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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 and invalidity 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." And he is the purported inventor of a "revolutionary new cancer treatment whereby pellets, the size of cupcake sprinkles, are administered by needles directly into tumors."[3]

As 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 bloodstream.[4] Dr. Kaplan's alleged innovations thus all relate to delivering cancer drugs in a concentrated and localized manner directly to cancerous tumor tissue.

[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

C. The Patents-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 four patents at issue in this case—United States Patent No. 9,636,401 (the "'401 Patent") (Exhibit A), United States Patent No. 9,636,402 (the "'402 Patent") (Exhibit B), United States Patent No. 8,821,835 (the "'835 Patent") (Exhibit C), and United States Patent No. 10,493,181 (the "'181 Patent") (Exhibit D) (together, "Kaplan Patents")—are all members of that patent family, are all titled, "Flexible and/or Elastic Brachytherapy Seed or Strand," and have all been assigned to Defendant Microspherix.

The Kaplan patent family members are 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 specification of the Kaplan Patents, 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 tissue. In this respect, ***brachytherapy*** is advantageous over conventional external beam ***radiation***.

'835 Patent at 1:28–38; '401 Patent at 1:29–40; '402 Patent at 1:30–41; '181 Patent at 1:39-44. 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 in the Kaplan Patents. Whereas the specification and all of the predecessor patents 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 Microspherix's patent family. Most recently, Microspherix filed United States Patent Application Number 15/492,293 (the "'293 Application") as a continuation of the '402 Patent on April 20, 2017—nearly 17 years after it filed the '128 Application, and more than six 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. Microspherix also notified Merck of the then-pending '293 Application, stating in a letter dated July 25, 2017: "We obviously will alert you as new claims are issued and, in fact, plan to submit new proposed claims this week." The '293 Application ultimately issued as the '181 Patent on December 3, 2019.

D. The Nexplanon® Implant Does Not Infringe the Kaplan Patents

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 Kaplan Patents 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.

E. The Kaplan Patents Are Invalid

1. Merck invented the Nexplanon system before Kapan's purported inventions

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 Kaplan Patents, 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 Patents.

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 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 "Flexible and/or Elastic Brachytherapy Seed or Strand" do not apply to Nexplanon® implants; they apply to localized cancer treatment seeds or strands. And even if the Kaplan Patents 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.

2. The Asserted Claims Lack Written Description and Are Not Enabled

Microspherix's stretching of its claims backfires for an additional reason: It renders Microspherix's claims invalid when considered in light of the disclosures of Microspherix's patents. Microspherix's attempt to divorce the asserted claims from the field of brachytherapy—the original and sole focus of the Kaplan Patents and the provisional applications they rely on—renders them invalid for lack of written description and enablement. Dr. Kaplan's original '128 Application is entitled "Improved Brachytherapy Seed and Spacer Element." The Field of Invention "relates to implantable brachytherapy devices," which present advantages over traditional systemic delivery methods "[b]ecause the seeds are localized near the disease tissue, [and] the radiation they emit is thereby concentrated on the cancerous cells." Nowhere does the '128 Application, or any subsequent Kaplan patent application or Kaplan patent, discuss the *systemic* administration of a contraceptive hormone; in fact, the Kaplan Patents' teachings are *directly opposed* to that method of drug delivery.

The specifications of the Kaplan Patents moreover contain *no example whatsoever* of any particular implant—much less use of the alleged invention to deliver a contraceptive hormone for systemic administration with the features set forth in the patents' claims. Instead, the specifications are directed to localized cancer therapy primarily with the use of a radioisotope—

specifically distinguishing themselves from traditional systemic delivery methods. In terms of disclosure, the specifications provide only long lists of drugs, polymers, etc. with no guidance on what combinations may or may not be operable for their intended purposes. Accordingly, the Kaplan Patents lack both written description and enablement.

* * *

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 and invalidity of the Kaplan Patents.

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 the validity of the Kaplan Patents and any alleged infringement by Merck thereof. 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.[5] *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." *Id.* at 4–5. On June 9, 2020, counsel for Microspherix publicly stated that Microspherix, "look[s] forward to proceeding with [its] district court litigation," reflecting that Microspherix will continue to litigate against Merck over its patents. And on, June 29, 2020 and July 13, 2020, respectively, Microspherix and Merck submitted a joint Proposed Order Lifting Stay and their respective proposed case schedules for proceeding with discovery in the Infringement Action.

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

[5] 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.

covering the Nexplanon® implant. While Merck strongly disputes both that the Kaplan Patents are valid and 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 has since been granted as U.S. Pat. No. 10,493,181. Accordingly, in regard to the Kaplan Patents, Microspherix has either directly accused or intentionally placed a cloud over Merck's Nexplanon® implant and demonstrated a clear intent and, indeed, taken affirmative actions to target Nexplanon® in the hopes of securing a damages award.

9. Microspherix has never expressed any intention to abandon these 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.

10. 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.

11. 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

12. Microspherix alleges that it is the assignee of and has the right to sue to recover damages for infringement of each of the Kaplan Patents. *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 Patents.

13. The sole named inventor of each of the Kaplan Patents is Edward J. Kaplan. On information and belief, Dr. Kaplan is the owner of Microspherix.

14. All of the Kaplan Patents claim priority to the '128 Application.

15. The '128 Application was filed on November 16, 2000. The '128 Application is the earliest-filed application to which the Kaplan Patents claim priority.

16. Merck disputes Microspherix's prior allegation that the Kaplan Patents are entitled to the priority date of November 16, 2000. But, in any event, none of the Kaplan Patents is entitled to claim the benefit of a filing date *earlier* than November 16, 2000 under either 35 U.S.C. §§ 119 or 120. Further, Microspherix has never during prosecution of the Kaplan Patents, nor of any other application claiming priority the '128 Application, sought to establish an invention date earlier than November 16, 2000.

17. On December 3, 2019, the '181 Patent was issued to Microspherix. The '181 Patent 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 ’181 Patent and no person or entity other than Microspherix has an ownership interest in any of the ’181 Patent.

MERCK’S ’037 PATENT

18. The ’037 Patent is titled “X-Ray Visible Drug Delivery Device.” The ’037 Patent was issued May 13, 2014, and claims priority to a foreign application filed March 19, 2004.

19. Defendant Merck Sharp & Dohme B.V. is the current assignee of the ’037 Patent.

20. The claims of the ’037 Patent are entitled to an invention date at least as early as March 9, 1999.

21. The inventions claimed in the ’037 Patent were conceived and reduced to practice by individuals at Organon USA and other Organon entities (collectively “Organon”) that are predecessors in interest to Plaintiffs here. It was Organon that originally developed the Nexplanon® system and its predecessor product, Implanon®.

22. Implanon® is described and claimed in U.S. Patent No. 5,150,718 (the “’718 Patent”). The ’718 Patent claims priority to an application filed on August 5, 1988, and was issued on September 29, 1992.

23. The ’718 Patent is prior art to the Kaplan Patents.

24. The Implanon® implant is substantially similar to the Nexplanon® implant, but differs in that it does not have barium sulfate.

25. By March 9, 1999, individuals at Organon had conceived of the idea to add barium sulfate to implants like Implanon® to make them X-ray visible. From the time of its conception and up through the filing date of the March 19, 2004 application leading to the ’037 Patent, Organon worked continuously on the development of Implanon® and the follow-on Nexplanon® system for marketing in the United States and elsewhere.

26. Organon's invention is corroborated by contemporaneous documentation. For example, a March 9, 1999 Organon progress report memorandum describes the results of studies demonstrating the feasibility of adding barium sulfate to implants like Implanon®. This March 9, 1999 report concludes that the development of an X-ray visible implant was feasible.

27. This report corroborates that the inventors of the '037 Patent, in collaboration with others at Organon, had conceived of the inventions claimed in the '037 Patent prior to March 9, 1999. Other contemporaneous documents further corroborate that Organon had already conceived of the invention claimed in the '037 Patent prior to earliest claimed priority date (November 16, 2000) of the Kaplan Patents, and had either actually reduced that invention to practice prior to November 16, 2000, or were diligently working to reduce that invention to practice, either actually or constructively, by no later than the filing of the March 19, 2004 application leading to the '037 Patent.

COUNT I

Declaratory Judgment of Non-infringement of the '402 Patent

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

29. As demonstrated *supra*, including at paragraphs 6–9, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the '402 Patent through its activities relating to the Nexplanon® system. Merck, therefore, has standing to seek declaratory judgment of non-infringement.

30. Merck has neither directly nor indirectly infringed any valid and enforceable claim of the '402 Patent and is not liable for any alleged infringement of the same because, among other

reasons, the ’402 Patent claims and disclosure are limited to brachytherapy and the localized delivery of a therapeutic agent via a brachytherapy strand to produce a therapeutic effect in tissue at the implantation site as opposed to the systemic release of a contraceptive hormone.

31. Merck is entitled to a declaratory judgment that it has not infringed, contributed to the infringement of, nor induced the infringement of the ’402 Patent; and that the manufacture, use, sale, offer for sale and/or importation of Nexplanon® does not infringe and will not infringe any valid and enforceable claims of the ’402 Patent.

COUNT II

Declaratory Judgment of Invalidity of the ’402 Patent

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

33. As demonstrated *supra*, including at paragraphs 6–9, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the ’402 Patent through its activities relating to Merck’s Nexplanon® system. Merck, therefore, has standing to seek declaratory judgment of invalidity.

34. Each claim of the ’402 Patent is invalid for failure to satisfy one or more requirements of the Patent Act, 35 U.S.C. § 1 *et seq.*, including, but not limited to, the conditions of patentability set forth in 35 U.S.C. §§ 102, 103, and 112. For example, the ’402 Patent claims are invalid in view of the prior art, including, but not limited to, the references cited on the face of the Kaplan Patents; articles and/or products that were publicly available or disclosed before the priority date of the Kaplan Patents, including, for example, U.S. Pat. Nos. 6,575,888 (“Zamora”), 5,626,862 (“Brem”), 5,150,718 (“De Nijs”), 5,983,583 (“Grimm”), 4,012,497 (“Schopflin”),

3,896,819 ("Zaffaroni"), 5,624,411 ("Tuch"), 5,651,174 ("Schwartz"), 8,722,037 ("Veenstra"), 6,113,938 ("Chen"), 6,375,978 ("Kleiner"), 5,629,008 ("Lee"), 6,197,324 ("Crittenden") and U.S. Patent No. 6,605,294 ("Sawhney"), the articles Alexandra Rothen-Weinhold et al., "Development and evaluation in vivo of a long-term delivery system for vapreotide, a somatostatin analogue," J. Controlled Release 52:205–13 (1998) ("Weinhold"), Koole et al., "Sustained local drug delivery from a radiopaque implanted reservoir," Nature Publishing Group 16:172–76 (1998) ("Koole"), and Zhang et al., "Controlled release of albumin from biodegradable poly(DL-lactide) cylinders," J. Controlled Release 25:61–69 (1993) ("Zhang"), and the prior art systems and products sold under the tradenames Implanon®, Norplant®, Jadelle®, Viadur®, Estring®, Progestasert®, Septopal®, Palmaz-Schatz® Stent, and prior art systems and products substantially similar thereto; and Merck's own prior invention, as described above.

35. In addition, the '402 Patent claims are invalid because the full scope of those claims is not enabled, nor described, by the written description of the '402 Patent, and those claims are furthermore indefinite. If the claims of the '402 Patent, whose specification is directed to localized cancer therapy primarily with the use of a radioisotope, are capable of encompassing a systemic contraceptive implant like the Nexplanon® implant, the '402 Patent fails to show that the named inventor was in possession of the full scope of the inventions claimed. Furthermore, if the claims of the '402 Patent are capable of covering the Nexplanon® implant, it is also the case that the specification of the '402 Patent fails to enable the full scope of the claims—for example, the near constant-release of contraceptive drug without eluting radiopaque material, which Microspherix has alleged is required of the claims.

36. Merck is entitled to a declaratory judgment that all of the claims of the '402 Patent are invalid.

COUNT III

Declaratory Judgment of Non-infringement of the ’401 Patent

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

38. As demonstrated *supra*, including at paragraphs 6–9, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the ’401 Patent through its activities relating to the Nexplanon® system. Merck, therefore, has standing to seek declaratory judgment of non-infringement.

39. Merck has neither directly nor indirectly infringed any valid and enforceable claim of the ’401 Patent and is not liable for any alleged infringement of the same because, among other reasons, the ’401 Patent claims and disclosure are limited to brachytherapy and the localized delivery of a therapeutic agent via a brachytherapy strand to produce a therapeutic effect in tissue at the implantation site as opposed to the systemic release of a contraceptive hormone.

40. Merck is entitled to a declaratory judgment that it has not infringed, contributed to the infringement of, nor induced the infringement of the ’401 Patent; and that the manufacture, use, sale, offer for sale and/or importation of Nexplanon® does not infringe and will not infringe any valid and enforceable claims of the ’401 Patent.

COUNT IV

Declaratory Judgment of Invalidity of the ’401 Patent

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

42. As demonstrated *supra*, including at paragraphs 6–9, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the ’401 Patent through its activities relating to Merck’s Nexplanon® system. Merck, therefore, has standing to seek declaratory judgment of invalidity.

43. Each claim of the ’401 Patent is invalid for failure to satisfy one or more requirements of the Patent Act, 35 U.S.C. § 1 *et seq.*, including, but not limited to, the conditions of patentability set forth in 35 U.S.C. §§ 102, 103, and 112. For example, the ’401 Patent claims are invalid in view of the prior art, including, but not limited to, the references cited on the face of the Kaplan Patents; articles and/or products that were publicly available or disclosed before the priority date of the Kaplan Patents, including, for example, Zamora, Brem, De Nijs, Grimm, Schopflin, Zaffaroni, Tuch, Schwartz, Veenstra, Chen, Kleiner, Lee, Crittenden, and Sawhney, the articles Weinhold, Koole, and Zhang, and the prior art systems and products sold under the tradenames Implanon®, Norplant®, Jadelle®, Viadur®, Estring®, Progestasert®, Septopal®, Palmaz-Schatz® Stent, and prior art systems and products substantially similar thereto; and Merck’s own prior invention, as described above.

44. In addition, the ’401 Patent claims are invalid because the full scope of those claims is not enabled, nor described, by the written description of the ’401 Patent, and those claims are furthermore indefinite. If the claims of the ’401 Patent, whose specification is directed to localized cancer therapy primarily with the use of a radioisotope, are capable of encompassing a systemic contraceptive implant like the Nexplanon® implant, the ’401 Patent fails to show that the named inventor was in possession of the full scope of the inventions claimed. Furthermore, if the claims of the ’401 Patent are capable of covering the Nexplanon® implant, it is also the case that the

specification of the ’401 Patent fails to enable the full scope of the claims—for example, the near constant-release of contraceptive drug without eluting radiopaque material, which Microspherix has alleged is required of the claims.

45. Merck is entitled to a declaratory judgment that all of the claims of the ’401 Patent are invalid.

COUNT V

Declaratory Judgment of Non-infringement of the ’835 Patent

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

47. As demonstrated *supra*, including at paragraphs 6–9, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the ’835 Patent through its activities relating to the Nexplanon® system. Merck, therefore, has standing to seek declaratory judgment of non-infringement.

48. Merck has neither directly nor indirectly infringed any valid and enforceable claim of the ’835 Patent and is not liable for any alleged infringement of the same because, among other reasons, the ’835 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.

49. Merck is entitled to a declaratory judgment that it has not infringed, contributed to the infringement of, nor induced the infringement of the ’835 Patent; and that the manufacture, use, sale, offer for sale and/or importation of Nexplanon® does not infringe and will not infringe any valid and enforceable claims of the ’835 Patent.

COUNT VI

Declaratory Judgment of Invalidity of the ’835 Patent

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

51. As demonstrated *supra*, including at paragraphs 6–9, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the ’835 Patent through its activities relating to Merck’s Nexplanon® system. Merck, therefore, has standing to seek declaratory judgment of invalidity.

52. Each claim of the ’835 Patent is invalid for failure to satisfy one or more requirements of the Patent Act, 35 U.S.C. § 1 *et seq.*, including, but not limited to, the conditions of patentability set forth in 35 U.S.C. §§ 102, 103, and 112. For example, the ’835 Patent claims are invalid in view of the prior art, including, but not limited to, the references cited on the face of the Kaplan Patents; articles and/or products that were publicly available or disclosed before the priority date of the Kaplan Patents, including, for example, Zamora, Brem, De Nijs, Grimm, Schopflin, Zaffaroni, Tuch, Schwartz, Veenstra, Chen, Kleiner, Lee, Crittenden, and Sawhney, the articles Weinhold, Koole, and Zhang, and the prior art systems and products sold under the tradenames Implanon®, Norplant®, Jadelle®, Viadur®, Estring®, Progestasert®, Septopal®, Palmaz-Schatz® Stent, and prior art systems and products substantially similar thereto; and Merck’s own prior invention, as described above.

53. In addition, the ’835 Patent claims are invalid because the full scope of those claims is not enabled, nor described, by the written description of the ’835 Patent, and those claims are furthermore indefinite. If the claims of the ’835 Patent, whose specification is directed to localized

cancer therapy primarily with the use of a radioisotope, are capable of encompassing a systemic contraceptive implant like the Nexplanon® implant, the ’835 Patent fails to show that the named inventor was in possession of the full scope of the inventions claimed. Furthermore, if the claims of the ’835 Patent are capable of covering the Nexplanon® implant, it is also the case that the specification of the ’835 Patent fails to enable the full scope of the claims—for example, the near constant-release of contraceptive drug without eluting radiopaque material, which Microspherix has alleged is required of the claims.

54. Merck is entitled to a declaratory judgment that all of the claims of the ’835 Patent are invalid.

COUNT VII

Declaratory Judgment of Non-infringement of the ’181 Patent

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

56. As demonstrated *supra*, including at paragraphs 6-9, there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the ’181 Patent through its activities relating to Merck’s Nexplanon® product. Merck, therefore, has standing to seek declaratory judgment of non-infringement.

57. Merck has neither directly nor indirectly infringed any valid and enforceable claim of the ’181 Patent and is not liable for any alleged infringement of the same because, among other reasons, the ’181 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.

58. Merck is entitled to a declaratory judgment that it has not infringed, contributed to the infringement of, nor induced the infringement of the ’181 Patent; and that the manufacture, use, sale, offer for sale and/or importation of Nexplanon® does not infringe and will not infringe any valid and enforceable claims of the ’181 Patent.

COUNT VIII

Declaratory Judgment of Invalidity of the ’181 Patent

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

60. As demonstrated *supra*, including at paragraphs 6-9 , there is an actual, substantial, continuing and justiciable controversy between the parties regarding whether Merck has, either directly or indirectly, infringed any valid and enforceable claim of the ’181 Patent through its activities relating to Merck’s Nexplanon® product. Merck, therefore, has standing to seek declaratory judgment of non-infringement.

61. Each claim of the ’181 Patent is invalid for failure to satisfy one or more requirements of the Patent Act, 35 U.S.C. § 1 *et seq.*, including, but not limited to, the conditions of patentability set forth in 35 U.S.C. §§ 102, 103, and 112. For example, the ’181 Patent claims are invalid in view of the prior art, including, but not limited to, the references cited on the face of the Kaplan Patents; articles and/or products that were publicly available or disclosed before the priority date of the Kaplan Patents, including, for example, Zamora, Brem, De Nijs, Grimm, Schopflin, Zaffaroni, Tuch, Schwartz, Veenstra, Chen, Kleiner, Lee, Crittenden, and Sawhney, the articles Weinhold, Koole, and Zhang, and the prior art systems and products sold under the tradenames Implanon®, Norplant®, Jadelle®, Viadur®, Estring®, Progestasert®, Septopal®,

Palmaz-Schatz® Stent, and prior art systems and products substantially similar thereto; and Merck's own prior invention, as described above.

62. In addition, the '181 Patent claims are invalid because the full scope of those claims is not enabled, nor described, by the written description of the '181 Patent, and those claims are furthermore indefinite. If the claims of the '181 Patent, whose specification is directed to localized cancer therapy primarily with the use of a radioisotope, are capable of encompassing a systemic contraceptive implant like the Nexplanon® implant, the '181 Patent fails to show that the named inventor was in possession of the full scope of the inventions claimed. Furthermore, if the claims of the '181 Patent are capable of covering the Nexplanon® implant, it is also the case that the specification of the '181 Patent fails to enable the full scope of the claims—for example, the near constant-release of contraceptive drug without eluting radiopaque material, which Microspherix has alleged is required of the claims.

Merck is entitled to a declaratory judgment that all of the claims of the '181 Patent are invalid.

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 valid and enforceable claim of any of the Kaplan Patents;

B. A determination and declaratory judgment that the claims of the Kaplan Patents are invalid;

C. 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;

D. All costs be taxed against Microspherix; and

E. 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

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Dated: July 22, 2020

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 the same 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.)

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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.

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