Douglas R. Weider
James L. Ryerson
GREENBERG TRAURIG LLP
500 Campus Drive Suite 400
Florham Park, NJ 07932
(973) 360-7900
weiderd@gtlaw.com
ryersonj@gtlaw.com

Additional counsel listed on signature page

Attorneys for Plaintiffs GE Healthcare Limited and Medi-Physics Inc., dba GE HealthCare

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

GE HEALTHCARE LIMITED, MEDI-PHYSICS INC., DBA GE HEALTHCARE, Plaintiffs, v. JUBILANT DRAXIMAGE INC., D.B.A. JUBILANT RADIOPHARMA, Defendant.	Civil Action No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GE Healthcare Limited ("GEHC Ltd.") and Medi-Physics Inc., dba GE HealthCare ("Medi-Physics") (collectively, "Plaintiffs") for their Complaint against Defendant Jubilant DraxImage Inc., d.b.a. Jubilant Radiopharma ("Jubilant" or "Defendant"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.* This action relates to Abbreviated New Drug Application ("ANDA") No. 217224 filed by Jubilant with the United States Food and Drug Administration ("FDA"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic version of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection) prior to the expiration of U.S. Patent No. 9,549,999 ("the '999 Patent").

PARTIES

2. Plaintiff GEHC Ltd. is a corporation organized and existing under the laws of the United Kingdom, having its principal place of business at Pollards Wood, Nightingales Lane, Chalfont St. Giles, United Kingdom HP8 4SP. GEHC Ltd. researches and develops innovative pharmaceutical products, including radiopharmaceutical products. GEHC Ltd. is the assignee of and owns the '999 Patent. Additionally, GEHC Ltd. is engaged in the development and commercialization of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection), and GEHC Ltd. participates in the flow of proceeds and records profits from U.S. sales of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection).

3. Plaintiff Medi-Physics is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 251 Locke Dr., Marlborough, Massachusetts, 01752. Medi-Physics develops, manufactures, and distributes diagnostic imaging agents and radiopharmaceutical products. Medi-Physics holds New Drug Application ("NDA") No. 20372 for MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection). Additionally, Medi-Physics is the exclusive distributor of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection) in the U.S., has certain rights in the '999 patent by license, and participates in the flow of proceeds and records profits from U.S. sales of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection).

4. On information and belief, Defendant Jubilant is a company organized and existing under the laws of Canada with a principal place of business at 16751 TransCanada Highway, Kirkland, Québec, Canada, H9H 4J4. Jubilant is registered with the State of New Jersey's Department of the Treasury's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID Number 0101056743 and has appointed CT Corporation System, 820 Bear Tavern Road, West Trenton, NJ, 08628 as its registered agent for service of process in New Jersey. On information and belief, Jubilant is in the business of, among other things, developing, manufacturing, importing, marketing, distributing, offering to sell, and/or selling radiopharmaceutical products in New Jersey and throughout the United States, and obtaining regulatory approval for radiopharmaceutical products that it markets, distributes, offers to sell, and/or sells in New Jersey and throughout the United States.

JURISDICTION AND VENUE

5. This action for patent infringement arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Jubilant is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including this District.

8. Additionally, Jubilant previously has not contested venue in this jurisdiction. *See Bracco Diagnostics Inc. v. Jubilant DraxImage Inc. et al.*, No. 3:18-cv-04422-MAS-TJB.

9. This Court has personal jurisdiction over Jubilant by virtue of its specific acts in, and its continuous and systematic contacts with, the State of New Jersey.

10. Specifically, this Court has personal jurisdiction over Jubilant by virtue of, among other things: (1) its substantial, continuous, and systematic contacts with New Jersey; (2) its acts of patent infringement that will result in foreseeable harm to Plaintiffs in New Jersey; (3) its sale and offer for sale of radiopharmaceutical products throughout the United States, including in New Jersey; and (4) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and its appointment of a registered agent in New Jersey for receipt of service of process.

11. Jubilant has purposefully availed itself of the benefits and protections of New Jersey's laws such that it would reasonably anticipate being haled into court here. On information and belief, Jubilant has sold a substantial volume of radiopharmaceutical products in New Jersey, including a substantial volume of generic radiopharmaceutical products. On

information and belief, Jubilant conducts marketing and sales activities in New Jersey, including but not limited to the systematic and continuous importation, distribution, marketing, offer for sale, and sale of radiopharmaceutical products to New Jersey residents. On information and belief, Jubilant develops and manufactures radiopharmaceutical products for importation into and marketing and sale within the United States, including New Jersey. Therefore, Jubilant transacts business within New Jersey and/or has engaged in systematic and continuous business contacts within New Jersey.

12. Further, Jubilant has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including harm and injury in New Jersey. For example, on information and belief, Jubilant developed a generic version of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection), has filed ANDA No. 217224 with the FDA to secure approval from the FDA to sell a generic version of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection) in New Jersey and throughout the United States, is actively preparing to make a generic version of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection) that is the subject of ANDA No. 217224, and is preparing to commercially manufacture, use, sell, offer to sell, and/or import such a generic version in New Jersey and this Judicial District. Plaintiffs' claims for patent infringement arose as a result of these acts and Jubilant sending the required notice of its ANDA filing.

13. Jubilant previously has not contested the jurisdiction of this Court. *See Bracco Diagnostics Inc. v. Jubilant DraxImage Inc. et al.*, No. 3:18-cv-04422-MAS-TJB.

14. Additionally, this Court will have personal jurisdiction over Jubilant under Fed. R. Civ. P. 4(k) once Plaintiffs either serve a summons or file a waiver of service.

15. Litigating in the District of New Jersey would not unduly burden Jubilant. Among other things, the United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Plaintiffs have a substantial interest in obtaining convenient and effective relief for violations of their property interests. In addition, New Jersey has an interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

16. For the above reasons, it would not be unfair or unreasonable for Jubilant to litigate this action in this District, and the Court has personal jurisdiction over Jubilant.

PLAINTIFFS' MYOVIEW™ 30 mL (KIT FOR THE PREPARATION OF TECHNETIUM Tc99m TETROFOSMIN FOR INJECTION)

17. Plaintiff Medi-Physics is the holder of NDA No. 20372 that has been approved by the FDA for the manufacture and sale of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection) ("MYOVIEW™ 30 mL kit").

18. The MYOVIEW™ 30 mL kit is approved by the FDA for the preparation of technetium Tc99m tetrofosmin for injection. Technetium Tc99m tetrofosmin is a radioactive diagnostic agent indicated for: (1) myocardial perfusion imaging under rest and/or exercise or pharmacologic stress conditions to delineate regions of reversible myocardial ischemia or infarcted myocardium in patients with known or suspected coronary artery disease; and (2) assessment of left ventricular function (left ventricular ejection fraction and wall motion) in patients with known or suspected heart disease.

19. Under NDA No. 20372, the MYOVIEW™ 30 mL kit is marketed as a kit for preparation of technetium Tc99m tetrofosmin for injection with a strength of 1.38 mg tetrofosmin per 30 mL vial.

THE PATENT-IN-SUIT

The '999 Patent

20. On January 24, 2017, the United States Patent and Trademark Office duly and legally issued the '999 Patent, titled "Radiopharmaceutical Composition," naming Janne Veggeland, Grethe Karin Madsen, and Stig Hemsted as the inventors. A copy of the '999 Patent is attached as Exhibit 1.

21. Plaintiff GEHC Ltd. is the owner, by assignment, of the '999 Patent, and plaintiff Medi-Physics has certain exclusive rights in the '999 Patent. Together, plaintiffs GEHC Ltd. and Medi-Physics have the full right to sue and to recover for infringement of the '999 Patent.

22. Pursuant to 21 U.S.C. § 355(b)(1)(viii), the '999 Patent is listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalent Evaluations* (the "Orange Book") as covering MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection), which is the subject of approved NDA No. 20372.

23. Jubilant knows that the '999 Patent is listed in the Orange Book as covering MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection).

JUBILANT'S ANDA SUBMISSION

24. By letter dated April 15, 2024 (the "Jubilant Notice Letter"), Jubilant notified Plaintiffs that it had submitted ANDA No. 217224 ("Jubilant's ANDA") to the FDA for Jubilant's kit for the preparation of technetium Tc99m tetrofosmin for injection 1.38 mg/vial (the "ANDA Product" or "Jubliant's ANDA Product"), which is a generic version of MYOVIEW™ 30 mL (kit for the preparation of technetium Tc99m tetrofosmin for injection).

25. On information and belief, Jubilant filed or caused to be filed Jubilant's ANDA No. 217224 with the FDA, seeking FDA approval to engage in the commercial manufacture, use,

sale, offer for sale, and/or importation of Jubilant's ANDA product prior to the expiration of the '999 Patent.

26. In the Jubilant Notice Letter, Jubilant notified Plaintiffs that, as part of its ANDA No. 217224, Jubilant had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '999 Patent. On information and belief, ANDA No. 217224 contains certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '999 Patent is invalid and/or will not be infringed by the commercial manufacture, use, sale, or importation of Jubilant's ANDA Product.

27. By filing or causing to be filed Jubilant's ANDA, Jubilant necessarily represented to the FDA that the ANDA Product has the same active ingredient, the same method of administration, the same dosage form, and the same strength as the MYOVIEW™ 30 mL kit and is bioequivalent to the MYOVIEW™ 30 mL kit.

28. On information and belief, if Jubilant's ANDA is approved by the FDA, Jubilant will, prior to the expiration of the '999 Patent, begin commercially manufacturing, using, selling, and offering to sell in the United States and/or importing into the United States Jubilant's ANDA Product.

29. On information and belief, if Jubilant's ANDA is approved by the FDA, Jubilant will, prior to the expiration of the '999 Patent, begin marketing Jubilant's ANDA Product for the preparation of technetium Tc99m tetrofosmin for injection as a radioactive diagnostic agent indicated for: (1) myocardial perfusion imaging under rest and/or exercise or pharmacologic stress conditions to delineate regions of reversible myocardial ischemia or infarcted myocardium in patients with known or suspected coronary artery disease; and (2) assessment of left

ventricular function (left ventricular ejection fraction and wall motion) in patients with known or suspected heart disease.

30. On information and belief, if Jubilant's ANDA is approved by the FDA, radiopharmacies and radiopharmacists will use Jubilant's ANDA product to prepare technetium Tc99m tetrofosmin for injection pursuant to the indications and instructions provided by Jubilant and doctors and patients will use Jubilant's ANDA Product for the indications marketed by Jubilant.

31. Jubilant had knowledge of the '999 Patent at least as of the date when Jubilant's ANDA was submitted to the FDA containing the Paragraph IV Certification with respect to the '999 Patent.

32. Jubilant's submission of ANDA No. 217224 to the FDA with the Paragraph IV Certification seeking approval to market Jubilant's ANDA Product is an act of infringement by Jubilant of one or more claims of the '999 Patent under 35 U.S.C. § 271(e)(2). This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 217224 be a date which is not earlier than the expiration date of the '999 Patent.

33. Jubilant's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Jubilant's ANDA Product will infringe one or more claims of the '999 Patent under 35 U.S.C. §§ 271(b) and/or (c).

34. This action is being commenced within forty-five days from the date Plaintiffs received the Jubilant Notice Letter. On information and belief, Jubilant does not have tentative approval from the FDA of its ANDA No. 217224.

COUNT I: INFRINGEMENT OF THE '999 PATENT

35. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

36. On information and belief, Jubilant's ANDA Product infringes claims 1-13 of the '999 Patent under the doctrine of equivalents.

37. By filing or causing to be filed ANDA No. 217224 under 21 U.S.C. § 355(j) with a Paragraph IV Certification regarding the '999 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Jubilant's ANDA Product before the expiration of the '999 Patent, Jubilant committed an act of infringement of one or more claims of the '999 Patent under 35 U.S.C. § 271(e)(2)(A).

38. If Jubilant commercially manufactures, uses, sells, or offers to sell the ANDA Product in the United States, or imports the ANDA Product into the United States, or induces any such conduct during the term of the '999 Patent, Jubilant would further infringe the '999 Patent under 35 U.S.C. §§ 271(b) and/or (c).

39. On information and belief, the use and/or administration of Jubilant's ANDA Product by radiopharmacies, radiopharmacists, doctors, and/or patients in accordance with and as directed by the proposed labeling for that product, before the expiration of the '999 Patent, would infringe one or more claims of the '999 Patent under 35 U.S.C. § 271(a), and if used or administered by another, Jubilant would be liable for inducing that infringement under 35 U.S.C. § 271(b) and/or contributing to that infringement under 35 U.S.C. § 271(c).

40. By seeking approval to distribute the ANDA Product with, on information and belief, its proposed labeling, Jubilant intends to cause others, specifically radiopharmacies,

radiopharmacists, and medical professionals, to perform acts that Jubilant knows will infringe the '999 Patent.

41. Unless enjoined by this Court, on information and belief, Jubilant intends to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Jubilant's ANDA Product immediately and imminently upon approval of Jubilant's ANDA.

42. Unless enjoined by this Court, on information and belief, Jubilant intends to, and will, actively induce infringement of the '999 Patent by others when Jubilant's ANDA is approved, and intends to, and will do so, immediately and imminently upon approval of Jubilant's ANDA.

43. On information and belief, Jubilant knows that Jubilant's ANDA Product and its proposed labeling, are especially made or adapted for use in infringing the '999 Patent, and that Jubilant's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. Unless enjoined by this Court, on information and belief, Jubilant intends to, and will, contribute to the infringement of the '999 Patent immediately and imminently upon approval of Jubilant's ANDA.

44. Jubilant had knowledge of the '999 Patent at least as of the date Jubilant's ANDA was submitted and is knowingly infringing the '999 Patent.

45. On information and belief, Jubilant acted without a reasonable basis for believing that it would not be liable for actively inducing infringement of the '999 Patent and/or contributing to the infringement of the '999 Patent.

46. Unless Jubilant is enjoined from actively inducing infringement of the '999 Patent and/or contributing to the infringement of the '999 Patent, Plaintiffs will suffer irreparable harm

for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

47. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 217224 to be a date which is not earlier than the expiration date of the '999 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Defendant;

B. Judgment that Defendant has infringed, by the doctrine of equivalents, the '999 Patent under 35 U.S.C. § 271(e)(2) by the submission of ANDA No. 217224;

C. Judgment declaring that commercial manufacturing, using, selling, offering to sell, and/or importing Jubliant's ANDA Product, or inducing or contributing to such conduct, will constitute active inducement of infringement and/or contributory infringement of the '999 Patent by Defendant under 35 U.S.C. §§ 271(b) and/or (c);

D. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 217224 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date no earlier than the date of expiration of the '999 Patent;

E. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65 enjoining Defendant, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, sale, offer to sell,

and/or importation within or into the United States of any product described in ANDA No. 217224, and any product that is similar to or only colorably different from those products, before the date of expiration of the '999 Patent;

F. Damages or other monetary relief, including prejudgment and postjudgment interest, if Defendant engages in the commercial manufacture, use, sale, offer to sell, or importation of Jubilant's ANDA Product, or any other products that infringe the '999 Patent, or that induce or contribute to the infringement of the '999 Patent, prior to the expiration of the '999 Patent; and

G. Such other and further relief as this Court may deem just and proper.

Dated: May 28, 2024

Respectfully submitted,

By: s/ Douglas R. Weider____
Douglas R. Weider
James L. Ryerson
GREENBERG TRAURIG LLP
500 Campus Drive Suite 400
Florham Park, NJ 07932
(973) 360-7900
weiderd@gtlaw.com
ryersonj@gtlaw.com

Of Counsel:

Jeffrey P. Kushan
Lauren Cranford Katzeff
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
jkushan@sidley.com
lkatzeff@sidley.com
chimes@sidley.com

Stephanie P. Koh
Rachel Zingg
SIDLEY AUSTIN LLP
One South Dearborn St.
Chicago, IL 60603
(312) 853-7000
skoh@sidley.com
rzingg@sidley.com

Attorneys for Plaintiffs GE Healthcare Limited and Medi-Physics Inc., dba GE HealthCare

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: May 28, 2024

Respectfully submitted,

By: s/ Douglas R. Weider

Douglas R. Weider
James L. Ryerson
GREENBERG TRAURIG LLP
500 Campus Drive Suite 400
Florham Park, NJ 07932
(973) 360-7900
weiderd@gtlaw.com
ryersonj@gtlaw.com

Of Counsel:

Jeffrey P. Kushan
Lauren Cranford Katzeff
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
jkushan@sidley.com
lkatzeff@sidley.com
chimes@sidley.com

Stephanie P. Koh
Rachel Zingg
SIDLEY AUSTIN LLP
One South Dearborn St.
Chicago, IL 60603
(312) 853-7000
skoh@sidley.com
rzingg@sidley.com

Attorneys for Plaintiffs GE Healthcare Limited and Medi-Physics Inc., dba GE HealthCare