source Products directly from JDI during the Class Periods. On certain agreements between Ionsouth and JDI, Ionsouth's previous legal name, Cox Nuclear Pharmacy d/b/a Ionsouth Diagnostic Pharmacy LLC, appears.

26. Plaintiff UPPI LLC, also known as United Pharmacy Partners, is a Delaware limited liability company with its principal place of business at 5400 Laurel Springs Parkway, Suite 405, Suwanee, Georgia, 30024. UPPI is the largest association of independent and institutional nuclear pharmacies in the United States. Over 70 independent nuclear pharmacies, including Ionsouth, are UPPI members. UPPI members are nuclear pharmacies that service communities across the country. UPPI provides its members national strength in buying relationships as well as access to customizable local programs that advance the profession. "As an organization, UPPI is well positioned to assist Nuclear Pharmacy owners in promoting their

[1] Jubilant Pharma Ltd., Supplemental Information (Sept. 24, 2018), *available at* http://www.jubl.com/Uploads/image/914imguf_Supplemental_Information_24_09_2018.pdf.

businesses and in managing growth. Through its network of Nuclear Pharmacies, UPPI facilitates the open exchange of information, leading to the development of strategies that enhance the delivery of quality nuclear pharmacy services and insure improved patient outcomes."[2]

27. UPPI has standing to bring this action for declaratory and injunctive relief in a representative capacity on behalf of its members, who are adversely affected by JDI's misconduct described herein and whose participation is not required for the declaratory and injunctive relief sought.

28. Defendant Jubilant DraxImage Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 16751 TransCanada Highway, Kirkland, Québec, Canada H9H 4J4. JDI has a U.S. office located at 790 Township Line Road, Suite 175, Yardley, PA, 19067, United States. As of June 2019, JDI does business as Jubilant Radiopharma. During the Class Periods, JDI marketed and sold radiopharmaceuticals in this District and throughout the United States.

III. RELEVANT NON-PARTIES

29. JDI is a wholly-owned subsidiary of Jubilant Pharma Limited ("JPL"), a corporation organized and existing under the laws of Singapore. JPL is a subsidiary of Jubilant Life Sciences Ltd. ("JLS"), a global pharmaceutical and life sciences company based in India.

30. Jubilant Pharma Holdings Inc. ("JPH") is a U.S. subsidiary of JPL and a Delaware corporation with its principal place of business at 790 Township Line Rd., Yardley, Pennsylvania, 19067.

[2] http://uppi.org/

31. In May 2017, a wholly-owned subsidiary of JPH, Jubilant DraxImage Radiopharmacies Inc. ("JDR") purchased substantially all of the assets of Triad Isotopes, Inc., the second-largest radiopharmaceutical network in the United States. JDR is a Delaware corporation with its principal place of business at 4204 Vineland Road, Orlando, FL 32811. In June 2019, JDI's parent company, JPL, announced that the Triad Isotope nuclear pharmacy business would be integrated with JDI's radiopharmaceutical manufacturing business, and both divisions would operate under the brand name Jubilant Radiopharma.

IV. JURISDICTION AND VENUE

32. This Court has subject matter jurisdiction over this action pursuant to Sections 4 and 16 of the Clayton Act (15 U.S.C. §§ 15(a) and 26) and pursuant to 28 U.S.C. §§ 1331 and 1337(a).

33. Venue is appropriate within this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (venue for antitrust matters brought under the federal antitrust laws) or 28 U.S.C. §1391(b) (federal venue statute). Defendant transacted business, was found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

34. The Court has personal jurisdiction over Defendant. Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District. Defendant's conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

V. TRADE AND COMMERCE AFFECTED

35. JDI is in the business of selling radiopharmaceutical products, including the Multi-Source Products and Sole-Source Products described above.

36. At all times pertinent to this Complaint, JDI has sold a substantial amount of Multi-Source Products and Sole-Source Products in interstate commerce in numerous states around the United States.

37. JDI's conduct has affected a substantial amount of interstate trade and commerce in the United States.

VI. INDUSTRY BACKGROUND

A. Nuclear Medicine

38. Nuclear medicine is a branch of medicine that allows physicians to identify, diagnose, and treat medical conditions by introducing small amounts of radioactive material into patients' bodies.

39. Thousands of nuclear medicine imaging procedures occur in the U.S. each day. In a typical procedure, a physician will administer a small, non-harmful amount of radioactive medicine—a radiopharmaceutical—into a patient's body. Depending on the drug and medical procedure being administered, the radiopharmaceutical may be injected directly into the patient's bloodstream, swallowed, or inhaled.

40. Diagnostic radiopharmaceuticals are designed to accumulate in the specific organ or area of the body that is being examined. The radioactive material in the drug emits a signal through radioactive decay that can be detected by a gamma camera or a positron emission tomography (PET) scanner. These special cameras then photograph the patient to create images

of the area being examined. Diagnostic radiopharmaceuticals are used to scan a number of different parts of the body, including the lungs, heart, brain, kidney, and bones.

41. Nuclear medicine is also used to treat certain conditions, including various forms of cancer such as thyroid and prostate cancer. Treatment is referred to as targeted radionuclide therapy or molecular radiotherapy and involves the intake of a radiopharmaceutical that travels to and delivers radiation directly to abnormal cells.

B. Nuclear Pharmacy

42. Nuclear pharmacy is a specialized area of pharmacy practice dedicated to the compounding and dispensing of radiopharmaceuticals. In 1978, it was the first pharmacy specialty established by the Board of Pharmaceutical Specialties.

43. There are hundreds of nuclear pharmacies across the United States. Cardinal Health, Inc., with over 130 nuclear pharmacies, operates the largest network of pharmacies. In May 2017, JDI's sister company, JDR, acquired Triad Isotopes Inc., the second largest nuclear pharmacy network in the United States. Triad Isotopes's network consists of more than 50 nuclear pharmacies in 21 states. As of June 2019, Triad Isotopes's nuclear pharmacy business was integrated with JDI's radiopharmaceutical manufacturing business. There are also dozens of independent nuclear pharmacies across the country.

44. Nuclear pharmacists require specialized training not required of traditional pharmacists. For example, in order to handle nuclear materials, nuclear pharmacists must be listed as an "Authorized Nuclear Pharmacist" on a pharmacy's or hospital's radioactive materials

license.[3] This license is issued by the United States Nuclear Regulatory Commission or a state's radiological health division.

45. The training to become an Authorized Nuclear Pharmacist requires a minimum of 500 practice hours under an approved instructor in a nuclear pharmacy and 200 classroom-based hours.[4] Nuclear pharmacists may also be recognized as an Authorized Nuclear Pharmacist through certification by a specialty pharmacy board.[5] Certification requires: (1) graduating from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or passing the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination; (2) holding a current, active license to practice pharmacy; (3) providing evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice; and (4) passing an examination in nuclear pharmacy administered by diplomates of the specialty board.[6]

C. Radiopharmaceuticals

46. The radiopharmaceutical industry is a multi-billion dollar industry. Based on revenue, JDI is the third largest radiopharmaceutical manufacturer selling in the United States. Most of JDI's products are cold kits used to prepare diagnostic radiopharmaceuticals, including its two key sole-source products MAA and DTPA.

47. Other major manufacturers of radiopharmaceutical products include Curium, a joint venture between Mallinckrodt Nuclear Medicine LLC and IBA Molecular, GE Healthcare Inc. ("GE"), Lantheus Medical Imaging, Inc. ("Lantheus"), and Pharmalucence.

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[3] 10 C.F.R. §§35.11-12; https://nuclearpharmacy.uams.edu/nuclear-pharmacists/becoming-a-nuclear-pharmacist/.

[4] 10 C.F.R. §35.55.

[5] *Id.*

[6] *Id.*

48. Unlike traditional retail drug manufacturers, radiopharmaceutical manufacturers do not sell products to retail pharmacies in a form that can be dispensed directly to a patient. Instead, radiopharmaceutical manufacturers sell the radioactive and non-radioactive components separately to specialized nuclear pharmacies that prepare patient-ready doses. Nuclear pharmacies may be based at a hospital, but, more commonly, they are freestanding pharmacies that prepare patient-ready doses in response to hospital or imaging center orders. When a healthcare provider needs to perform a medical procedure or test that requires a certain radiopharmaceutical, the provider places an order for the radiopharmaceutical with a nuclear pharmacist who then prepares a dose of the medicine.

49. Broadly speaking, there are two types of radiopharmaceutical doses prepared by nuclear pharmacists: non-compounded doses that are drawn from manufacturer product containers and doses that are compounded.

50. Generally, non-compounded radiopharmaceuticals are "hot" products. These products are manufactured in multi-dose liquid vials, which contain a radioactive ingredient in a solution estimated to yield a defined quantity of radioactivity (typically expressed in millicuries ("mCi"), a unit used to measure the intensity of radioactivity in a sample of material). From these vials, nuclear pharmacists extract patient-ready doses into individual capsules or syringes intended to yield the amount of radioactivity ordered by the physician for the time of administration.

51. Because radiopharmaceutical products decay over time, the amount of radioactivity in the patient-ready dose at the time it is extracted at the pharmacy will generally be more than the amount in the dose at the time it is administered to the patient. Accordingly, the number of doses obtainable from a particular vial is indeterminate and will depend on the size of

the patient, the time of preparation in relation to the time of administration to the patient, radioactive decay rates, and other factors.

52. Compounded radiopharmaceuticals are the more common type of radiopharmaceutical. Preparing a compounded radiopharmaceutical consists of several steps. First, the nuclear pharmacist must produce the radioactive material needed for the radiopharmaceutical. The most commonly used isotope in nuclear medicine is Tc^{99m}, the daughter product of Molybdenum ("Mo^{99}"). In nuclear science, a "daughter product" is an isotope formed by the radioactive decay of some other isotope. Nuclear pharmacists attain Tc^{99m} by "milking" an onsite nuclear generator containing Mo^{99}. Milking involves passing sodium chloride over the Mo^{99} generator to elute, or remove, a Tc^{99m} solution. The Tc^{99m} solution, or eluate, is then collected in a shielded vial. In order to provide protection while handling radioactive material, most compounding is done behind leaded glass shielding and using leaded glass syringe shields and lead containers to hold the radioactive material.

53. After obtaining the radioactive eluate, the nuclear pharmacist "tags" or "radiolabels" the non-radioactive materials—which are contained in a cold kit—with the radioactive material. Radiopharmaceutical manufacturers produce dozens of types of cold kits which contain all the materials necessary for a nuclear pharmacist to prepare a radiopharmaceutical except for the radioactive material. Cold kits contain a specific molecular compound—"ligand" or "reagent"—that is known to localize in a specific area of the body. The contents of cold kits are lyophilized, a type of freeze-drying used for organic matter. Using a shielded syringe, the Tc^{99m} solution is added directly into the vial containing the ligand which reconstitutes the lyophilized material in the vial and brings about the chemical reaction necessary for binding the radioactive isotope to the ligand.

54. The vial is then tested. Radio-chromatography is the most-often used test to determine the purity and identity of radioactive materials. Radiochemical purity measures the percent of tagged and untagged-Tc^{99m} present in a dose of medicine. The cold kit's product insert provides the minimum radiochemical purity required for administration. The product insert for DTPA, for example, states that an injection should only be used "if the radiochemical purity is 90% or greater."[7]

55. For certain radiopharmaceuticals, such as MAA, the nuclear pharmacist must also ensure that the particle size is acceptable. For MAA, "at least 90% of all particles must be in the range of 10-90 micrometers."[8] If the test shows a properly prepared radiopharmaceutical, the medicine is delivered to a healthcare provider in a syringe for administration. An indeterminate number of patient-ready doses can be extracted into individual syringes from the radiolabeled vial.

56. Because of the short half-life of Tc^{99m} (approximately 6 hours), radiopharmaceuticals need to be prepared and delivered to the ordering physician quickly. Thus, hospitals and clinics prefer nuclear pharmacies located close to their facilities so doses can be delivered within a short time frame.

57. In general, radiopharmaceutical preparations derived from cold kits are intended for use within 12 hours of being reconstituted. Any unused reconstituted product must then be discarded.

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[7] DTPA Product Insert, *available at* https://www.draximage.com/wp-content/uploads/2016/11/DTPA-PI-Dec-2017-1.pdf.

[8] https://nucmedtutorials.files.wordpress.com/2018/03/pulmonary-perfusion-imaging-with-tc-99m-maa.pdf.

D. Fractionation

58. Some procedures requiring nuclear medicine are less common than others. For less common procedures, on a daily basis, a nuclear pharmacy uses a smaller quantity of the required radiopharmaceutical product than it uses for other, more common procedures. For instance, a nuclear pharmacy might only receive three orders per day of MAA, a compounded radiopharmaceutical necessary to perform a ventilation/perfusion ("V/Q") scan, a lung imaging test so named because it studies both airflow (ventilation) and blood flow (perfusion) in the lungs (the initials V-Q are used in mathematical equations that calculate airflow and blood flow). Cold kits used to prepare MAA, as well as other cold kits, however, contain large amounts of reagent sufficient for radiolabeling multiple patient-ready doses of medicine.

59. To reduce waste and mitigate costs when preparing compounded radiopharmaceuticals, a nuclear pharmacist may engage in a practice called "fractionating." Fractionating refers to the process of reconstituting the lyophilized contents of a cold kit with normal saline, transferring aliquots, or portions, of the solution into separate vials for radiolabeling, and storing the vial containing the surplus, non-radioactive contents of the cold kit in a freezer for radiolabeling at a later date. This process allows a nuclear pharmacist to prepare just the right amount of doses of medicine requested for that day and to preserve any excess amounts of cold kit reagent for future use without having to discard it.

60. By way of example, every vial of JDI's MAA cold kit contains at least three million particles of lyophilized materials; specifically, albumin aggregated, human serum albumin, stannous chloride, and sodium chloride. Some vials may contain up to eight million particles. Per JDI, the recommended number of particles per single injection of Tc^{99m} MAA Injection for adults is 200,000 to 700,000 with the suggested number being approximately

350,000.[9] For children and other sensitive patients, the recommended number of particles is lower. For instance, patients with pulmonary hypertension may require a reduction of particles to 100,000, and failure to observe this can have serious or fatal repercussions for the patient. Similarly, pediatric patients may require particle counts as low as 50,000-60,000. Fractionation allows nuclear pharmacists to effectively prepare doses with lower particle counts when patient needs demand such doses. Moreover, because the number of particles contained in a kit is so much higher than the amount actually needed to prepare a dose of MAA, a nuclear pharmacist likely will not need to use an entire kit in one day. Fractionation provides nuclear pharmacists with an efficient, cost-effective way to preserve excess amounts of the reagent.

61. Fractionation also provides nuclear pharmacists with an optimal way to handle unscheduled emergency requests for preparation of a radiopharmaceutical received outside of normal business hours. For instance, a nuclear pharmacy preparing a single dose of MAA for a late-night emergency lung scan will use only a small portion of the entire multi-use vial. Unless the cold kit is fractionated, the vast majority of it will be wasted. The nuclear pharmacy will have radiolabeled an entire kit for that single emergency dose, and it may be the case that too many hours will pass before another dose will be ordered, making those remaining MAA doses unusable the next business day. For nuclear pharmacies to provide emergency, "on call" services in an economically viable way, fractionation is imperative.

62. Because a nuclear pharmacist is required to test each radiopharmaceutical before delivering it to a physician or other provider for administration, a nuclear pharmacist is able to confirm that a vial of medicine created with a fractionated cold kit vial is of the proper radiochemical purity and is in no way inferior to a dose created using a non-fractionated vial.

[9] https://www.draximage.com/wp-content/uploads/2016/11/MAA-PI-Oct-2017-1.pdf.

63. A study published in 2013 examined the feasibility of fractionation of MDP and DTPA cold kits and confirmed that the diagnostic images created with radiopharmaceuticals that had been previously fractionated "were of acceptable quality" and had adequate radiochemical purity measurements.[10] The study concluded that "[f]ractionation of common cold kits can be practiced as a cost saving method if done with proper technique in low volume departments."[11]

64. The United States Pharmacopeial Convention is a nonprofit scientific organization that develops and publishes quality standards for drug substances, drug products, excipients, and dietary supplements. Those standards are published in *USP-NF*, a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Under the Federal Food, Drug and Cosmetic Act, "[t]he term 'official compendium' means the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them."[12] In June 2019, USP, General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, was updated and provided revised standards related to compounding radiopharmaceuticals. The revised standards make clear that fractionation is an appropriate nuclear pharmacy practice when performed properly:

> Kit-splitting (also referred to as "fractionation") may be used to meet patient need. For example, the contents of a kit vial can be reconstituted with 0.9% sodium chloride injection and aliquoted into other containers for storage and subsequent radiolabeling. The individual responsible must consider all possible interactions of kit components with these other containers (e.g., container walls, closures), as well as possible alterations in stability (e.g., physical

[10] Nisha Bhatia & Vandana Kumar Dhingra, *Fractionation of common cold kits as a cost-saving method in a low volume nuclear medicine department*, Indian Journal of Nuclear Medicine, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3868035/.

[11] *Id.*

[12] Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 (2012)

> stability, chemical stability) that may affect radiolabeling yields or performance parameters . . . .[13]

65. There is no substantiated evidence that fractionation has an adverse impact on patient care. In fact, *decades* of practice confirm that the practice of fractionating is safe and effective.

66. Fractionating is an industry standard practice in nuclear pharmacy. It is widely known and accepted that most pharmacies, including nuclear pharmacies that are part of large pharmacy networks, engage in fractionation. Fractionation is an important component of a pharmacy's economic sustainability due to the high cost of certain radiopharmaceuticals.

VII. RELEVANT MARKET

A. Relevant Product Markets

67. There are five relevant product markets in this case: (1) the market for cold kits designed for the preparation of Tc^{99m} MAA injections; (2) the market for cold kits designed for the preparation of Tc^{99m} DTPA injections; (3) the market for cold kits designed for the preparation of Tc^{99m} MDP; (4) the market for cold kits designed for the preparation of Tc^{99m} Sestamibi injections; and (5) the market for Sodium Iodine I-131 (together the "Relevant Products").

68. Each of the markets for the Relevant Products is a distinct product market because it is distinguishable in the eyes of radiopharmaceutical manufacturers, radiopharmacies, and end-user healthcare professionals. Each Relevant Product is used for a specific nuclear medicine imaging test or therapeutic treatment and is not reasonably interchangeable with other products.

[13] General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, Section 11.2.

1. MAA

69. JDI is the sole supplier of cold kits designed for the preparation of Tc^{99m} MAA injections in the United States.

70. MAA was first introduced into clinical medicine in the early 1960s. After U.S. Food and Drug Administration (FDA) approval, in the early 1970s, many companies began marketing MAA tagged with the nuclear isotope Tc^{99m}. These included Mallinckrodt (now known as Curium), CIS-US (now known as Pharmalucence), and Merck–Frost (that later became JDI).

71. Once tagged with Tc^{99m}, MAA functions as a lung-imaging agent used as an adjunct during the perfusion stage of a V/Q scan. MAA is the only radiopharmaceutical currently available in the U.S. for imaging perfusion in the lungs. MAA may also be used in adults as an imaging agent to aid in the evaluation of peritoneovenous shunt patency.

72. A V/Q scan is a nuclear medicine procedure that uses radioactive material to assess the flow of air and blood in the lungs. Physicians use it to detect pulmonary embolism or other lung irregularities. Pulmonary embolism is common. Studies have estimated that as many as one million people in the United States are affected by pulmonary embolism per year, with 100,000 to 200,000 of these being fatal.

73. A V/Q scan consists of two different tests, a perfusion scan and a ventilation scan. The scans are typically performed together but can be done separately. If the patient's lungs are properly functioning, the two scans will match. If the images differ, the patient may have a blood clot.

74. During the perfusion phase, a health care provider injects MAA intravenously. The lungs are then scanned by a special camera that detects the distribution of blood flow in the

lungs. If the patient does have a blood clot, the images from this scan will reveal areas of the lungs that are not receiving enough blood.

75. For many patients, there is no substitute for a V/Q scan. While a computed tomography scan ("CT scan") may be suitable for diagnosing pulmonary embolism in a select patient population, the effective radiation dose to the patient is considerably higher, making it inappropriate—or even dangerous—for many individuals. For instance, CT scans pose a greater risk to females, as the effective radiation dose to the breast is 20–40 times greater with a CT scan than V/Q. The higher radiation exposure of CT scans can lead to an increased risk of developing breast cancer.

76. JDI's MAA cold kit is a product with a unique indication and lacks readily available substitutes. Therefore, nuclear pharmacies, including Ionsouth and members of the Class, are at a severe competitive disadvantage unless they carry it.

2. DTPA

77. JDI is the sole supplier of cold kits designed for the preparation of Tc^{99m} DTPA injections in the United States.

78. As with MAA, DTPA has been in existence for many years and was previously manufactured by others, including Pharmalucence.

79. DTPA is a widely used nuclear medicine imaging agent with a variety of indications, including renal and brain imaging. It is the only renal radiopharmaceutical available that can be used to measure glomerular filtration rate, the best test to measure a patient's level of kidney function.

80. In 2018, the FDA approved pulmonary indications for JDI's DTPA. JDI's DTPA cold kit is now indicated to be used in aerosol form in conjunction with MAA to perform a V/Q scan. Specifically, it is used during the ventilation part of the test.

81. During the ventilation scan, the patient breathes in a radioactive gas, such as DTPA, through a mask or tube and is scanned again. The scanner picks up the distribution pattern of the inhaled radioisotope in the lungs.

82. JDI's DTPA is a product with unique indications; it lacks readily available substitutes. Therefore, nuclear pharmacies, including Ionsouth and members of the Class, are at a severe competitive disadvantage unless they carry it.

3. MDP

83. JDI produces MDP, a cold kit designed for the preparation of Tc^{99m} Medronate.

84. MDP cold kits are used to prepare an imaging agent indicated for examining imperfections in a patient's bones. Using an MDP injection for bone scintigraphy is highly effective and, since the 1970s, it has been considered the primary choice for nuclear imaging of the skeletal system.

85. The bone imaging capabilities of MDP are unique to the product.

86. Pharmalucence currently manufactures a competing product. [redacted]

4. Sestamibi

87. JDI produces a cold kit designed for the preparation of Tc^{99m} Sestamibi injection.

88. This kit is used to prepare a myocardial perfusion agent indicated for detecting coronary artery disease and evaluating myocardial function.

89. Lantheus was the first company to produce a cold kit designed to prepare Tc^{99m} Sestamibi injections. Lantheus continues to sell its Sestamibi cold kits under the brand name Cardiolite®.

90. Generic Sestamibi cold kits became available in 2008. In addition to JDI, Curium and Pharmalucence currently manufacture generic Sestamibi cold kits. [redacted]

[redacted]

5. Sodium Iodine I-131

91. JDI also produces Sodium Iodine I-131 Solution, which it sells under the brand name HICON®.

92. Sodium Iodine I-131 Solution is not a cold kit. Instead, it is a "hot" radioactive therapeutic agent indicated for the treatment of hyperthyroidism and certain cases of thyroid cancer. I-131 radiotherapy has improved the survival rate of patients with differentiated thyroid cancers that have spread to the neck or other areas and has become the standard treatment for such cases.

93. While JDI currently has the only FDA-approved Sodium Iodine I-131 on the market, International Isotopes Inc. distributes Sodium Iodine I-131 as a radiochemical grade product. In November 2016, International Isotopes submitted an Abbreviated New Drug Application to the FDA for a sodium iodide radiopharmaceutical product. While FDA approval is pending, International Isotopes is able to sell its sodium iodide radiochemical product. As a radiochemical product, International Isotopes' sodium iodide is not subject to certain FDA standards, however, the product has the same indications and uses as JDI's Sodium Iodine I-131 Solution.

94. [redacted]

B. Relevant Geographic Market

95. For each of the Relevant Products, the relevant geographic market is the United States. Radiopharmaceutical manufacturers, such as JDI, ship their products to nuclear pharmacies located across the United States.

C. Barriers to Entry

96. There are significant barriers to entry in the relevant markets, including patent and other regulatory protections and high costs of entry and expansion.

97. In a 2018 earnings call, JDI's ultimate parent company, JLS, publicly acknowledged the high barriers to entry in the radiopharmaceuticals industry. When asked whether there was impending competition for JDI's products, CEO of JPL, Pramod Yadav, responded: "This business, as you may be aware, has quite a high entry barrier."[14]

98. In a 2017 earnings call, when asked whether competition would return for MAA specifically, JLS Chairman, Shyam S. Bhartia, stated: "MAA is a very difficult product to manufacture and that is why there are high entry barriers."[15]

99. The high barriers to entry are exacerbated by the JDI Master Agreement, [redacted] The JDI Master Agreement states:

[14] Jubilant Life Sciences, Q4 FY 2018 Earnings Conference Call, *available at*, http://www.aceanalyser.com/Conference%20Call/130019_20180509.pdf.

[15] Jubilant Life Sciences, Q2 & H1 FY 2017 Earnings Conference Call, *available at*, http://www.aceanalyser.com/Conference%20Call/130019_20161027.pdf.

100. This provision impedes the ability of any emerging JDI competitor competing on price to capture customers from JDI, creating another barrier to entry.

101. Mr. Bhartia pointed to this fact when asked about the emergence of potential competitors:

> We do not expect any competition in the short run in next 1–2 years' time but we never know, nobody knows in next 4–5 years if there is competition coming or not, it is very difficult to estimate that, but even then we have an excellent marketing infrastructure to market this product . . . . When we sign contract, we sign for 3 years like this year we will be signing. 3 years will be ending this year and will be signing another 3 years. So our market is, that way, very well protected . . . .[16]

[16] *Id.*

VIII. JDI's MARKET POWER

102. JDI has monopoly power in the markets for cold kits used to prepare Tc^{99m} MAA injections and for cold kits used to prepare Tc^{99m} DTPA injections. JDI has 100% of the market for both of these products in the United States.

103. JDI possesses monopoly power in the markets for Sodium Iodine I-131 and MDP. As of June 30, 2016, JDI claimed to have 64% of the market for I-131 and 74% of the market for MDP.[17]

IX. JDI's ANTICOMPETITIVE CONDUCT

A. JDI Acquired Competing NDAs for MAA and DTPA to Initiate Price Hikes

104. By 2011, JDI had become the sole supplier of MAA and DTPA cold kits in the United States. Even though JDI was the sole supplier of these kits, prices were relatively stable. In 2013, MAA and DTPA cold kits both cost $22.00 per vial.

105. While JDI was the only company manufacturing MAA and DTPA cold kits, Pharmalucence continued to hold valid NDAs for Pulmolite (Application No.: N017776) (the "Pulmolite NDA"), a branded-competing product to JDI's MAA cold kit, and for AN-DTPA (Application No.: N017714) (the "AN-DTPA NDA"), a competing DTPA cold kit. The existence of the Pulmolite NDA and the AN-DTPA NDA posed a real threat to JDI's monopolies in the MAA and DTPA cold kit markets.

106. In 2013, to foreclose the possibility of competing products coming onto the market and eroding its monopolies, JDI purchased the Pulmolite and AN-DTPA NDAs.

[17] Jubilant Pharma Limited, Senior Note Offering Memorandum, *available at* http://www.jubl.com/uploads/image/333imguf_Disclsoure_October7,2016.pdf.

107. Before JDI's acquisitions, at least two entities—UPPI and Lantheus—approached Pharmalucence about purchasing the Pulmolite NDA. Both wanted to market an MAA cold kit to compete with JDI's.

108. On two occasions, a UPPI director and two other UPPI members spoke to the then-president of Pharmalucence about purchasing the Pulmolite NDA. He told UPPI that he would not sell the Pulmolite NDA. A vice president of Lantheus also had unsuccessful discussions with Pharmalucence about purchasing the Pulmolite NDA.

109. Despite serious interest from UPPI and Lantheus, Pharmalucence sold the Pulmolite NDA to JDI in 2013.

110. By acquiring Pharmalucence's Pulmolite NDA and AN-DTPA NDA, JDI eliminated potential competitors from entering the markets for MAA and DTPA cold kits. JDI also refused to license products under these NDAs, ensuring that competing products would be blocked from entry. This conduct allowed JDI to unlawfully maintain its monopolies in the markets for MAA and DTPA cold kits.

111. JDI's post-purchase action makes its purpose clear. Having eliminated the threat of competition—and just months after it purchased the NDAs—JDI *significantly* raised prices for MAA and DTPA cold kits and sold them to its captive customers, Ionsouth and members of the Class, at supra-competitive prices.

112. Specifically, on February 25, 2014, JDI announced massive, market-wide price increases for MAA and DTPA cold kits. The price increases went into effect on March 1, 2014. The cost of a single vial of MAA went from $22 to $400, ***a 1718% increase***; the price of a vial of DTPA rose from $22 per vial to $138 per vial, ***a 527% increase***. Prior to this, between 2007 and 2014, year-to-year price increases for MAA and DTPA were never greater than 53%.

113. Since 2014, the prices of MAA and DTPA have continued to rise. [redacted]

114. These exorbitant price hikes transformed JDI from a $30 million-a-year company in 2012 to a $100 million-a-year company—the third largest radiopharmaceutical manufacturer by revenue in the United States.

115. While these price hikes have greatly enhanced JDI's bottom line, they have negatively affected patient care. Shortly after the price hikes, the Society of Nuclear Medicine and Molecular Imaging ("SNMMI") posted a letter stating that it was "deeply concerned about the long-term effects of the [price] increase on the volume of nuclear medicine lung scans."[18] SNMMI's concerns have come true: the price hikes have caused healthcare providers that are unable to absorb the higher costs to substitute CT scans for V/Q scans. While less expensive, CT scans expose patients to more radiation. The substitutions are being made on "purely economic grounds," rather than the best interest of patients.[19] A radiologist at Penn State Health's Hershey Medical Center has said that he thinks that "there's been considerable fallout in patient care. And it started with the price hikes."[20] Other hospitals have had to divert precious funds to cover for the price hikes. The Cleveland Clinic Foundation, for instance, indicated that it added an extra $1 million to its imaging department because of JDI's price increases.

[18] *Letter to the SNMMI Membership Regarding MAA*, *available at* https://web.archive.org/web/20160511001416/http://snmmi.rd.net/NewsPublications/NewsDetail.aspx?itemNumber=11245.

[19] Ed Silverman, *In an overlooked corner of pharma, drastic price hikes hit medicines for radiology scans*, STAT, *available at* https://www.statnews.com/pharmalot/2017/06/29/radiology-medicine-price-hike/.

[20] *Id.*

B. JDI's New Master Supply and Distribution Agreement Is Anticompetitive Because It Imposes Tying Arrangements and Other Onerous Restraints on Nuclear Pharmacies

116. In addition to blocking competing products from entering the market, JDI has engaged in other anticompetitive conduct to monopolize or attempt to monopolize the relevant markets for Multi-Source products and to unreasonably restrain trade.

117. Beginning in 2017, JDI began coercing nuclear pharmacies to enter into the JDI Master Agreement. The JDI Master Agreement contained several new provisions that were immediately met with resistance from nuclear pharmacies and UPPI. Despite the resistance, Ionsouth and members of the class have been forced to agree to the JDI Master Agreement in order to continue to procure JDI's Sole-Source Products.

118. The JDI Master Agreement is anticompetitive in at least four ways:

i. First, the Agreement imposes an unlawful tying obligation. In order to purchase JDI's MAA and DTPA cold kits—which they must—nuclear pharmacy customers must also commit to purchasing a guaranteed minimum amount of [redacted]

ii. Second, the JDI Master Agreement prohibits nuclear pharmacies from [redacted]

iii. Third, [redacted], the Agreement artificially inflates demand for its cold kits. For JDI's MAA and DTPA cold kits, the prohibition amounts to further monopoly maintenance and is an unreasonable restrain on trade. When—as here—excess product can be safely used for its

intended purpose, there is no pro-competitive justification for requiring the nuclear pharmacies to throw away the excess material and re-order more cold kits from JDI.

iv. Fourth, [redacted] After Triad Isotopes became JDI's affiliate, the danger that JDI could use competitively sensitive information it gleaned from its customers against them materialized.

1. Tying Arrangement

119. Beginning with the 2017 JDI Master Agreement, JDI has unlawfully tied the sale of its Sole-Source Products to the sale of its [redacted]

120. [redacted]

i. **Sodium Iodine I-131:** [redacted], in 2017, the contract price for JDI's Sodium Iodine I-131 was between [redacted] In 2017, Ionsouth and members of the Class were able to purchase Sodium Iodine from International Isotopes for [redacted]. Since 2017, [redacted]

ii. **MDP:** [redacted], in 2017, the contract price for JDI's MDP was between [redacted]. In 2017, Ionsouth and members of the Class were able to purchase MDP from Pharmalucence [redacted]

iii. **Sestamibi:** [redacted], in 2017, the contract price for JDI's Sestamibi was between [redacted]. In 2017, Ionsouth and members of the Class were able to purchase Sestamibi from Pharmalucence for [redacted]; from Lantheus for [redacted]; and from Curium for between [redacted]. [redacted]

121. In order to secure JDI's Sole-Source Products—MAA and DTPA cold kits— [redacted]

122. [redacted] This conduct has resulted in nuclear pharmacies and end users being forced to pay higher prices for Sodium Iodine I-131, MDP, and Sestamibi than they otherwise would pay in a competitive market free of JDI's anticompetitive restraints.

123. [redacted] The JDI Master

Agreement reads: [redacted]

124. [redacted] state pharmacy laws that allow pharmacies to purchase a percentage of the total number of units they dispense in a year from other pharmacies.

125. As the inventory of a nuclear pharmacy is dependent on its customer base, some nuclear pharmacies would be capable of satisfying their annual need of JDI products just by purchasing units from other pharmacies. [redacted]

126. There is no procompetitive reason for JDI to include such a limitation. The provision only exists to coerce nuclear pharmacies to enter into the JDI Master Agreement. This provision is an unreasonable restraint on trade and functions as further monopoly maintenance by JDI as it forecloses Ionsouth from [redacted]

127. [redacted] The JDI Master Agreement provides: [redacted]

128. [redacted] Fractionating is a decades-old industry practice in nuclear medicine. It permits the safe, effective, and efficient use of radiopharmaceutical products and encourages cost savings in patient care. [redacted]

130. JDI's cold kit products are multi-dose vials, which contain enough cold kit reagent for several doses. As the Council of Radionuclides and Radiopharmaceuticals (CORAR), an organization to which JDI belongs, has recognized, the number of patient-ready doses a nuclear pharmacist can prepare is "based on the amount of radioactivity ordered by the physician, the scheduled time for administration to the patient, and the decay rates."[21] Because of this, the actual number of doses a nuclear pharmacist can prepare with a multi-dose vial is "indeterminate."[22] It is not uncommon that the amount of reagent available in a JDI cold kit is greater than the amount needed to prepare the number of doses requested by healthcare providers on a given day.

131. Given the millions of particles in each multi-dose vial of MAA, a nuclear pharmacist could reasonably make at least eight doses of Tc^{99m} MAA Injection from a single vial

[21] Complaint at 12, *Council on Radionuclides and Radiopharmaceuticals, Inc. v. Azar et al.*, No. 18-cv-00633 (D.D.C., Mar. 19, 2018), ECF 1.

[22] *Id.*

of cold kit. Many nuclear pharmacies are unlikely to get eight requests for MAA in a single day. On an average day, smaller nuclear pharmacies, such as those servicing rural or less-populated markets, are unlikely to get more than three daily orders of Tc^{99m} MAA Injection from physicians.

132. The difference between the number of particles in a cold kit vial of MAA and the number of particles needed to make a single effective injection means that it is beneficial for a nuclear pharmacy to fractionate MAA cold kits to preserve extra lyophilized materials for use at a later date. Otherwise, the nuclear pharmacy must dispose of thousands of dollars' worth of safe and usable product.

133. Similarly, every 10 mL multi-dose vial of DTPA contains a sterile, non-pyrogenic, non-radioactive lyophilized powder of 20 mg of pentetic acid, 5 mg of p-aminobenzoic acid, 3.73 mg of calcium chloride dihydrate, and not less than 0.25 mg stannous chloride dihydrate and not more than 0.385 mg maximum tin expressed as stannous chloride dihydrate. The amount of reagent in the vial allows nuclear pharmacist to produce several doses of DTPA injection.

134. Similar to MAA, the difference between the amount of reagent in a cold kit vial of DTPA and the amount needed to make an effective injection means that it is beneficial for a nuclear pharmacy to fractionate DTPA cold kits to preserve extra lyophilized materials for use at a later date. Otherwise, again, the nuclear pharmacy would be forced to dispose of thousands of dollars' worth of safe and usable product.

135. Nuclear pharmacies, their customers, and patients benefit from the safe, effective, and efficient use of radiopharmaceuticals. [redacted]

[redacted], JDI acknowledged that efficient vial utilization by nuclear pharmacists was cutting into its profits. At the 2014 SNMMI Annual Meeting, a JDI vice president cited the fact that "radiopharmacies and our customers have become very skilled and efficient at increasing their vial utilization" as one justification for the MAA price increases.[23]

136. Notably, fractionation was an accepted practice at Triad Isotopes prior to it being acquired by JDI in 2017. [redacted]

137. [redacted] The provision is anticompetitive on its face.

138. [redacted]

[23] Kathy Mahdoubi, *MAA price spike: Jubilant DraxImage address dodges antitrust concern*, HealthImaging (June 13, 2014), *available at* https://www.healthimaging.com/topics/molecular-imaging/maa-price-spike-jubilant-draximage-address-dodges-antitrust-concern.

4. JDI's Product Monopolies Also Enable It to Impose

139. As set out in the agreement, a nuclear pharmacy must make all particularly MAA and DTPA—where it is a monopolist—and to enforce the Agreement's

140. Such information is of little relevance to JDI's radiopharmaceutical manufacturing business and is being collected for the benefit of JDI's nuclear pharmacy business, Triad Isotopes.

141. Nevertheless, it allows JDI to gain insights into the markets for Multi-Source Products and into products that it does not manufacture. Such information is especially valuable to JDI's nuclear pharmacy business, Triad Isotopes, as it deals in the distribution of these products and competes with Ionsouth and

members of the Class. [redacted] JDI to learn competitively sensitive information about Triad Isotopes' direct competitors.

142. When JPL announced the integration of JDI's radiopharmaceutical drug development and manufacturing business with Triad Isotopes' radiopharmacy business, it stated that "the company will be expanding its US radiopharmacy footprint."[24] [redacted] JDI is able to use the competitively sensitive business information it gains from nuclear pharmacies to eliminate competition in both areas where Triad Isotopes already has nuclear pharmacies and in areas where it does not (yet) have nuclear pharmacies. In fact, several independent nuclear pharmacies and/or UPPI members have closed their businesses [redacted]

145. [redacted] there was a plan in place to falsely report Ionsouth to the State Boards of Pharmacy for failing to keep sterile compounding procedures in compliance with USP, General Chapter <797> standards.

[24] https://www.draximage.com/introducing-jubilant-radiopharma/

146. The specific conduct aimed at Plaintiff Ionsouth is illustrative of JDI's broader goal to eliminate competition.

C. FTC Investigation

147. On September 24, 2018, JDI's parent company, JPL, disclosed that in May 2017 it was "notified that the United States Federal Trade Commission ('USFTC') had begun a non-public investigation into certain competition law matters relating to our sales and distribution practices in our radiopharmaceuticals business and our then pending acquisition of substantially all of the assets which comprised Triad's radiopharmacy business." Additionally, it disclosed that "[i]n February 2018, our Company and Triad received two civil investigative demands ('CIDs') from the USFTC requesting certain information about our business and operations."[25]

148. Upon information and belief, the FTC continues to actively investigate potentially anticompetitive conduct by JDI.

X. ANTITRUST IMPACT

149. JDI's anticompetitive practices, as alleged above, have restrained trade and have maintained and enhanced JDI's market power. JDI's conduct has harmed competition in the markets for the Relevant Products and has caused injury to Ionsouth and members of the Class.

150. JDI has maintained and enhanced its monopoly power in the markets for MAA and DTPA cold kits. JDI has foreclosed competition in the markets for these products and has established and maintained prices at artificially high levels. As a result of JDI's illegal conduct, Ionsouth and Class Members, and, consequently, their customers and consumers, have paid, and will continue to pay, artificially inflated prices for MAA and DTPA cold kits. The prices paid are

[25] Jubilant Pharma Ltd., Supplemental Information (Sept. 24, 2018), *available at* http://www.jubl.com/Uploads/image/914imguf_Supplemental_Information_24_09_2018.pdf.

substantially higher than prices that Ionsouth and Class Members would have paid absent the illegal conduct alleged in this complaint.

151. JDI has unlawfully exercised its monopoly power in the markets for MAA and DTPA cold kits by conditioning nuclear pharmacies' purchases of these cold kits on the additional purchase of a guaranteed minimum amount of [redacted] JDI's actions have foreclosed a substantial volume of commerce in the markets for Multi-Source Products. JDI has deprived competing radiopharmaceutical manufacturers of free and open access to the markets for Sodium Iodine I-131, MDP, and Sestamibi. At the same time, JDI has prevented nuclear pharmacies, like Ionsouth and members of the Class, from purchasing [redacted], forcing them to pay JDI's supra-competitive prices. Such conduct constitutes an unlawful tying arrangement and restraint of trade in violation of federal antitrust law under either a *per se* or rule of reason analysis.

152. JDI's prohibitions [redacted] are yet additional unlawful restraints that have caused Ionsouth and members of the Class to incur unnecessary costs and to lose profits.

XI. PLAINTIFFS' CLAIMS ARE TIMELY

153. This complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Ionsouth and members of the Class are entitled to recover damages they suffered during the limitations period.

154. A cause of action accrued for Ionsouth and members of the Class each time Ionsouth or members of the Class: (i) purchased MAA or DTPA cold kits from JDI at inflated prices; (ii) were required to purchase [redacted] from JDI; or (iii) incurred costs and

lost profits as a result of the restraints on competition that exist in the Master Supply Agreement. JDI's coercion of nuclear pharmacies to sign the JDI Master Agreement in 2017 and every subsequent sale of MAA and DTPA cold kits or [redacted] tied to MAA and DTPA cold kits also constitute overt acts in furtherance of JDI's anticompetitive scheme.

XII. CLASS ACTION ALLEGATIONS

155. Ionsouth brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, seeking equitable relief, injunctive relief, and treble damages on behalf of the following class (the "Class"):

> All entities that purchased the Sole-Source Products directly from JDI in the United States beginning at least as early as August 12, 2015 until the effects of Defendant's conduct ceases (the "Sole-Source Product Class Period") or purchased the Multi-Source Products directly from JDI in the United States at least as early as January 1, 2017 until the effects of Defendant's conduct ceases (the "Multi-Source Product Class Period").

156. The following persons and entities are excluded from the above-described proposed Class:

i. Defendant and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

ii. All governmental entities;

iii. All Counsel of Record; and

iv. The Court, Court personnel, and any member of their immediate families.

157. Members of the Class are so numerous and geographically dispersed that joinder of all members of the Class is impracticable. Plaintiffs believe that there are hundreds of members of the Class widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual

claims and join them together. The Class is readily identifiable from information and records in Defendant's possession.

158. Ionsouth's claims are typical of the claims of members of the Class. Ionsouth and members of the Class were harmed by the same wrongful conduct by Defendant.

159. Ionsouth will fairly and adequately protect and represent the interests of the members of the Class. Ionsouth's interests are coincident with, and not antagonistic to, those of the members of the Class.

160. Ionsouth is represented by counsel with experience in the prosecution of class action antitrust litigation and with experience in class action antitrust litigation involving pharmaceutical products.

161. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual members of the Class. JDI acted on grounds generally applicable to the entire class, making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendant's wrongful conduct.

162. Questions of law and fact common to the Class include:

i. Whether JDI maintained or enhanced monopoly power in the MAA and DTPA cold kit markets;

ii. Whether JDI maintained or attempted to acquire or maintain monopoly power in the markets for the Multi-Source Products;

iii. Whether JDI's actions, in whole or in part, have substantially affected interstate commerce;

iv. Whether JDI's conduct, as alleged, caused injury to the business and property of Ionsouth and other members of the Class;

v. Whether the JDI Master Agreement imposes an unlawful tying arrangement on Ionsouth and members of the Class;

vi. Whether the tying arrangement in the JDI Master Agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of Ionsouth and the members of the Class;

vii. Whether the JDI Master Agreement is a contract that unreasonably restrains trade;

viii. The proper measure of damages; and

ix. The scope and nature of the equitable relief for Ionsouth and members of the Class.

163. 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 engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

164. Ionsouth knows of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

XIII. CLAIMS FOR RELIEF

COUNT I
Violation of 15 U.S.C. § 2
Monopolization of MAA And DTPA Markets

165. Plaintiffs incorporate the preceding paragraphs by reference.

166. JDI has, and at all relevant times had, monopoly power in the market for sale of MAA and DTPA cold kits in the United States. Since at least as early as 2013 JDI has engaged in various activities to maintain and enhance its monopoly power in the MAA and DTPA cold kit markets.

167. As a direct, substantial, and proximate result of JDI's anticompetitive and unlawful actions, Ionsouth and members of the Class have been injured in their business or property in an amount to be established at trial. Ionsouth and members of the Class are each entitled to treble damages for JDI's violations of the Sherman Act alleged herein.

168. Ionsouth and members of the Class are threatened with future injury to their business and property unless the injunctive relief requested is granted. UPPI's nuclear pharmacy members are threatened with future injury to their business and property unless the injunctive relief requested is granted.

COUNT II
Violation of 15 U.S.C. § 1 and Clayton Section 3
Unlawful Tying

169. Plaintiffs incorporate the preceding paragraphs by reference.

170. Beginning in January 2017, JDI has engaged in an unlawful tying scheme in unreasonable restraint of trade and commerce in violation of Section 1 of the Sherman Act and Section 3 of the Clayton Act.

171. JDI has tied the sale of its Sole-Source Products (the tying products) to the purchase of its [redacted] (the tied products) by withholding its Sole-Source Products altogether unless a nuclear pharmacy agrees to purchase specified amounts of JDI's [redacted]

172. Each of the individual products in JDI's Master Agreement are separate and distinct products that are used for different applications and are not functionally interchangeable.

173. At all times relevant to this action, JDI has had monopoly power in the relevant markets for MAA and DTPA cold kits. Moreover, there are high barriers to entry in the market for MAA and DTPA, including both technological and regulatory barriers.

174. JDI used its monopoly power in the markets for its Sole-Source Products to coerce nuclear pharmacies to purchase [redacted]

175. [redacted]

176. The amount of interstate commerce affected by JDI's unlawful tying is not insubstantial.

177. JDI's conduct in conditioning the sale of its Sole-Source Products on the purchase of its [redacted] constitutes an illegal tying agreement and is a *per se* violation of Section 1 of the Sherman Act (15 U.S.C. § 1) and Section 3 of the Clayton Act (15 U.S.C. § 14). In the alternative, JDI's conduct is unlawful under the rule of reason, in that any purported pro-competitive justification for the tie is outweighed by the anticompetitive effects in the markets for [redacted]

178. There is no legitimate business or pro-competitive justification for JDI's conduct, and any purported legitimate business justifications are mere pretexts. Even if such a justification existed, any purported pro-competitive benefits could be achieved through alternative means less restrictive of competition.

179. As a direct, substantial, and proximate result of JDI's anticompetitive and unlawful actions, Ionsouth and members of the Class have been injured in their business or property in an amount to be established at trial. Ionsouth and members of the Class are each entitled to treble damages for JDI's violations of the Sherman Act alleged herein.

180. Ionsouth and members of the Class are threatened with future injury to their business and property unless the injunctive relief requested is granted. UPPI's nuclear pharmacy members are threatened with future injury to their business and property unless the injunctive relief requested is granted.

COUNT III
Violation of 15 U.S.C. § 2
Monopolization of MDP and Sodium Iodine I-131 Markets

181. Plaintiffs incorporate the preceding paragraphs by reference.

182. At all times relevant to this action, JDI had monopoly power in the markets for cold kits used to prepare Tc^{99m} MDP and the market for Sodium Iodine I-131. As of June 30, 2016, JDI purported to have 74% of the market share for MDP and 64% of the market share for I-131.[26]

183. JDI has engaged in anticompetitive conduct designed to foreclose competition on the merits in the relevant markets for these products and thereby willfully maintained or enhanced its monopoly in these markets.

184. JDI's anticompetitive conduct has decreased price competition in the markets for MDP cold kits and Sodium Iodine I-131 and deprived purchasers of free and open choice.

185. There is no legitimate business or pro-competitive justification for JDI's conduct, and any purported legitimate business justifications are mere pretexts. Even if such a justification

[26] http://www.jubl.com/uploads/image/333imguf_Disclsoure_October7,2016.pdf

existed, any purported pro-competitive benefits could be achieved through alternative means that are less restrictive of competition.

186. As a direct, substantial, and proximate result of JDI's anticompetitive and unlawful actions, Ionsouth and members of the Class have been injured in their business or property in an amount to be established at trial. Ionsouth and members of the Class are each entitled to treble damages for JDI's violations of the Sherman Act alleged herein.

187. Ionsouth and members of the Class are threatened with future injury to their business and property unless the injunctive relief requested is granted. UPPI's nuclear pharmacy members are threatened with future injury to their business and property unless the injunctive relief requested is granted.

COUNT IV
Violation of 15 U.S.C. § 2
Attempted Monopolization of MDP, Sestamibi, and Sodium Iodine I-131 Markets

188. Plaintiffs incorporate the preceding paragraphs by reference.

189. JDI specifically intended to monopolize the markets for Sodium Iodine I-131 and cold kits used to prepare Tc^{99m} MDP and Tc^{99m} Sestamibi injections. There is a dangerous probability of JDI succeeding in monopolizing these markets.

190. In furtherance of this attempt, JDI has engaged in anticompetitive conduct, as alleged in this complaint, to foreclose competition in the markets for MDP and Sestamibi cold kits and Sodium Iodine I-131.

191. JDI's anticompetitive conduct has increased prices in the markets for MDP and Sestamibi cold kits and Sodium Iodine I-131 and deprived purchasers of free and open choice.

192. There is no legitimate business or pro-competitive justification for JDI's conduct, and any purported legitimate business justifications are mere pretexts. Even if such a justification

existed, any purported pro-competitive benefits can be achieved through alternative means less restrictive of competition.

193. Should JDI be successful in maintaining its desired anticompetitive conduct, there is a dangerous probability that it will succeed in achieving monopoly power in the markets for MDP and Sestamibi cold kits and Sodium Iodine I-131.

194. As a direct, substantial, and proximate result of JDI's attempt to monopolize the markets for MDP and Sestamibi cold kits and Sodium Iodine I-131, Ionsouth and members of the Class have been injured in their business property and trade in an amount to be established at trial. Ionsouth and members of the Class are each entitled to treble damages for JDI's violations of the Sherman Act alleged herein.

195. Ionsouth and members of the Class are threatened with future injury to their business and property unless the injunctive relief requested is granted. UPPI's nuclear pharmacy members are threatened with future injury to their business and property unless the injunctive relief requested is granted.

COUNT V
Violation of 15 U.S.C. § 1 and Clayton Section 3
Contract in Restraint of Trade

196. Plaintiffs incorporate the preceding paragraphs by reference.

197. As set forth above, JDI has used its monopoly power in the markets for MAA and DTPA cold kits to force its customers, Ionsouth and members of the Class, to enter into the JDI Master Agreement. The JDI Master Agreement includes written exclusionary provisions that act as unreasonable restraints on trade.

198. [redacted]

[redacted]

199. These provisions: (a) substantially foreclosed and excluded competition in the markets for JDI Sole-Source and Multi-Source products; (b) resulted in JDI maintaining its monopoly power in the markets for the Sole-Source products; (c) allowed JDI to extract unlawful profits from Ionsouth and members of the Class; and (d) enabled JDI to glean competitively sensitive information about Triad Isotopes' competitors.

200. There is no legitimate business or pro-competitive justification for JDI's conduct, and any purported legitimate business justifications are mere pretexts. Even if such a justification existed, any purported pro-competitive benefits can be achieved through alternative means less restrictive of competition.

201. As a direct, substantial, and proximate result of JDI's anticompetitive and unlawful actions, Ionsouth and members of the Class have been injured in their business or property in an amount to be established at trial. Ionsouth and members of the Class are each entitled to treble damages for JDI's violations of the Sherman Act alleged herein.

202. Ionsouth and members of the Class are threatened with future injury to their business and property unless the injunctive relief requested is granted. UPPI's nuclear pharmacy members are threatened with future injury to their business and property unless the injunctive relief requested is granted.

COUNT VI
Unjust Enrichment

203. Plaintiffs incorporate the preceding paragraphs by reference.

204. Alternatively, from the acts of JDI as alleged above, JDI has been unjustly enriched at the expense of Ionsouth and members of the Class.

205. JDI has knowingly accepted and retained a financial benefit [redacted] By interfering with this standard practice of nuclear pharmacy, Ionsouth and members of the Class had to purchase more JDI cold kits than they needed or desired. It is against equity and good conscience to permit JDI to retain any profits from sales made on account of this policy.

206. [redacted] The Court should issue a trust compelling JDI to disgorge to Ionsouth and members of the Class all unlawful or inequitable proceeds

XIV. DEMAND FOR JUDGMENT

207. Accordingly, Ionsouth, on behalf of itself and the proposed Class, and UPPI respectfully demand that this Court:

i. 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, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to members of the Class, and declare Ionsouth as the representative of the Class;

ii. Enter a judgment against the Defendant and in favor of Plaintiffs and members of the Class;

iii. Award Ionsouth and members of the Class damages, trebled, in an amount to be determined at trial;

iv. Permanently enjoin Defendant and its agents and employees from enforcing [redacted]

v. Grant Plaintiffs and members of the Class all other equitable relief in the nature of disgorgement, restitution, and/or the creation of a constructive trust to remedy Defendant's unjust enrichment;

vi. Award Plaintiffs and members of the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

vii. Award such further and additional relief the Court may deem just and proper.

XV. JURY DEMAND

208. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury on all issues so triable.

DATED: August 12, 2019

By: */s/ Douglas L. McCoy*

Douglas L. McCoy
HAND ARENDALL HARRISON SALE LLC
Merchants Plaza
104 Saint Francis Street, Suite 300
Mobile, AL 36602
Telephone: 251-694-6255
DMccoy@handfirm.com

Gregory S. Asciolla (*pro hac vice pending*)
Jay L. Himes (*pro hac vice pending*)
Christopher J. McDonald (*pro hac vice pending*)
Robin A. van der Meulen (*pro hac vice pending*)
Jonathan S. Crevier (*pro hac vice pending*)
LABATON SUCHAROW LLP
140 Broadway
New York, New York 10005
Telephone: (212) 907-0700
gasciolla@labaton.com
jhimes@labaton.com
cmcdonald@labaton.com
rvandermeulen@labaton.com
jcrevier@labaton.com

Attorneys for Ionsouth and the Proposed Class

—and—

Jeffrey S. Jacobovitz (*pro hac vice pending*)
ARNALL GOLDEN GREGORY LLP
1775 Pennsylvania Ave., N.W.
Suite 1000
Washington D.C. 20008
Telephone: (202) 677-4056
Jeffrey.jacobovitz@agg.com

Attorneys for UPPI, LLC