John E. Flaherty
Cynthia S. Betz
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry St.
Newark, New Jersey 07102
(973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

OF COUNSEL:
Y. Ernest Hsin (*pro hac vice forthcoming*)
Betty X. Yang (*pro hac vice forthcoming*)
Andrew Blythe (*pro hac vice forthcoming*)
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street, Suite 3000
San Francisco, CA 94105
(415) 393-8224
ehsin@gibsondunn.com
byang@gibsondunn.com
ablythe@gibsondunn.com

Attorneys for Plaintiffs
Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., and Organon USA, Inc.

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

MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V., AND ORGANON USA, INC., Plaintiffs, v. MICROSPHERIX LLC, Defendant.	Civil Action No. _____ JURY TRIAL DEMANDED *Electronically Filed*

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Merck Sharp & Dohme Corp. ("MSD Corp."), Merck Sharp & Dohme B.V. ("MSDBV") and Organon USA, Inc. ("Organon") (collectively, "Merck" or "Plaintiffs"), by and through their attorneys, hereby file this Complaint for Declaratory Judgment of patent non-infringement against Defendant Microspherix LLC ("Microspherix") and allege as follows.

INTRODUCTION

For more than 125 years, Merck has been a leader among pharmaceutical companies, developing groundbreaking and innovative drugs and medical devices in pursuit of its mission to save and improve lives. As one of the premier research-intensive biopharmaceutical companies in the world, Merck invests years of time researching, engineering, and developing each of its many products. Every year, Merck scientists specializing in their respective fields publish hundreds of scientific and technical papers in leading peer-reviewed journals. And through the efforts of Merck's product development, regulatory affairs, and other business teams, this research is transformed into pharmaceutical products and medical devices available to patients and doctors to prevent illness, treat disease, and improve health outcomes.

A. Merck's Nexplanon® System

The Nexplanon® system is one of Merck's groundbreaking innovations in the field of contraception. The Nexplanon® system has two primary components: (1) a matchstick-sized implant containing etonogestrel, a synthetic hormone that prevents pregnancy by inhibiting ovulation, and (2) a novel applicator device used to insert the implant subcutaneously at the proper location in the upper arm. Once inserted, the Nexplanon® implant systemically delivers an ongoing low dose of etonogestrel into the bloodstream, which then prevents ovulation in the ovaries. When used correctly, Nexplanon® is over 99% effective at preventing pregnancy for up

to three years.[1] Nexplanon® offers women a reliable option for contraception that is as effective as birth control pills, but without the inconvenience of daily dosing.

B. Dr. Kaplan's Brachytherapy Implants

Defendant Microspherix is a company founded by Dr. Edward Kaplan. According to Microspherix's website, Dr. Kaplan is a radiation oncologist who is trained in radiotherapy for prostate cancer and has "conducted extensive cancer research." Microspherix's website specifically highlights Dr. Kaplan's expertise in "brachytherapy"—or "the treatment of cancer, especially prostate cancer, by the insertion of radioactive implants directly into the tissue."[2] Dr. Kaplan is a member of the American Brachytherapy Society, whose mission is to "promot[e] the highest possible standards of practice of brachytherapy . . . [and] encourag[e] improved and continuing education for radiation oncologists and other health care professionals involved in the treatment of cancer."[3] According to Microspherix website, Dr. Kaplan is the purported inventor of a "revolutionary new cancer treatment whereby pellets, the size of cupcake sprinkles, are administered by needles directly into tumors."[4]

As also described on Microspherix's website, the advantage of Dr. Kaplan's "patented chemotherapy treatment" is that "pellet[s] carr[ying] time-released nanoparticles of chemotherapy drugs" are directly "injected into a tumor" (rather than *systemically* throughout the body)—thereby purportedly "reduc[ing] side effects" of the cancer treatment and resulting in a drug concentration in the tumor "1,000 times higher than if the drug had been injected intravenously" into the

[1] https://www.nexplanon.com/what-is-nexplanon/
[2] https://www.lexico.com/en/definition/brachytherapy
[3] https://www.americanbrachytherapy.org/about-abs/about-abs/
[4] http://www.entotherapy.com/microspherix.html

bloodstream.[5] Dr. Kaplan's alleged innovations thus all relate to delivering cancer drugs in a concentrated and localized manner directly to cancerous tumor tissue.

C. The Patent-In-Suit

On November 16, 2000, Dr. Kaplan filed Provisional Application No. 60/249,128 ("'128 Application") titled, an "Improved Brachytherapy Seed and Spacer Element." The patent at issue in this case—United States Patent No. 10,994,058 (the "'058 Patent")—is the latest member of the patent family claiming priority to the '128 Application ("the Kaplan Patent Family"). In a related litigation, Microspherix has asserted three closely related members of the Kaplan Patent Family against Merck—United States Patent No. 9,636,401 (the "'401 Patent"), United States Patent No. 9,636,402 (the "'402 Patent"), United States Patent No. 8,821,835 (the "'835 Patent").

The latest Kaplan Patent Family member is directed toward "[a] flexible or elastic brachytherapy strand that includes an imaging marker and/or a therapeutic, diagnostic, or prophylactic agent . . . that can be delivered to a subject upon implantation into the subject through the bore of a brachytherapy implantation needle." As explained in the specifications of the Kaplan Patent Family, brachytherapy "is an established technique for treating various medical conditions, most notably prostate cancer." Whereas traditional cancer treatments are often delivered systemically—for example, via intravenous injection into the bloodstream—"[i]n a typical application of brachytherapy for treating prostate cancer, about 50-150 small seeds containing a radioisotope . . . are surgically implanted in the diseased tissue" *directly*. This method of delivering radiation *locally* to the site of the tumor presents particular advantages, according to Microspherix's patents:

> Because the seeds are ***localized near the diseased tissue***, the radiation they emit is thereby concentrated on the ***cancerous cells*** and not on distantly located healthy

[5] *Id.*

> tissue. In this respect, ***brachytherapy*** is advantageous over conventional external beam ***radiation***.

'835 Patent at 1:28–38. In other words, and as explained on the Microspherix website, the specific advantage of brachytherapy is "localized [delivery] near the diseased tissue" to concentrate the drug in the diseased tissue without affecting healthy tissue, *as opposed to* a systemic delivery method that circulates the drug throughout the bloodstream to the entire body.

Over a decade after Dr. Kaplan first filed the provisional patent for his brachytherapy implant invention, Microspherix began efforts to secure patents directed to inventions not described therein. Whereas all specifications in the Kaplan Patent Family are clearly directed to the localized treatment of cancer with radioactive implants (*i.e.*, brachytherapy), Microspherix over the years apparently has strategically attempted to move away from the field of brachytherapy and localized cancer tissue treatment and target Merck's *systemic* hormone delivery system Nexplanon®, despite the fundamental disconnect between the Microspherix patents and Merck's Nexplanon® system and the repeated criticisms of systemic drug delivery present throughout all of the disclosures in the Kaplan Patent Family. Most recently, Microspherix filed United States Patent Application Number 16/696,195 (the "'195 Application") as a continuation of U.S. Patent Number 10,493,181 (the "'181 Patent"), which is in turn a continuation of the '402 Patent. Microspherix filed the '195 Application on November 26, 2019—19 years after it filed the '128 Application, and more than nine years after Merck launched its Nexplanon® system in the United States.

On June 5, 2017, Microspherix filed a lawsuit against Merck in the District of New Jersey, alleging that the Nexplanon® implant infringes the '401 Patent, the '402 Patent, and the '835

Patent, and Microspherix has since pursued Merck in litigation for infringement of those patents.[6] During the course of this litigation, the '195 Application ultimately issued as the '058 Patent on May 4, 2021. Where Microspherix previously granted a covenant not to sue under the '181 Patent (which also issued after the litigation was filed) in the interest of promoting efficient use of the parties' and the Court's resources, Microspherix has refused to negotiate with Merck for a covenant not to under the '058 Patent, despite the '195 Application's having been granted a Notice of Allowance on January 14, 2021 and Microspherix's having paid the issue fee on January 15, 2021. By refusing to provide a covenant not to sue (or even to engage in negotiating such a covenant), Microspherix has left a cloud over Merck's products, and Merck has a reasonable apprehension that Microspherix will file an action alleging that the Nexplanon® implant infringes the '058 Patent.

D. The Nexplanon® Implant Does Not Infringe the '058 Patent

Notwithstanding Microspherix's attempts to manipulate and stretch its patent disclosures to try to cover Nexplanon®, those disclosures—directed to the *opposite approach* from a *systemic contraceptive* implant such as the Nexplanon® implant—simply cannot stretch far enough. None of the claims of the '058 Patent actually cover Nexplanon®, for many reasons. Among them, the Nexplanon® implant is not a brachytherapy implant; it is not used to treat cancer or any other *disease*; and it is not implanted into any diseased tissue for localized treatment. Rather, the Nexplanon® implant is a contraceptive device implanted into the arm for systemic release of a hormone into the bloodstream for circulation through the entire body—the exact type of drug delivery method that Microspherix *distinguishes* from its patents.

[6] The '181 Patent was also shortly at issue in that case, but the parties agreed to a stipulated order dismissing counterclaims of invalidity and that the '181 Patent was not infringed by Merck in exchange for a covenant not to sue granted by Microspherix.

E. Merck invented the Nexplanon system before Kaplan's purported invention

Contraceptive implants were first developed and marketed *decades* before Dr. Kaplan filed the '128 Application. As just one example, the Norplant® contraceptive implant, which is similar to the Nexplanon® implant in features relevant to the claims of the '058 Patent, was known and used in the United States by no later than 1983—*17 years* before Microspherix's earliest claimed priority date. Norplant® was visible by X-ray and was comprised of five matchstick-shaped implants. Additionally, Merck's first generation contraceptive implant, Implanon®—which differed from Nexplanon® in the applicator for insertion and the presence of barium sulfate—was sold in a number of countries worldwide beginning in 1998, two years before the earliest priority date for the Kaplan Patent Family.

And *Merck itself began developing the Nexplanon® implant (the very product Microspherix is claiming infringes its patents) more than 18 months before* the earliest Kaplan Patent Family application was filed. Early market feedback on the first generation Implanon® product suggested that doctors would on occasion insert the implant too deep in the skin, such that proper insertion could not be confirmed by merely palpating the implant. Among the various ways of addressing this circumstance is locating the implant using ultrasound or MRI. In developing countries like Indonesia where Implanon® was then sold, however, these imaging technologies were not always easily available.

Merck's second generation product Nexplanon® resolved this issue in two ways. First, Merck designed an improved applicator that greatly reduced the likelihood of insertion errors. Second, in the rare instance in which the implant was still inserted too deeply to be palpated, Merck added barium sulfate to make the implant visible on X-ray, a widely available imaging technology. By no later than March 1999, Merck began conducting what Merck documents describe as "Feasibility Experiments for the Development of an X-ray visible Implant." The explicit aim of

the study was "to investigate if skin-core implants . . . like Implanon® . . . could be made X-ray visible by adding $BaSO_4$ [barium sulfate] to the core of the implant." The 1999 study concluded that the development of an X-ray visible implant was possible without major problems.

Over the next few years, Merck worked continuously on the development of both Implanon® and Nexplanon®. By May 2000, scientists at Merck had begun experimenting with different designs for an X-ray visible implant, including the design ultimately adopted—mixing the barium sulfate into the implant. Merck also developed the design for its improved applicator. On May 13, 2014, the United States Patent and Trademark Office ("USPTO") awarded Merck United States Patent 8,722,037 ("'037 Patent") over its invention—an "X-ray visible drug delivery device for subdermal administration of a *contraceptive* or hormone replacement therapy" (emphasis added).

Microspherix's patents for brachytherapy seeds do not apply to Nexplanon® implants; they apply to localized cancer treatment seeds or strands. And even if the Kaplan Patent Family could be contorted to cover something beyond localized treatment of cancer (they do not properly stretch so far), Merck independently made the Nexplanon® implant for the systemic delivery of contraceptive hormones, and did it before Dr. Kaplan ever thought of it.

* * *

In bringing its patent infringement suit, Microspherix—a company with no expertise in contraceptive devices—sought to claim credit for the years of development work by *Merck's scientists* on the Nexplanon® system. Merck is entitled to remove the cloud of litigation over its hard work through a declaratory judgment of non-infringement of the '058 Patent.

PARTIES

1. Merck Sharp & Dohme Corp. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

2. Merck Sharp & Dohme B.V. is incorporated in the Netherlands with a place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands.

3. Organon USA, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, NJ, 07033 and One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

4. Defendant Microspherix is a Florida corporation having a principal place of business at 21283 Rockledge Lane, Boca Raton, Florida 33428.

JURISDICTION & VENUE

5. The Court has jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 (federal question), 1338(a) (any Act of Congress relating to patents), and 2201 and 2202 (declaratory judgment).

6. There is an actual case and controversy between Merck and Microspherix regarding any alleged infringement by Merck of the '058 Patent. Microspherix filed an Amended Complaint for patent infringement against Plaintiffs on October 18, 2017 in this Court, alleging that Merck's Nexplanon® implant infringes the '401 Patent, the '402 Patent, and the '835 Patent.[7] *Microspherix LLC v. Merck Sharp & Dohme Corp. et al.*, C.A. No. 2:17-cv-03984-(CCC/MF), Dkt. No. 27 (D.N.J. Oct. 18, 2017) ("Infringement Action"). Microspherix has pursued the Infringement Action and has argued in the Infringement Action that it "should be given its day in court soon."

[7] Microspherix also asserted that Plaintiffs infringe United States Patent No. 6,514,193 ("the '193 Patent"), however, all asserted claims of the '193 were subsequently cancelled by Microspherix during an *Inter Partes* Review proceeding brought by Plaintiffs.

Id. at 4–5. Moreover, as discussed above, Microspherix has refused Merck's request to enter into a covenant not to sue.

7. As previously discussed, the prosecution history of the Kaplan Patent Family makes clear that Microspherix has impermissibly stretched and distorted its claims in a specific (though unsuccessful) attempt to capture Merck's Nexplanon® contraceptive implant. Indeed, in prosecuting the '402 Patent, Microspherix alleged an interference with Merck's own '037 Patent covering the Nexplanon® implant. While Merck strongly disputes that the Nexplanon® implant infringes those patents, the prosecution history of those patents demonstrates a clear intent and years-long sustained strategic actions by Microspherix to try to target the Nexplanon® implant in litigation.

8. Microspherix's threats of infringement go beyond the Infringement Action alone. In a July 25, 2017 letter from its counsel, Microspherix informed Merck that it was "continuing to develop its patent estate though [sic] a pending patent application: U.S. Pat. App. No. 15/492,293," a continuation to the '402 Patent that later granted as the '181 Patent during the pendency of the Infringement Action. In order to resolve Microspherix's threats, Merck filed a declaratory judgment action alleging that the '181 Patent was invalid and otherwise not infringed by Merck's products. Ultimately, Merck stipulated to dismiss without prejudice those claims in return for a covenant not to sue granted by Microspherix.

9. On May 4, 2021 the '195 Application, a continuation of the '181 Patent, ultimately issued as the '058 Patent. The '195 Patent has similar claims to the '181 Patent and other patents within the Kaplan Patent Family. Despite the '195 Application's having been granted a Notice of Allowance on January 14, 2021, and Microspherix's having paid the issue fee on January 15, 2021, Microspherix refused in the intervening four months to execute a covenant-not-to sue on the then-

pending '195 Application. Microspherix has thus left a cloud over Merck with regard to this most recently granted member of the Kaplan Patent Family. Given Microspherix's refusal to execute a covenant for the '058 Patent, Merck is left with a reasonable apprehension that Microspherix will file an action alleging that the Nexplanon® implant infringes the '058 Patent.

10. Microspherix has never expressed any intention to abandon its enforcement efforts, nor have the parties reached any agreements regarding a potential settlement or license. The Court should exercise its discretion under 28 U.S.C. § 2202 to exercise subject matter jurisdiction over this case.

11. Additionally, Microspherix has voluntarily submitted to the personal jurisdiction of the United States District Court, District of New Jersey, by virtue of, *inter alia*, bringing the Infringement Action in this Court against Merck. *See Bel–Ray Co. Chemrite (Pty) Ltd*., 181 F.3d 435, 443 (3d Cir. 1999). Accordingly, Microspherix is subject to personal jurisdiction in this judicial district for the purposes of Merck's Complaint for Declaratory Judgment.

12. For the same reason, venue is proper under 28 U.S.C. §§ 1391(b) and 1400(b) because Microspherix has consented to venue in this Court by filing the Infringement Action in this Court, and this complaint for Declaratory Judgment involves common issues of fact and law. *See Koninklijke Philips N.V. v. ASUSTeK Computer Inc.*, No. CV 15-1125-GMS, 2017 WL 3055517, at *3 (D. Del. July 19, 2017). New Jersey is also the most convenient forum for litigating this case. Both Organon USA and MSD Corp. are headquartered in New Jersey, and most of the key witnesses and documents are present in this state. Microspherix, on the other hand, is a non-practicing entity with no apparent physical location.

MICROSPHERIX'S BRACHYTHERAPY PATENT FAMILY

13. Microspherix alleges that it is the assignee of and has the right to sue to recover damages for infringement of the Kaplan Patent Family. *See* Infringement Action, D.I. 27, ¶¶ 43, 50 and 54. On information and belief, no person or entity other than Microspherix has an ownership interest in any of the Kaplan Patent Family.

14. The sole named inventor of each of the '058 Patent is Edward J. Kaplan. On information and belief, Dr. Kaplan is the owner of Microspherix.

15. On May 4, 2021, the '058 Patent was issued to Microspherix. The '058 Patent is a continuation of the '181 Patent, which is a continuation of the '402 Patent. On information and belief, Microspherix is the assignee of and has the right to sue to recover damages for infringement of the '058 Patent and no person or entity other than Microspherix has an ownership interest in any of the '058 Patent.

COUNT I

Declaratory Judgment of Non-infringement of the '058 Patent

16. The foregoing paragraphs are realleged and incorporated by reference as if fully stated herein.

17. As demonstrated *supra*, including at paragraphs 6–10, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any claim of the '058 Patent through its activities relating to Merck's Nexplanon® product. Merck, therefore, has standing to seek declaratory judgment of non-infringement.

18. Merck has neither directly nor indirectly infringed any claim of the '058 Patent and is not liable for any alleged infringement of the same because, among other reasons, the '058

Patent claims and disclosure are limited to brachytherapy and the localized delivery of a therapeutic agent via a brachytherapy seed to produce a therapeutic effect in tissue at the implantation site as opposed to the systemic release of a contraceptive hormone.

19. Merck is entitled to a declaratory judgment that it has not infringed, contributed to the infringement of, nor induced the infringement of the '058 Patent; and that the manufacture, use, sale, offer for sale and/or importation of Nexplanon® does not infringe and will not infringe any claims of the '058 Patent.

PRAYER FOR RELIEF

FOR THESE REASONS, Merck respectfully requests that this Court enter judgment in its favor and grant the following relief:

A. A determination and declaratory judgment that Merck does not infringe any claim of the '058 Patent;

B. An order declaring that this is an exceptional case and awarding Merck its costs, expenses, reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes, rules, and common law;

C. All costs be taxed against Microspherix; and

D. Any such other relief as the Court may deem appropriate and just under the circumstances.

JURY DEMAND

Merck demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ John E. Flaherty

John E. Flaherty
Cynthia S. Betz
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry St.
Newark, New Jersey 07102
(973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

Attorneys for Plaintiffs

OF COUNSEL:
Y. Ernest Hsin (*pro hac vice forthcoming*)
Betty X. Yang (*pro hac vice forthcoming*)
Andrew Blythe (*pro hac vice forthcoming*)
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street, Suite 3000
San Francisco, CA 94105
(415) 393-8224
ehsin@gibsondunn.com
byang@gibsondunn.com
ablythe@gibsondunn.com

Dated: May 4, 2021

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action involves a continuation of the patents at issue in the matter *Microspherix LLC v. Merck Sharp & Dohme Corp. et al*., No. 2:17-cv-03984-(CCC/MF) (D.N.J.).

By: /s/ *John E. Flaherty*
John E. Flaherty
Cynthia S. Betz
McCarter & English, LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
(973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO L. CIV. R. 201.1(d)

Pursuant to Local Civil Rule 201.1, I hereby certify the above-captioned matter is not subject to compulsory arbitration in that, *inter alia,* the Plaintiff seeks non-monetary injunctive relief and the amount in controversy exceeds the $150,000 threshold exclusive of interest and costs and any claim for punitive damages.

By: /s/ *John E. Flaherty*
John E. Flaherty
Cynthia S. Betz
McCarter & English, LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
(973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

Attorneys for Plaintiffs