United States District Court
Southern District of New York

DEY, INC., ET AL.,

Plaintiffs, **07 Civ. 2353 (JGK)**

- against - **OPINION AND ORDER**

SEPRACOR, INC.,

Defendant.

JOHN G. KOELTL, District Judge:

This patent infringement action involves pharmaceuticals containing a substance called formoterol. The plaintiffs, Dey L.P., Dey, Inc., and Mylan, Inc., (collectively, "Dey") are pharmaceutical companies. Dey is the assignee of two families of patents for certain pharmaceutical substances containing formoterol and certain methods for the administration of those substances. The defendant, Sunovion Pharmaceuticals, Inc. ("Sunovion"), formerly known as Sepracor, Inc., produces Brovana, a product that contains formoterol and is used for the treatment of chronic obstructive pulmonary disease ("COPD"). Dey alleges that Brovana infringes on its two families of patents. Sunovion has moved for partial summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure.

Sunovion makes two primary contentions in support of its motion. First, Sunovion contends that Dey's second family of patents is invalid under 35 U.S.C. § 102(b) because Sunovion's

Brovana product was publicly used by Sunovion in a clinical trial more than a year before Dey filed the first application associated with its second family of patents. Second, Sunovion argues that, pursuant to 35 U.S.C. §§ 252 and 307, Dey is precluded from obtaining damages from Sunovion for any alleged infringement of Dey's first family of patents that occurred before the conclusion of the reexamination of that family of patents by the United States Patent and Trademark Office ("USPTO") because Dey substantively amended the claims of those patents in the reexamination proceeding.

Jurisdiction is proper pursuant to 28 U.S.C. §§ 1331 and 1338(a).

I.

The standard for granting summary judgment is well established. "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Gallo v. Prudential Residential Servs., Ltd. P'ship, 22 F.3d 1219, 1223 (2d Cir. 1994). "[T]he trial court's task at the summary judgment motion stage of the litigation is carefully limited to discerning whether there are any genuine issues of material fact to be tried, not to deciding

them. Its duty, in short, is confined at this point to issue-finding; it does not extend to issue-resolution." Gallo, 22 F.3d at 1224. The moving party bears the initial burden of informing the district court of the basis for its motion and identifying the matter that it believes demonstrates the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. The substantive law governing the case will identify those facts that are material and "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

Summary judgment is appropriate if it appears that the nonmoving party cannot prove an element that is essential to the nonmoving party's case and on which it will bear the burden of proof at trial. See Cleveland v. Policy Mgmt. Sys. Corp., 526 U.S. 795, 805-06 (1999); Celotex, 477 U.S. at 322; Powell v. Nat'l Bd. of Med. Exam'rs, 364 F.3d 79, 84 (2d Cir. 2004). In determining whether summary judgment is appropriate, a court must resolve all ambiguities and draw all reasonable inferences against the moving party. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986) (citing United States v. Diebold, Inc., 369 U.S. 654, 655 (1962)); see also Gallo, 22 F.3d at 1223. Summary judgment is improper if there is any evidence in the record from any source from which a

reasonable inference could be drawn in favor of the nonmoving party. See Chambers v. TRM Copy Ctrs. Corp., 43 F.3d 29, 37 (2d Cir. 1994). If the moving party meets its initial burden of showing a lack of a material issue of fact, the nonmoving party must produce evidence in the record and "may not rely simply on conclusory statements or on contentions that the affidavits supporting the motion are not credible." Ying Jing Gan v. City of New York, 996 F.2d 522, 532 (2d Cir. 1993); see also Scotto v. Almenas, 143 F.3d 105, 114-15 (2d Cir. 1998); Gameologist Group, LLC v. Scientific Games Intern., Inc., No. 09 Civ. 6261, 2011 WL 5075224, at *1 (S.D.N.Y. Oct. 25, 2011).

II.

The facts are undisputed unless otherwise indicated.

A.

Two families of patents are at issue in this case. Dey's first family of patents is composed of United States Patent Numbers 6,667,344 (the "'344 patent") and 6,814,953 (the "'953 patent"). These patents were filed on June 22, 2001 and May 3, 2002, and issued on December 23, 2003 and November 9, 2004, respectively. Claim 1 of the '344 patent, one of the two

independent claims at issue in this family of patents,[1] originally claimed:

> A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable fluid, wherein the composition is stable during long term storage, the fluid comprises water, and the composition is formulated at a composition suitable for direct administration to a subject in need thereof.

(See Hurd Decl. Ex. 1 ("'344 Patent"), at col. 17, ll. 52-57.) Both the '344 and '953 patents include dependant claims that recite variations of the independent claims with limitations for certain formoterol concentration ranges, certain buffer concentrations and compositions, and certain ionic strength ranges, among other limitations. (See, e.g., '344 Patent, col. 17, l. 58 – col. 22, l. 65.)

In July, 2009, after the commencement of this litigation, the USPTO granted Sunovion's May, 2009, request for an ex parte

---

[1] The '953 patent originally included two independent claims, both of which are similar to claim 1 of the '344 patent. One of those claims, independent claim 74 of the '953 patent, is also at issue. It originally claimed:

> A method for the treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders, comprising administering an effective amount of a pharmaceutical composition to a subject in need of such treatment, wherein the pharmaceutical composition comprises formoterol or a derivative thereof formulated at a concentration suitable for direct administration to a subject in need thereof, in a pharmacologically suitable fluid, wherein the composition is stable during long term storage and the fluid comprises water.

(See Hurd Decl. Ex. 2 ("'953 Patent"), at col. 21, ll. 49-58.) The other independent claim in the original '953 Patent, claim 1, is no longer at issue in this litigation.

reexamination of the ’344 and ’953 patents. (See Hurd Decl. Ex. 25 (“’344 Reexamination Order”), at 2; Hurd Decl. Ex 26 (“’953 Reexamination Order”), at 2.) The USPTO found that Sunovion’s request had raised five substantial new questions of patentability with regard to some of the claims in the ’344 patent, including independent claim 1. (See ’344 Reexamination Order at 5-12). The USPTO found that Sunovion had raised five virtually identical substantial new questions of patentability with regard to certain claims in the ’953 patent, including independent claim 74. (See ’953 Reexamination Order at 5-12). On June 8, 2010, pursuant to 35 U.S.C §§ 102(b), 102(e), and 103(a), the USPTO rejected a number of claims in the ’344 patent, including independent claim 1, as anticipated by, obvious over, or otherwise unpatentable in light of prior art. (Hurd Decl. Ex. 27 (“’344 Rejection”), at 1, 6-34.) The USPTO also rejected a number of claims in the ’953 patent, including independent claim 74, for similar reasons. (See Hurd Decl. Ex. 28 (’953 Rejection”), at 6-39.)

On April 7, 2011, Dey submitted amended claims for the ’344 and ’953 patents, along with new, additional claims, and extensive argument regarding why the claims should be allowed. (See generally Hurd Decl. Ex. 29 (“’344 Rejection Response”); Hurd Decl. Ex. 30 (“’953 Rejection Response”).) On May 19, 2011, the USPTO withdrew its previous prior art rejections “in

view of both the amendments to the claims and the arguments by the Patent Owner of 04/07/2011." (Hurd Decl. Ex. 31, at ¶ 8 (final action by USPTO regarding '344 patent); see also Hurd Decl. Ex. 32, at ¶ 7 (final action by USPTO regarding '953. patent).) Thereafter, in October, 2011, the USPTO issued re-examination certificates for the '344 and '953 patents.[2]

B.

Dey's second family of patents is composed of United States Patent Numbers 7,348,362 (the "'362 patent"); 7,462,645; 7,465,756; 7,473,710; and 7,541,385. Dey filed its provisional application for the '362 patent on July 10, 2003, and the patent ultimately issued on March 25, 2008. (Hurd Decl. Ex. 3 ("'362 Patent"), at [45].) The other patents in the second family were filed in March, 2007, and issued between 2008 and 2009. (See Hurd Decl. Exs. 4-7 at [22], [45].) Each of these patents related to the initial, July 10, 2003 provisional application. (See, e.g., Hurd Decl. Ex. 4 at [60].) The second family of patents, like the first family, claims various doses and methods of administration for stable, storable formoterol solutions. (See, e.g., '362 Patent, col. 19, l. 44 – col. 21, l. 23.)

[2] See U.S. Patent No. 6,667,344, Reexamination Certificate C1 (8624th) (issued Oct. 4, 2011); U.S. Patent No. 6,814,953, Reexamination Certificate C1 (8630th) (issued Oct. 12, 2011).

c.

The allegedly infringing product in this case, Brovana, is a drug manufactured and marketed by Sunovion for the treatment of COPD. Brovana is a formoterol-based[3] drug, taken by nebulizer.

In February, 1998, Sunovion filed an Investigational New Drug Application ("INDA") with the Food and Drug Administration (FDA), expressing an intent to develop a formoterol "Inhalation Solution for the prevention of reversible airway obstruction . . . ." (See Hurd Decl. Ex. 10 ("INDA"), at 1.) The INDA sought to begin human clinical trials to test this solution. (See INDA at 1-2.) Sunovion was, at the time, the assignee of at least one patent, the application for which was filed in 1998, claiming pharmaceutical compositions containing formoterol. (See Hurd Decl. Ex. 35 (Patent No. 6,040,344, or the "Gao Patent"), at col. 20, ll. 33-59.)

Sunovion later began those trials, testing various formoterol solutions in a variety of human trials. (See Hurd Decl. Ex. 11 ("Sunovion NDA"), at 16-17.) One of those trials,

[3] Brovana uses (R,R)-formoterol. (R,R)-formoterol is an enantiomer of racemic formoterol. (See Hurd Decl. Ex. 10 ("INDA"), at 1); see generally Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263, 1265-66 (Fed. Cir. 2007) (discussing enantiomers and racemic mixtures). For the purpose of the current motion, (R,R)-formoterol will be referred to as formoterol.

Study 50, was a double-blind, randomized clinical study of the effect of particular formoterol solutions on the treatment of patients with COPD. (See Sunovion NDA at 17.) Study 50 used three batches of formoterol doses, batches 3501A, 3501B, and 3501C. (Sunovion NDA at 17.)[4] The parties do not dispute for the purposes of this motion that Batch 3501A is the composition that was ultimately marketed as Brovana.

Sunovion manufactured batch 3501A for use in the trials in June 2001. (Def.'s R. 56.1 Stmt. at ¶ 4; Pl.'s R. 56.1 Resp. at ¶ 4.) The following properties of the Batch 3501A doses are undisputed: they were manufactured in sterile unit doses, in volumes of 2 milliliters each, with a formoterol free base concentration of 7.5 micrograms per milliliter ("µg/mL"); they had an ionic strength of approximately 0.16, and had a pH of approximately 5.0; they comprised water, contained a citrate buffer, and did not contain a propellant; they were intended for direct administration, by nebulization, "without dilution or modification" of the doses, and were so administered; they were packaged in unit dose vials wrapped in a laminate pouch; and they were projected to be able to retain over 96% of their formoterol content after 3 years of refrigerated storage, and were able to retain over 94% of their formoterol content after 3

[4] Batch 3501A was also used in another clinical trial conducted by Sunovion, Study 51, on the treatment of patients with COPD. (Sunovion NDA at 17.)

months of room temperature storage. (Def.'s R. 56.1 Stmt. at ¶¶ 5-18; Pl.'s R. 56.1 Resp. at ¶¶ 5-18.)

Sunovion began screening subjects for Study 50 on February 27, 2002. (See Hurd Decl. Ex 19 ("Study 50 Report"), at 1.) The study was designed to observe subjects over the course of 12 weeks of treatment for COPD. (See, e.g., Study 50 Report at 1.) 587 subjects completed the study, including 124 who received Batch 3501A. (Study 50 Report at 1.) Potential participants were initially screened at a medical facility where they received a medical evaluation. After the screening period, participants again visited a medical facility, at which point they entered a two week period, Period I, during which they received and were taught to home-administer a placebo. The next phase of the study, Period II, lasted 12 weeks, with visits to the medical facility every 3 weeks. At the beginning of Period II, participants were given one of five treatments: three different concentrations of a formoterol solution (25 µg/mL, 12.5 µg/mL, or 7.5 µg/mL), a 42 µg/mL salmeterol dose of a pharmaceutical called Serevent, or a placebo. Period II was double-blinded, and neither the participants nor the investigators knew at the time which subjects were given which treatments during Period II. The participants self-administered the treatments at home, using a nebulizer and an inhaler. (Hurd Decl. Ex 18 ("Study 50 Design"), at 5-10, 20-22.) Period III,

the final period of the study, lasted up to a week, and included two final visits to the medical facility to assess the effects of the treatment. (Study 50 Design at 8-9.)

Before entering the study, the participants were required to review and sign a consent form. The consent form explained that participants were being asked "to participate in a research study of the effects of []formoterol . . . to treat COPD" and that the "purpose of this research study is to determine the safety, tolerability, and effectiveness of three doses (15 µg, 25 µg, 50 µg)[5] of []formoterol . . . in opening narrowed airways." (Hurd Decl. Ex. 22 ("Study 50 Consent Form"), at 1.) The consent form explained that "[]formoterol is made by Sepracor, Inc." (Study 50 Informed Consent at 1.) The consent form explained that the participants would take the formoterol with a nebulizer, and that they would be required to use both a nebulizer and a metered dose inhaler ("MDI") during the course of the study, although for participants who had been assigned formoterol, the MDI would contain a placebo.[6] The consent form further explained that the "study staff will instruct you on how

[5] Because the treatments were administered in 2 mL doses, these dosages correspond to 7.5 µg/mL, 12.5 µg/mL, and 25 µg/ML, respectively.

[6] Because the control medication, Serevent, is taken with an MDI, subjects were required to use both an MDI and a nebulizer in order to prevent them from knowing which medication they might be taking. (Study 50 Informed Consent at 2.)

to prepare and use all medications, equipment and materials." (Study 50 Informed Consent at 2.) The consent form did not restrict the ability of participants to discuss the study with others, and explained that participants "may wish to discuss this study and your participation in it with your regular doctor." (Study 50 Informed Consent at 17.) Participants were required to return all of the medication they were given during the course of the study, as well as "documents (logs, etc.)." (Study 50 Informed Consent at 17.) Participants were allowed to keep the nebulizer.

The record indicates that at least some subjects in Study 50 received their doses of the Batch 3501A before July 10, 2002. For example, Subjects 16, 19 and 23, who received Batch 3501A doses, completed the study on July 8, 2002, and Subject 820 completed the study two days later, on July 10, 2002. (Hurd Decl. Ex. 20 ("Study 50 Clinical Data"), at 1, 3.) Subject 815 completed the study in June, 2002. (Study 50 Clinical Data at 2.) A small sample of the data from Study 50 indicates that at least 10 participants received the Batch 3501A 7.5 µg/mL formoterol solution before July 9, 2002. (Study 50 Clinical Data at 1-5; see also, e.g., Hurd Reply Decl. Ex. 43 ("Study 50 Drug Accountability Log"), at 57 (indicating that Subject 179 received 128 vials of the Batch 3501A substance between June 5 and July 9, 2002).) At least two of those participants did not

return all of their doses. (Study 50 Drug Accountability Log at 56-57.) The last subject in Study 50 had the final visit with Sunovion's investigators on June 18, 2003. (Study 50 Report at 1.)

Sunvion asserts, and Dey does not contest, that Brovana received final approval from the Food and Drug Administration ("FDA") in April, 2007, and was thereafter marketed to the public. (See Compl. ¶ 5; Ans. ¶ 5.)

D.

Dey filed this lawsuit in March, 2007, alleging patent infringement based on the "imminent launch" of Brovana. Sunovion, in response, filed counterclaims alleging the invalidity of the various patents at issue. After extensive discovery and motion practice by the parties, including, in March, 2010, the voluntary dismissal of the claims and counterclaims relating to certain claims in the '953 patent, Sunovion moved for summary judgment on all claims. That motion was dismissed without prejudice in February, 2011 in light of the ongoing reexamination by the USPTO of the '344 and '953 patents. After the reexamination was complete, Sunovion filed the current motion for partial summary judgment.

Sunovion has conceded for the purpose of this motion that its Brovana product infringes the various patent claims asserted by Dey.

III.

Sunovion first argues that summary judgment should be granted declaring the second family of patents invalid under 35 U.S.C. § 102(b) because Sunovion was publicly using the invention claimed in that family of patents in its own clinical trial more than one year prior to the earliest application date associated with that family of patents.

A.

A person is not entitled to a patent if "the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). "A bar under § 102(b) arises where, before the critical date, the invention is in public use and ready for patenting." Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1379 (Fed. Cir. 2005); see also Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60, 64 (1998) (noting that "reluctance to allow an inventor to remove existing knowledge from public use" informs both the "on sale" and "public use" bars).

It is undisputed for the purposes of this motion that the Batch 3501A composition used by Sunovion in the Study 50 clinical trial was "ready for patenting." Nor could it be contested, because the invention at issue is Dey's, and Dey cannot concede that its own invention was not ready for patenting. Moreover, Sunovion has conceded for the purposes of this motion that the Batch 3501A composition falls within the asserted claims stemming from Dey's second family of patents. It is further undisputed that the critical date at issue is July 10, 2002, or one year before the filing of the provisional application for the '362 patent. See 35 U.S.C. § 102(b). The record establishes that at least some participants in the Study 50 trial received, took home, and used the Batch 3501A doses prior to June 10, 2002. (See, e.g., Study 50 Clinical Data at 1-5.) The sole issue is whether the Study 50 trial constituted a "public use" of the invention claimed by Dey's second family of patents. Whether a public use has occurred is a question of law. Baxter Int'l, Inc. v. COBE Labs., Inc., 88 F.3d 1054, 1058 (Fed. Cir. 1996); see Netscape Commc'ns Corp. v. Konrad, 295 F.3d 1315, 1320 (Fed. Cir. 2002).

"Public use includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." Id., (internal quotation marks and alteration omitted); see also

Invitrogen, 424 F.3d at 1380 ("The proper test for the public use prong of the § 102(b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited."); Allied Colloids Inc. v. American Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995) (courts consider, among others, "such factors as the nature of the activity that occurred in public; the public access to and knowledge of the public use; whether there was any confidentiality obligation imposed on persons who observed the use; whether progress records or other indicia of experimental activity were kept; whether persons other than the inventor or acting for the inventor conducted the experiments; how many tests were conducted; the scale of the tests compared with commercial conditions; the length of the test period in comparison with tests of similar products; and whether payment was made for the product of the tests.").

"[T]hird party prior use accessible to the public is a section 102(b) bar." Eolas Techs. Inc. v. Microsoft Corp., 399 F.3d 1325, 1334 (Fed. Cir. 2005) (citing Baxter, 88 F.3d at 1058-59). However, "secret activity" by a third party who "elect[s] to avoid the patent system" does not constitute public use. Id. at 1334-35 (citing W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983)). With regard to third party prior public use, "[s]ection 102(b) may bar patentability by anticipation if the device used in public

includes every limitation of the later claimed invention." Zenith Elecs. Corp. v. PDI Commc'n Sys., Inc., 522 F.3d 1348, 1356 (Fed. Cir. 2008) (internal quotation omitted). Where, as here, there is no dispute that the substance in public use included every limitation of the claimed invention, (see Def.'s R. 56.1 Stmt. at ¶¶ 4-18; Pl.'s R. 56.1 Resp. at ¶¶ 4-18), the issue is simply whether or not the use was public.

The Court of Appeals for the Federal Circuit has explained that a third party public use "itself need not be enabling. Rather, [a court] must simply determine whether the public use related to a device that embodied the invention." Zenith, 522 F.3d at 1356 (citation omitted). Moreover, "[i]t is not public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it." New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1299 (Fed. Cir. 2002) (internal quotation marks omitted). While even "[a] single instance of public use can give rise to Section 102(b)'s bar to patentability," Sys. Mgmt. Arts Inc. v. Avesta Techs., Inc., 87 F. Supp. 2d 258, 268 (S.D.N.Y. 2000), the issue of whether or not the use is public often turns on whether there were assurances or expectations of confidentiality. Id. (collecting and comparing cases).

B.

In this case, the Study 50 trial was a public use within the meaning of § 102(b). As an initial matter, the record indicates that the participants had some knowledge of the compositions that they were receiving. They were informed that they might be receiving formoterol at one of three different, specified dosage levels, and that the study was designed to test the effects of formoterol. They were aware that the formoterol might be in a form capable of nebulization (indeed, they were taught to self-administer the drug by nebulization), and that it was being used to treat their COPD. (See Study 50 Informed Consent at 1-2.)

Whatever the limits of that knowledge, though, the core issue is not public knowledge of the invention, but the public use of it. See New Railhead, 298 F.3d at 1299. The record reflects that at least 10 participants received substantial quantities of the batch 3501A, 7.5 µ/mL formoterol, single-dose, nebulizable substance before the critical date. Over a period of several months, the participants took several weeks' worth of the drug at a time to their homes, where they ostensibly nebulized it twice daily to treat their COPD. (See Study Design at 21-22.) In other words, whether or not they would have been able to reverse engineer batch 3501A, the Study 50 participants used the invention as intended. Zenith, 522 F.3d at 1356.

The participants were under no obligation of confidentiality to Sunovion (let alone Dey), and indeed, they were explicitly told that they "may wish to discuss this study and your participation in it with your regular doctor." (See Study 50 Informed Consent at 14.) The informed consent form provided that participants "may also request that the person who is in charge of this study speak directly with your doctor." (See Study 50 Informed Consent at 14.) The participants' personal physicians also owed no duty of confidentiality to Sunovion or Dey. Moreover, while the participants were asked to return unused medication, the record indicates that some participants failed to do so, and were given more doses anyway. (See Study 50 Drug Accountability Log at 56 (indicating that Subject 99 lost six doses from the 48 he received, and was given a fresh batch of 48 doses upon the subject's next visit).) Study participants were not required to refrain from speaking about the trial and the substance they were or might be taking, and were not prevented from using their personal supply of that substance however they saw fit. See Baxter, 88 F.3d at 1058-59 (use of a centrifuge in a government research facility was a public use where the centrifuge was viewed by people "who were under no duty to maintain it as confidential," despite the fact that "use of the centrifuge was not publicly known or accessible, and ethical constraints would have limited or

precluded those who saw the centrifuge in operation from disclosing their knowledge of it").

Dey argues that the staff who monitored the clinical trial, and essentially all other non-participants involved in the trial, were obligated to maintain confidentiality. This argument is unpersuasive. First, because the participants' unfettered use of the composition for weeks at a time itself constituted a public use, a restriction on the trial administrators is irrelevant. Moreover, while administrators of the clinical trial may have had a confidentiality obligation to Sunovion, there is no evidence to suggest that anyone involved in the study was "under [any] limitation, restriction or obligation of secrecy to the [putative] inventor" or the putative inventor's assignee, Dey. Netscape, 295 F.3d at 1320; see also id. at 1322-23 ("Konrad is the inventor of the patents; the limitation, restriction, or obligation of secrecy of others using the invention is owed to him, not the persons or entities providing the funding. The onus is on him, as the inventor, to protect the confidentiality of his invention and its use by others before the critical date.") (citation omitted).

Nor does the evidence indicate that Sunovion acted so as to hide a "trade secret" from the patent system, such that the trial was not a public use. See, e.g., Eolas, 399 F.3d at 1334-35. Here, there is no evidence that Sunovion was suppressing

disclosure of the invention through the patent system. Sunovion had applied in 1998 for regulatory permission to conduct human trials using formorterol. (See, e.g., INDA at 1.) The Study 50 trial was a Phase III clinical trial, the final clinical step before approval for marketing from the FDA. Moreover, Sunovion was, at the time of the trial, the assignee of a patent claiming pharmaceutical compositions containing formoterol. (Gao Patent, col. 20, ll. 33-59.) The evidence indicates that Sunovion was, at the time, operating within the patent and regulatory system, and had not "deliberately chose[n] to . . . avoid disclosure," Eolas, 399 F.3d at 1334, or to engage in the "secret commercialization" of the invention without the patent system, Gore, 721 F.2d at 1550.

The cases that have addressed whether clinical trials of pharmaceuticals constitute a "public use" are not contrary to the conclusion that the trial in this case was an invalidating public use. These cases have addressed clinical trials in the context of a patentee's ostensible public use. See, e.g. In re Omeprazole Patent Litig., 536 F.3d 1361 (Fed. Cir. 2008); Janssen Pharmaceutica, N.V. v. Eon Labs Mfg., Inc., 134 F. App'x 425 (Fed. Cir. 2005); Bayer Schering Pharma AG v. Barr Labs., Inc., No. 05 Civ. 2308, 2008 WL 628592 (D.N.J. March 3, 2008). In that situation, where the issue is whether the plaintiff-patentee's clinical trials constituted public use, the

"experimental use" doctrine can negate the application of § 102(b) notwithstanding the public use.[7] See In re Omeprazole Patent Litig., 490 F. Supp. 2d 381, 507 (S.D.N.Y. 2007) (finding that the clinical trials at issue had "resulted in some public disclosure of the inventions at issue," but holding that "such disclosure was the result of experimental use, and is thus beyond § 102's public use bar"), aff'd on other grounds, Omeprazole, 536 F.3d at 1372; see also Janssen, 134 F. App'x at 431 (affirming judgment of the district court, after bench trial, of no public use where the "evidence supports Janssen's

[7] "[E]vidence of experimental use . . . operates to negate application of section 102(b)." EZ Dock v. Schafer Sys., Inc., 276 F.3d 1347, 1351 (Fed. Cir. 2002); see generally Pfaff, at 525 U.S. at 64 ("[A]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye."). The purpose of the experimental use exception is to "allow the inventor to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application." In re Hamilton, 882 F.2d 1576, 1581 (Fed. Cir. 1989); see also Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1327 (Fed. Cir. 2009) ("[T]he experimental use negation of the § 102(b) bar only exists to allow an inventor to perfect his discovery through testing without losing his right to obtain a patent for his invention."). Thus, "[i]f it is not the inventor or someone under his control or 'surveillance' who does these things, there appears to us no reason why he should be entitled to rely upon them to avoid the statute." Hamilton, 882 F.2d at 1581.

Here, the putative public use at issue is Sunovion's clinical trial, and the inventions at issue are Dey's. The parties appear to be in agreement that the "experimental use" exception does not apply to clinical trials by a third party. (See Oral Arg. Tr. at 25 ("[Dey is] not alleging experimental use.")

position that the use [in clinical trials by the plaintiff-patentee] was confidential and controlled by Janssen.").

Here, however, the public use at issue is not that of the patentee, but of a third party, and thus the experimental use exception does not apply. See Baxter, 88 F.3d at 1060-61 ("[P]ublic testing before the critical date by a third party for his own unique purposes of an invention previously reduced to practice and obtained from someone other than the patentee, when such testing is independent of and not controlled by the patentee, is an invalidating public use, not an experimental use."). Neither party cites a similar case where an allegedly infringing third party alleges that its use of the patented invention in a clinical trial was a public use and the patent holder claims that it was not a public use. However, all of the indicia of lack of confidentiality for the clinical trial in this case, coupled with the plain lack of any control or obligations to the patent holder, demonstrate that the patented invention was in public use when Sunovion used it in its clinical trial.

Dey relies on Bayer, which found that the clinical trial in that case was not a public use within the meaning of § 102(b). Bayer is distinguishable for several reasons. First, as in other cases, Bayer dealt with public use by the plaintiff-patentee, and not by the allegedly infringing defendant, as in

this case. See 2008 WL 628592, at *42. Moreover, in Bayer, the individuals conducting the trial had an obligation of confidentiality to the putative inventor, who was sponsoring the trial, and the patent holder was able to exercise control over the trial. That is not the case here. Second, Bayer relied on the fact that while "the [clinical trial] patients were informed of the compound, they were not informed of the alleged innovation," a new type of coating for drug capsules. Id. at *41. This proposition is difficult to square with the Federal Circuit's holding that "[i]t is not public knowledge of [an] invention that precludes the inventor from obtaining a patent for it, but a public use." New Railhead, 298 F.3d at 1299. But, in any event, the participants here were made aware of the potentially relevant details of the invention: a ready-to-administer dose of a fluid containing a specific concentration of formoterol that was taken by nebulization. Moreover, the court in Bayer relied on the fact that the test monitors imposed strict controls on the participants' use of the drug, precluding the trial subjects' use from being public. See 2008 WL 628592, at *41. Here, however, the evidence in the record indicates there were participants who lost multiple doses of the drug and were given more. (See, e.g., Study 50 Drug Accountability Log at 56.)

Public use by a third party need not disclose the claimed invention in great detail, or to a wide body of the public. Rather, it must only make the use of the claimed invention available to some members of the public without restriction, limitation, or obligation to the inventor. Netscape, 295 F.3d at 1320. Because the invention claimed by the second family of patents was made accessible to and used by members of the public, with no obligation to Dey or enforceable restriction on that use, before the critical date, Dey's second family of patents is invalid under § 102(b), and summary judgment is granted in favor of Sunovion on the invalidity of the second family of patents.

IV.

Sunovion next moves for summary judgment precluding Dey from recovering any damages for any alleged infringement of Dey's first family of patents that took place before the issuance of the reexamination certificates by the USPTO in October 2011.

A.

Under 35 U.S.C. §§ 252 and 307, when claims in a patent undergo reexamination and are subsequently amended, a patentee cannot recover for any infringement of the reexamined claims

that occurred prior to the resolution of the reexamination, unless the amended claims are substantially identical to the original, asserted claims. See Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 827 (Fed. Cir. 1984) ("Congress . . . has explicitly limited claim continuity to claims in [a] reissued patent identical to claims in the original patent. . . . The statute permits . . . the claims of the reissue patent to reach back to the date the original patent issued, but only if those claims are identical with claims in the original patent. With respect to new or amended claims, an infringer's liability commences only from the date the reissue patent is issued."); see also 35 U.S.C. § 252 ("[I]n so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent."); id. at § 307(b) (applying § 252 to claims amended during a reexamination proceeding); accord DuVal Wiedmann, LLC v. InfoRocket.com, Inc., 620 F.3d 496, 504 (Fed. Cir. 2010) ("If claims amended during reexamination are not 'identical' to the claims in the original patent, the patentee has no right to recover infringement

damages for periods prior to the date that the reexamination certificate issued.") (internal quotation marks omitted).

For the purposes of § 252, "identical means without substantive change." Id. (internal quotation marks omitted). "An amendment that clarifies the text of the claim or makes it more definite without affecting its scope is generally viewed as identical. . . ." Bloom Eng'g Co., Inc. v. N. Am. Mfg. Co., Inc., 129 F.3d 1247, 1250 (Fed. Cir. 1997). The Court of Appeals for the Federal Circuit has held that, while it is not a per se rule, it is "difficult to conceive" that a claim that has been amended to avoid rejection on the basis of prior art could be substantively identical to the original claim. Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1348 (Fed. Cir. 1998). Moreover, where there has been a substantive change in an independent claim, the dependent claims will be found to have been substantively changed as well. See, e.g., Abbey v. Robert Bosch GMBH, 217 F.3d 853, 1999 WL 819683, at *3 (Fed. Cir. 1999) (table).

Whether claims have been substantively changed on reexamination is a legal question, and ordinary principles of claim construction apply. Laitram, 163 F.3d at 1347. "[T]o determine whether a claim change is substantive it is necessary to analyze the claims of the original and the reexamined patents in light of the particular facts, including the prior art, the

prosecution history, other claims, and any other pertinent information. This inquiry, however, is circumscribed by the well-established principle that a court may not import limitations from the written description into the claims." Id. (internal quotation marks and citation omitted). Limitations may not be imported into the claims from the title of the patent, see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1312 (Fed. Cir. 1999), or from the specifications, see Laitram, 163 F.3d at 1347. "Thus, it is the claims, not the written description, which define the scope of the patent right." Id. The specifications are not irrelevant. "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (citation omitted); see also Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998).

B.

Here, independent claim 1 of the '344 Patent and independent claim 74 of the '953 Patent were rejected by the

USPTO upon reexamination in June, 2010. (See '344 Rejection; '953 Rejection.) Dey subsequently amended independent Claim 1 of the '344 patent as follows:

> A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable ~~fluid~~ [aqueous solution], wherein the composition is stable during long term storage, ~~the fluid comprises water, and~~ the composition is formulated at a concentration [effective for bronchodilation by nebulization, and the composition is] suitable for direct administration to a subject in need thereof[, without propellant and without dilution of the composition prior to administration].
>
> ('344 Rejection Response at 3 (deletions struck through and additions in brackets and with emphasis).)

Dey amended independent claim 74 of the '953 patent as follows:

> A method for the treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders, comprising administering an effective amount of a pharmaceutical composition [by nebulizer] to a subject in need of such treatment, wherein the pharmaceutical composition comprises formoterol or a derivative thereof[,] formulated at a concentration suitable for direct administration to a subject in need ~~thereof~~ [of bronchodilation], [wherein said formoterol or derivative is present] in a pharmacologically suitable ~~fluid~~ [aqueous solution], [and] wherein the composition is stable during long term storage ~~and the fluid comprises water~~.
>
> ('953 Rejection Response at 10.)

The issue is whether any of these changes constituted a substantive change. Sunovion asserts five amendments that they allege are substantive changes. There is no dispute that if the Court finds even one substantive change, then § 252 bars Dey

from receiving damages for any infringement of the original claims. See Bloom Eng'g, 129 F.3d at 1250.

1.

First, Sunovion argues that the addition of "without propellant" to independent claim 1 of the '344 patent was a substantive change. Dey argues that its original claim phrase "pharmacologically suitable fluid" was defined in its claim specifications as "not a liquified propellant gas," ('344 Patent, col. 5, ll. 16-17), and that, therefore, the addition of "without propellant" to the amended claim did not modify the scope of the claim. Dey advances no other argument for why the "fluid" described in its original independent claim necessarily would not include a propellant.

The original claim language, on its face, does not rule out the possibility of a fluid which includes a propellant. It would be improper, then, to read a "no propellant" limitation into the original claim language based solely upon the specifications. See Laitram, 163 F.3d at 1347 ("Claims are not to be interpreted by adding limitations appearing only in the specification.") (quoting Electro Med. Sys. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994). Even accepting Dey's assertion that the specifications' definition of the fluid as "not a liquified propellant gas" is relevant to the

analysis, the fluid's being "not a liquified propellant gas" is not the same as the fluid being "without propellant." The former includes fluids that contain some propellant but are "not a liquefied propellant gas." The latter, by contrast, categorically excludes fluids that contain any propellant.

Moreover, the prosecution history indicates that the addition of "without propellant" was used by Dey to distinguish prior art and to overcome the rejection of the claim on that basis. (See, e.g., '344 Rejection Response at 37 ("Claim 1 has also been amended to call for a formulation . . . without propellant . . . . Maesen's formulation uses a propellant.").)[8] The addition of "without propellant" limited the scope of the amended claim as compared to original independent claim 1, and it is therefore a substantive change to the '344 Patent.

[8] As Dey explained during the reexamination, "Maesen's formulation [of formoterol] is for a metered dose inhaler," and "a metered dose inhaler . . . uses a propellant." ('344 Rejection Response at 37.) Dey explained that MDIs require much higher formoterol concentrations "than the concentrations specified in independent claim 1." ('344 Rejection Response at 37.) However, as explained in greater detail below, the original dependent claims recited formoterol concentrations significantly higher than the range that Dey attributed to Maesen in its arguments to the USPTO. Thus, the addition of "without propellant," along with changes that Dey made to the concentration ranges claimed in the dependent claims, also distinguished the amended claims from Maesen.

2.

Second, Sunovion argues that the addition of "effective for bronchodilation by nebulization" to independent claim 1 of the '344 Patent, and "by nebulization" to independent claim 74 of the '953 Patent, were substantive changes. The original independent claims did not explicitly specify nebulization.

The original independent claims speak only of a composition "suitable for direct administration." Dey does not argue that, on its face, "suitable for direct administration" can only mean "by nebulization." To the contrary, Dey acknowledged in its arguments to the USPTO that there "are three methods for producing an aerosol for inhalation therapy: nebulizers, metered dose inhalers, and dry powdered inhalers." ('344 Rejection Response at 36; '953 Rejection Response at 38.) These are also methods of "direct administration," inasmuch as they might each be ready to administer a dose, as-is. Dey argues that the specifications in the '344 and '953 patents speak only of administration by nebulization. However, even if that were correct, it remains the case that the plain language of the independent claims permits other, available methods of "direct administration."[9] The amended claim language, by contrast, is

[9] In any case, the specifications do not indicate that the claimed invention was unsuitable for direct administration by methods other than nebulization. (See, e.g., '344 Patent, col. 3, ll. 48-52 ("In certain embodiments, the compositions are

limited to nebulization. The plain language of the claims must govern their scope. See Laitram, 163 F.3d at 1347. Therefore, the addition of "by nebulization" is a substantive change.

This conclusion is further supported by the fact that the addition of "by nebulization," as well as other amendments to the independent and dependent claims that helped exclude other forms of direct administration,[10] were used by Dey to distinguish prior art and overcome the previous objections. In its arguments to the USPTO, Dey repeatedly claimed that the references cited by the USPTO as raising substantial new questions of patentability did not disclose compositions that were effective specifically for nebulization. (See, e.g., '344

---

administered via nebulization. Administration of a nebulized aerosol is preferred over the use of dry powders for inhalation in certain subject populations, including pediatric and geriatric groups.").)

[10] For example, as discussed in greater detail below, the range of formoterol concentrations disclosed by the dependent claims in the '344 and '953 patents was dramatically reduced during the amendment process. As Dey explained to the USPTO, a typical formoterol concentration for an MDI inhaler would be 120-400 µg/mL, and that level "is far more concentrated than what is acceptable for nebulization." ('344 Rejection Response at 37; '953 Rejection Response at 39.) The original dependent claims in the '344 and '953 patents disclosed formoterol concentrations at up to 2000 µg/mL. (See '344 Patent col. 19, ll. 18-30 (claims 22-26); '953 Patent col. 23, ll.14-26 (claims 94-98).) The amended claims disclosed concentrations no higher than 118 µg/mL. Similarly, MDI inhalers generally use a propellant, (see, e.g., '344 Response at 37), and thus the unequivocal exclusion of any propellant through the addition of "without propellant" indicated that the amended claims were limited to nebulization.

Rejection Response at 49 (distinguishing Gao); ’953 Rejection Response at 51 (same); ’344 Rejection Response at 51 (distinguishing Murakami); ’953 Rejection Response at 53 (same); ’344 Rejection Response at 64 (distinguishing Hochrainer); ’953 Rejection Response at 66 (same).) In sum, the scope of the amended independent claims was plainly limited to compositions suitable and intended for nebulization, while their original scope was not so limited. This change in the scope of the claims was a substantive change to the ’344 and ’953 Patents.

3.

Third, Sunovion argues that the addition of “without dilution of the composition prior to administration” to independent Claim 1 of the ’344 patent was a substantive change.

Dey’s original independent claim speaks of a composition “formulated at a concentration suitable for direct administration to a subject in need thereof.” The plain meaning of the term “direct administration” excludes administration that requires additional preparation, for example, dilution. Indeed, another court evaluating the same language found that the addition of “without dilution” during the reexamination was not a substantive change, because “a person of ordinary skill in the art would understand the phrase ‘formulated at a concentration

suitable for direct administration' to mean that the compositions must be 'ready to use,' and that the compositions are 'ready to use' when they can be administered without diluting or mixing." Dey, L.P. v. Teva Parenteral Meds., Inc., No. 09 Civ. 87, 2011 WL 2461888, at *7 (N.D. W.Va. June 17, 2011). While Sunovion argues that the original claim language would have allowed for some dilution, any method that required additional preparation, including diluting the compound, would not have been "suitable for direct administration." This addition therefore merely clarified the inherent meaning of the claim and was not substantive.

4.

Fourth, Sunovion argues that the replacement of the term "pharmacologically suitable fluid . . . [that] comprises water" with the term "pharmacologically suitable aqueous solution" in both of the independent claims at issue was a substantive change.

The issue here is whether there is a substantive difference between a "fluid" that "comprises water" and an "aqueous solution." Sunovion argues that "comprises" is a broad term that does not preclude the fluid from containing a very small amount of water, whereas "aqueous" means that the composition was "predominantly, if not totally, water." Dey argues in

response that there is no statement of the exact amount of water to be used in either the original or the amended claims, and that there is no basis for the assertion that an "aqueous solution" is exclusively or predominantly made of water.

The issue is whether the term "aqueous solution" as used in the amended claims is more limited in scope than the term "fluid . . . [that] comprises water." Whether this change is substantive is not necessarily obvious from the words of the claim themselves: an aqueous solution, by its plain meaning, contains water and some other substance; a fluid that comprises water also contains water and may contain other substances. See Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997) ("'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); In re Baxter, 656 F.2d 679, 686 (C.C.P.A. 1981) ("As long as one of the monomers in the reaction is propylene, any other monomer may be present, because the term 'comprises' permits the inclusion of other steps, elements, or materials.").

However, the prosecution history and the specifications indicate that this change was substantive, because it narrowed the scope of the claims. In the first paragraph of its "Summary of the Invention," in the '344 and '953 Patents, Dey explained

that, “[p]harmacologically suitable fluids include, but are not limited to, polar fluids, including protic fluids[,]” and that “[i]n certain embodiments herein, the compositions are aqueous solutions.” (’344 Patent, col. 2, ll. 29-32; ’953 Patent, col. 2, ll. 36-39.) The detailed description of the original claim term “pharmacologicially suitable fluid” in the specifications provided that such a fluid was “a solvent suitable for pharmaceutical use which is not a liquified propellant gas. Exemplary pharmacologically suitable fluids include polar fluids, including protic fluids such as water.” (’344 Patent, col. 5, ll. 15-19; ’953 Patent, col. 5, ll. 26-30.) The specifications further explained that, “[a]s used herein, fluid . . . encompasses compositions that are in the form of semi-solids, pastes, solutions, aqueous mixtures, gels, lotions, creams and other such compositions.” (’344 Patent, col. 5, ll. 23-26; ’953 Patent, col. 5, ll. 33-36.) The terms of the specifications indicate that some, but not all, of the fluids encompassed by the original claim terms were “aqueous solutions” or “aqueous mixtures”, and therefore that some of the fluids encompassed by the original claim language were not aqueous solutions.

This construction is supported by Dey’s arguments with regard to the prior art. In rejecting the original ’344 and ’953 patents over prior art, the USPTO explained that Maesen, in

the prior art, "discloses a pharmaceutical composition of formoterol administered as a solution in lecithin,"[11] and that, because another prior art reference established that "lecithin contains water," "the lecithin in Maesen contains water, which meets the claim 1 [of the '344 patent] limitation directed to fluid comprises water." ('344 Rejection at 6-7; see also '953 Rejection at 6-7 (same for '953 Patent).) After amending the claim language to claim an "aqueous solution," Dey argued to the USPTO that "all of the pending claims call for an aqueous formoterol solution" and that "[t]here is nothing in Maesen that says that its formoterol solution was an aqueous solution." (See '344 Rejection Response at 33; '953 Rejection Response at 35.) The difference, Dey explained, was that an aqueous solution is "water-based," and must contain more than the 1.5% water found in a "phospholipid-based fluid" such as Maesen's. (See '344 Rejection Response at 33-34; '953 Rejection Response at 35.) A "phospholipid-based fluid" that is 1.5% water is plainly a "fluid . . . [that] comprises water." Yet this same fluid was, according to Dey, excluded from the scope of the amended claim as not having enough water. The substitution of

[11] "Lecithin is a natural organic substance occurring in practically all living cells and in considerable quantities in egg yolk and in seeds of most plants." American Lecithin Co. v. Warfield Co., 128 F.2d 522, 523 (7th Cir. 1942).

"aqueous solution" in the '344 and '953 Patents was therefore a substantive change.

E.

Finally, Sunovion argues that Dey limited the concentrations of formoterol covered by the dependent claims in the '344 and '953 Patents in order to distinguish prior art, and that these limitations constituted an explicit disavowal of the original, broader range of claimed concentrations for the independent claims and thus a substantive change to the scope of the independent claims.

An explicit disavowal of the scope of a claim, even where the claim language is silent, can operate to limit the claim. See Omega Engineering, Inc, v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution."). A prosecution disclaimer can operate as a "substantive change" that limits damages under § 252 and § 307. See University of Virginia Patent Foundation v. General Elec. Co., 755 F. Supp. 2d 738, 748-49 (W.D. Va. 2011) (noting that "[s]ection 307(b) was intended to reach instances where the patent holder effects a change in claim scope in reexamination to secure its validity

over prior art while avoiding an explicit change in wording" and holding that, because "arguments to the [US]PTO can just as effectively limit claim scope as explicit amendments," the term "amended" in § 307(b) applies to changes in claim scope due to prosecution disclaimer); see generally American Piledriving Equipment, Inc. v. Geoquip, Inc., 637 F.3d 1324, 1336 (Fed. Cir. 2011) ("[A]n applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well.") (finding disavowal of particular definition of claim term based on arguments made on reexamination).

Here, the original dependent claims in the '344 and '953 patents claimed formoterol concentrations ranging from 5 µg/mL to 2000 µg/mL. (See '344 Patent, col. 19, ll. 18-30 (claims 22-26); '953 Patent, col. 23, ll. 14-26 (claims 94-98). The dependent claims were amended to disclose formoterol concentrations of between 5 µg/mL to 118 µg/mL. ('344 Rejection Response at 6; '953 Rejection Response at 13.) The issue is whether this constitutes a substantive change to the independent claims.

An independent claim generally must have a meaning broad enough to encompass any claims that are dependent on it. See AK Steel Corp. v. Sollac and Ugine, 344 F.3d 1234, 1242 (Fed Cir.

2003) (“Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend.”). Sunovion argues from this premise that the scope of the independent claims was altered during the amendment process, because the original independent claim language, “formulated at a concentration suitable for direct administration,” which appeared in both patents, necessarily included formoterol concentrations of up to 2000 µg/mL, whereas the amended independent claims needed only to be broad enough in their meaning to cover up to 118 µg/mL of formoterol. Dey argues that the language of the dependent claims is irrelevant, because there is no limitation on the formoterol concentration in the independent claims. Rather, Dey argues, the independent claims contain only a “functional” limitation, and cover any formoterol concentration capable of meeting the functional limitation that the concentration be “suitable for direct administration.”

The flaw in Dey’s argument is that there was a substantive change in the functional limitations to the independent claims that corresponds to the change in concentration ranges. The amended independent claims were changed to limit the administration of the composition to administration “by nebulization,” or “by nebulizer.” As Dey explained during reexamination in distinguishing prior art that had disclosed

formoterol compositions for an MDI inhaler, higher concentrations of formoterol, like the 120-400 µg/mL dose typically used with an inhaler, are "far more concentrated than what is acceptable for nebulization" and "far more concentrated than the concentrations specified in independent claim 1." ('344 Rejection Response at 37; see also '953 Rejection Response at 39.) In other words, Dey explicitly disavowed during reexamination formoterol concentrations exceeding 120 µg/mL from the scope of the independent claims, despite the fact that the original independent claims must have included formoterol concentrations that greatly exceeded that amount. This change to the independent claims was substantive, because it narrowed the scope of the independent claims.

The interplay between the various additions and amendments—the addition of "by nebulization," "aqueous solution," and without propellant, and the narrowing of the concentration ranges—highlights the broader substantive change effected by the amendments in combination: taken together, these changes reduced the scope of the independent claims from a ready-to-use formoterol composition that might be administered in a number of ways and forms, to a more specific invention that was for administration by nebulization only. The scope of the independent claims was narrowed substantially in the process. Sunovion is therefore entitled to partial summary judgment

precluding any damages for any alleged infringement of the '344 and '953 patents that occurred before October, 2011, when the reexamination certificates were issued for those patents.

CONCLUSION

The Court has considered all of the arguments raised by the parties. To the extent not specifically addressed above, the arguments are either moot or without merit.

Sunovion's motion for partial summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure is **granted**. The Clerk is directed to close **Docket No. 136**.

SO ORDERED.

Dated: New York, New York
March 1, 2012

John G. Koeltl
United States District Judge