UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DURAMED PHARMACEUTICALS, INC.,

Plaintiff,

v.

PADDOCK LABORATORIES, INC.,

Defendant.

09 Civ. 1905 (LBS)

OPINION

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SAND, J.

In this patent infringement action, Plaintiff Duramed Pharmaceuticals, Inc. (now Teva Women's Health, Inc.) ("Duramed") brings a motion for partial summary judgment, and Defendant Paddock Laboratories, Inc. ("Paddock") brings a motion for summary judgment of non-infringement. Duramed holds a patent that it contends covers its product Cenestin, a conjugated estrogen tablet used in hormone replacement therapy. Duramed contends that Paddock infringed its patent when Paddock sought to manufacture and market a generic version of Cenestin. In order to succeed on its patent infringement claim, Duramed must prove that the "moisture barrier coating" ("MBC") in Paddock's tablet is equivalent to Cenestin's MBC. Paddock counters that Duramed's actions in prosecuting its patent before the Patent and Trademark Office ("PTO") estop Duramed from asserting equivalency.

The Court finds that the doctrine of prosecution history estoppel bars Duramed from relying on the doctrine of equivalents to prove infringement, thereby defeating Duramed's patent infringement claim. Accordingly, Duramed's motion is denied, and Paddock's motion is granted in part.

I. Background

The products in question in this case are conjugated estrogen pills used in hormone replacement therapy to treat menopause symptoms. In the early 1990s, the FDA withdrew its approval for generic versions of Wyeth Pharmaceutical's patented conjugated estrogen product Premarin due to concerns that overly rapid dissolution of the pills could be harmful. (Duramed 56.1 ¶ 24.) In response, Duramed's inventors sought to create a pill with a suitable dissolution profile to compete with Premarin. They did so

by designing a pill that controlled the release rate of the estrogen, prevented the estrogen from disintegrating through contact with excess water during storage, and limited stress on the pill's moisture barrier coating to prevent cracking. (Duramed 56.1 ¶¶ 10-19.)

On July 25, 1996, Duramed applied for a patent on its invention. The patent application included one independent claim, claim 1, and 27 additional dependent claims. In the independent claim, Duramed originally claimed a tablet using any type of moisture barrier coating. (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074850) (claiming "[a] pharmaceutical composition . . . wherein said solid unit dosage form is coated with a moisture barrier coating."). Dependent claim 7 of the original patent application also specifically claimed "[a] pharmaceutical composition of claim 1 wherein said moisture barrier coating comprises ethylcellulose." (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074851.) Duramed then withdrew certain claims, and the patent examiner then rejected all remaining claims, including claim 1 and claim 7, as obvious in light of U.S. Patent No. 5,547,948 ("Barcomb"). (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074895-96.) The examiner explained that "Barcomb teaches . . . tablets having at least one coating . . . . Such coatings would read on the instantly claimed ethyl cellulose as a moisture barrier." (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074895-96.)

On November 30, 1998, the patent examiner conducted an in-person interview with Duramed, and suggested three amendments that would enable it to overcome the prior art and secure the patent. The interview summary stated that the "examiner suggests amending claim 1 to require the tablet to be substantially free of 'inorganic excipients' (which lead to cracking of coat) and insert limitations of claims 7 and 9 into

claim 1. These limitations overcome[] art and render[] claims allowable." (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074900.) The examiner's suggestion was thus that Duramed insert three further limitations into its overly broad independent claim to make the claim more specific: (1) the pill must be substantially free of inorganic excipients; (2) the pill must have a "moisture barrier coating compris[ing] ethylcellulose" (from dependent claim 7); and (3) the pill must comprise "about 30-70% gel-forming organic excipient and about 30-70% non-gel forming organic excipient by weight (from dependent claim 9). (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074851, 900.)

Duramed made the three suggested amendments "[i]n response to the Office Action dated June 4, 1998 [(the rejection)] and an Examiner's interview of November 30, 1998." (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074902.) Dependent claims 7 and 9 were deleted, and their limitations were added to the independent claim. (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074902.) In support of its amendments, Duramed argued that "the indication that a moisture barrier may be used [in the prior art Barcomb patent] does not suggest, or read upon, the claimed use of ethyl cellulose as a moisture barrier *in combination with* the claimed formulations comprising conjugated estrogens coated onto organic excipients, forming compositions having less than about 2.5% *free* water, which are coated with a moisture barrier over the tableted formulation." (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074906) (emphases in original). In response to Duramed's amendments, the examiner allowed certain amended claims, including the independent claim. (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074908.) In the notice of allowability mailed December 23, 1998, the examiner remarked that "applicants have adopted the suggestion made at the personal

interview of November 30, 1998." (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074911.)

The PTO granted U.S. Patent 5,908,638 ("the '638 patent") on June 1, 1999. Duramed began selling Cenestin that same year, and it was the only "modified-release conjugated estrogen alternative to Premarin" on the market at the time. (Duramed 56.1 ¶ 31.)

In October 2008, Paddock filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), which sought approval to sell a generic version of Duramed's Cenestin tablets. (Duramed 56.1 ¶ 38.) Under the Hatch-Waxman Act,[1] a company may seek expedited approval to market a generic version of a drug previously approved by the FDA by filing an ANDA. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1244 (Fed. Cir. 2000) (citation omitted). If the generic company can show "bioequivalence" between its proposed generic drug and the previously approved drug, it may forego safety and efficacy studies. *Id.* (citation omitted). Paddock's ANDA certified that Duramed's patent was invalid and that the patent would not be infringed by Paddock's generic drug, and Paddock submitted statutorily required notice letters to Duramed explaining its position. (Compl. ¶¶ 11-15.)

In March 2009, Duramed brought this patent infringement action against Paddock. By filing this lawsuit, Duramed obtained an automatic 30-month stay of FDA approval for Paddock's proposed generic drug. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The automatic stay remains in effect until the district court enters a judgment of non-infringement or patent invalidity, or the expiration of thirty

[1] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994) and 35 U.S.C. § 271(d)-(h) (1995). This legislation is commonly referred to as the Hatch-Waxman Act.

months, whichever occurs first. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I); 21 C.F.R. § 314.107(b)(3).

The parties agree that the MBC in Paddock's proposed generic tablets does not literally infringe the '638 patent. (Duramed 56.1 ¶ 51.) The '638 patent teaches a moisture barrier comprising ethylcellulose, while Paddock's proposed generic tablets use a polyvinyl alcohol ("PVA") MBC, marketed under the name Opadry AMB. Because Paddock's MBC does not literally infringe Duramed's patent, Duramed must rely on the doctrine of equivalents to succeed on its patent infringement claim. "[F]or a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device. A patentee must prove that the accused product contain(s) each limitation of the claim or its equivalent." *Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1384 (Fed. Cir. 2005) (citation and internal quotation marks omitted). Paddock argues that Duramed abandoned all equivalents to ethylcellulose MBCs pursuant to the doctrine of prosecution history estoppel.

II. Standard of Review

Summary judgment is warranted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A material fact is one that might affect the outcome of a suit under governing law. *Kinsella v. Rumsfeld*, 320 F.3d 309, 311 (2d Cir. 2003). A "genuine" issue exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When deciding cross-motions for summary

judgment, the Court analyzes each motion on its own merits, drawing all reasonable inferences in the light most favorable to the nonmoving party. *Heublein, Inc. v. United States*, 996 F.2d 1455, 1461 (2d Cir. 1993). Patent cases are amenable to summary judgment. *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984).

III. Discussion

Prosecution history estoppel is designed to prevent a patentee from recapturing through litigation what it has surrendered during patent prosecution to appease a skeptical patent examiner. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 734 (2002) ("*Festo VIII*").[2] The doctrine provides that if an applicant seeking a patent is rejected by the patent examiner on the grounds that the original patent application swept too wide,[3] and the applicant then adopts a narrowing amendment to mollify the patent examiner, the patentee is estopped from asserting that any of the abandoned territory constitutes an "equivalent" to the patented invention. *See, e.g.*, *id.* at 740-41 ("A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim."). Hence, when a patent application is rejected for overbreadth, the applicant must either (1) immediately appeal the rejection to maintain the breadth, or (2) craft a narrower application to secure the patent, but forever relinquish the ability to later

[2] The numbering of the various *Festo* opinions has been inconsistently applied *Compare Honeywell Intern., Inc. v. Hamilton Sundstrand Corp.* 523 F.3d 1304 (Fed. Cir. 2008) (referring to 493 F.3d 1368 (2007) as "*Festo X*") *with Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*, 493 F.3d 1368 (2007) (referring to 344 F.3d 1359 (2003) as "*Festo X*"). We adopt the numbering used in *Honeywell.*

[3] "[A] number of statutory requirements must be satisfied before a patent can issue. The claimed subject matter must be useful, novel, and not obvious. . . . In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention." *Festo VIII*, 535 U.S. at 736 (citations omitted). "[A] narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." *Id.* In this case, the original patent application swept too wide because it was obvious in light of prior art. (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074895-96.)

maintain in litigation that the surrendered territory is "equivalent" to the narrowed claims. "[An applicant's] decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim." *Id.* at 734. "Given a choice of imposing the higher costs of careful prosecution on patentees, or imposing the costs of foreclosed business activity on the public at large, this court believes the costs are properly imposed on the group best positioned to determine whether or not a particular invention warrants investment at a higher level, that is, the patentees." *Sage Products, Inc. v. Devon Industries, Inc*., 126 F.3d 1420, 1425 (Fed. Cir. 1997).

In order to determine if prosecution history estoppel applies, a court first asks "whether an amendment filed in the Patent and Trademark Office ("PTO") has narrowed the literal scope of a claim." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1366-67 (Fed. Cir. 2003) ("*Festo IX*"). An amendment narrows the literal scope of a claim when it renders a general description more specific, as when a genus is replaced with a species. *See, e.g.*, *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003) ("[T]he amendment of claim 1 from a 'multiplier' to a 'switching analog' multiplier narrowed the literal scope of the claim."). Here, it is plain that Duramed's amendment narrowed the literal scope of the claim.[4] Duramed originally claimed estrogen tablets with any kind of moisture barrier coating, and Duramed then amended the claim to reach only estrogen tablets with "moisture barrier coating[s] comprising ethylcellulose." (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074850, DPI_CENESTIN0074902.)

[4] In opposing Paddock's motion for summary judgment, Duramed does not argue otherwise. (*See* Pl.'s Mem. Opp. Def.'s Mot. Summ. J. 3.)

"[I]f the accused infringer establishes that the amendment was a narrowing one, then the second question is whether the reason for that amendment was a substantial one relating to patentability." *Festo IX*, 344 F.3d at 1366-67. "The burden is on the patent holder to establish that the reason for the amendment is not one related to patentability," and "[w]here no explanation is established, a court should presume that the applicant had a substantial reason related to patentability for the amendment." *Pioneer Magnetics*, 330 F.3d at 1362 (*citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32-33 (1997)). This is referred to as the *Warner-Jenkinson* presumption. *Id.* In opposing estoppel, Duramed makes no serious attempt to argue that the *Warner-Jenkinson* presumption does not apply. Nor could it, given that the prosecution history clearly shows that Duramed's original patent application was rejected as obvious in light of prior art, the patent examiner then suggested the ethylcellulose narrowing amendment in order to overcome prior art, and Duramed followed the examiner's advice and emphasized that the combination of the narrowing amendments established patentability.[5] As the Court of Appeals for the Federal Circuit stated in *Pioneer Magnetics*, "[o]ur own examination of the prosecution history convinces us that the amendment was made to avoid prior art, the classic basis for the application of prosecution history estoppel." *Pioneer Magnetics*, 330 F.3d at 1357.

Since the *Warner-Jenkinson* presumption has not been rebutted, the *Festo* presumption applies, which presumes "that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation." *Festo IX*, 344

[5] (*See* Paddock Ex. 36, '638 file history, DPI_CENESTIN0074895-96) (patent examiner's rejection of original application as obvious); (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074900) (patent examiner's suggestion of ethylcellulose narrowing amendment, *inter alia*, to overcome prior art); (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074906) (Duramed's argument that its adoption of the examiner's suggested narrowing amendments overcame prior art).

F.3d at 1367. The patentee bears the burden of rebutting the *Festo* presumption, and whether it has done so is a "question of law to be determined by the court, not a jury." *Id.* There are "three ways in which the patentee may overcome the [*Festo*] presumption[: (1)] by demonstrating that the equivalent would have been unforeseeable at the time of the amendment, [(2)] that the rationale underlying the amendment bore no more than a tangential relation to the equivalent in question, or [(3)] that there was some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 1365 (quotations, alterations, and footnote omitted). Duramed argues that material issues of fact prevent summary judgment on prongs one and two; Duramed does not dispute Paddock's claim that prong three is inapplicable here. (*See* Pl.'s Mem. Opp. Def.'s Mot. Summ. J. 3.)

a. Foreseeability

Under the foreseeability prong, a patentee must show that the equivalent which it seeks to claim—in this case Paddock's PVA MBC—was "unforeseeable at the time of the amendment and thus beyond a fair interpretation of what was surrendered." *Festo IX*, 344 F.3d at 1369. "An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown."[6] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*, 493 F.3d 1368, 1382 (2007) ("*Festo X*"). "Foreseeability does not require that the accused infringing product or process be foreseeable, nor that any equivalent exist at the time; rather foreseeability only requires that one of ordinary skill in

[6] "The parties agree that a person skilled in the art of the '638 patent would have had pharmaceutical formulation development experience." (Pl.'s Mem. Opp. Def.'s Mot. Summ. J. 4.)

the art would have reasonably foreseen the proposed equivalent at the pertinent time." *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1312 (Fed. Cir. 2008) (*citing Festo X*, 493 F.3d at 138). If an equivalent was developed after the date of the amendment, it is more likely to be unforeseeable; if it was developed before the amendment, it is more likely to be foreseeable. *Festo X*, 493 F.3d at 1369. If the equivalent not only preexisted the amendment but was "known in the prior art in the field of the invention, it *certainly* should have been foreseeable at the time of the amendment." *Id.* (emphasis added); *see also id.* at 1379 ("[A]n alternative is foreseeable if it is disclosed in the pertinent prior art in the field of the invention" at the time of the amendment); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1313 (Fed. Cir. 2006) ("[I]f an equivalent is known in the field, then it is foreseeable."); *Pioneer Magnetics*, 330 F.3d at 1357 ("As noted, the Carpenter [patent] discloses a non-switching multiplier circuit. Therefore, a non-switching circuit was known in the art and would have been foreseeable at the time of the amendment.").

Polyvinyl alcohol MBCs were indeed "disclosed in the pertinent prior art in the field of the invention" at the time of Duramed's narrowing amendment in 1998. *Festo X*, 493 F.3d at 1379. Colorcon, the manufacturer of Opadry AMB, filed an international patent application pursuant to the Patent Cooperation Treaty ("Colorcon PCT") on July 12, 1995. (Paddock Ex. 49, COL0008.) The Colorcon PCT was published on January 25, 1996, more than two years before Duramed's amendment. (Paddock Ex. 49, COL0008.) The Colorcon PCT not only describes PVA as "a moisture barrier coating for pharmaceutical tablets and the like," (Paddock Ex. 49, COL0008), but contains a claim disclosing exactly the same chemicals in the same concentrations as are used in the

Opadry AMB coatings on some of Paddock's generic tablets. (Paddock Ex. 49, COL0026; Paddock Ex. 45, COL0006-7.) The publication of the Colorcon PCT establishes that Polyvinyl Alcohol moisture barrier coatings for pharmaceutical tablets were "disclosed in the prior art," and were foreseeable at the time of Duramed's narrowing amendment.[7] *Festo X*, 493 F.3d at 1379.

Even discounting *arguendo* the four pre-1998 documents discussing Opadry AMB that Duramed claims were not published,[8] several additional facts reinforce our finding that PVA MBCs were foreseeable at the time of Duramed's narrowing amendment on December 3, 1998. (Paddock Ex. 36, '638 file history, DPI_CENESTIN0074902-07.) Colorcon produced invoices for sales of Opadry AMB in the same formulation as used in Paddock's proposed generic tablets as early as September 1996. (Paddock Ex. 57, 58.) Colorcon also averred that it marketed Opadry AMB at least since 1996 through one-on-one meetings, promotional literature, and

[7] Courts writing in the context of patent obviousness have noted that international patent applications (PCT applications) are considered prior art so long as they are published more than a year before the domestic patent application. *See, e.g., C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1347 (Fed. Cir. 1998) ("The PCT application was filed on March 31, 1982 and was published on October 13, 1983. It is prior art to the United States patents in suit."); *Rocep Lusol Holdings Ltd. v. Permatex, Inc.*, 470 F. Supp. 2d 448 (D. Del. 2007). (finding patent invalid as anticipated by prior art PCT application). There is no indication that the term "prior art" has a meaning in prosecution history estoppel cases different from its meaning in other areas of patent law. *See generally* BLACK'S LAW DICTIONARY, Art, (8th ed. 2004) ("[P]rior art. Patents[:] Knowledge that is publicly known, used by others, or available on the date of invention to a person of ordinary skill in an art, including what would be obvious from that knowledge. Prior art includes (1) information in applications for previously patented inventions; (2) information that was published more than one year before a patent application is filed; and (3) information in other patent applications and inventor's certificates filed more than a year before the application is filed. The U.S. Patent and Trademark Office and courts analyze prior art before deciding the patentability of a comparable invention.") (*citing* 35 U.S.C. § 102). Accordingly, the Colorcon PCT is prior art for the purposes of the instant foreseeability analysis.

[8] Paddock points to an article in the journal "Manufacturing Chemist" from December 1995 extolling the virtues of Opadry AMB, and three scientific articles discussing PVA MBCs authored for distribution at scientific conferences in May 1995, May 1998, and November 1998. (Paddock Ex. 50, 52, 53, 55.) Duramed argues that a bench trial is necessary to determine whether the article was publicly available in a university library, and whether the conference articles were actually distributed to the conference attendees. Because these four documents are not necessary to establish foreseeability given the other evidence in the record, the Court will not consider them.

advertising at relevant scientific conferences. (Paddock Ex. 22 ("Colorcon Dep."), 37-43.) Such sales provide further evidence that PVA MBCs were "disclosed in the prior art." *Festo X*, 493 F.3d at 1379; *see also Kothmann Enterprises, Inc. v. Trinity Industries, Inc.*, 394 F. Supp. 2d 923, 965 (S.D. Tex. 2005) ("Trinity began selling the TRACC in 1999, long before the amendment was submitted to the PTO on July 27, 2002. . . . [Plaintiff] cannot assert that the TRACC product, which it claims is an equivalent, was unforeseeable when it filed the amendment.").

Paddock points to a patent issued in 1976 that teaches coating tablets with PVA to ensure "moisture tight[ness]" and "insolub[ility] in the gastrointestinal tract." (Paddock Ex. 48, PADCE0049432.) Duramed's only response to this evidence is to claim that it does not "relate to Opadry AMB or the use of PVA in moisture barrier coatings in pharmaceutical applications." (Pl.'s Mem. Opp. Def.'s Mot. Summ. J. 8 n.5.) However, prior art references need not disclose the exact equivalent product in order to establish foreseeability. "Foreseeability does not require that the accused infringing product or process be foreseeable, nor that any equivalent exist at the time; rather foreseeability only requires that one of ordinary skill in the art would have reasonably foreseen the proposed equivalent at the pertinent time." *Honeywell*, 523 F.3d at 1312 (citation omitted).[9]

Duramed's arguments against all of the foregoing evidence are based on a dubious construction of the legal standard used to determine foreseeability. Duramed relies on one of the Court of Appeals for the Federal Circuit's many restatements of the standard for determining foreseeability: "an equivalent is foreseeable if the equivalent was *generally known* to those skilled in the art at the time of amendment as available in

[9] Furthermore, although the foreseeability inquiry is objective, Duramed's own patent makes reference to Colorcon, increasing the likelihood that Colorcon and its line of coatings would be known to those skilled in the art at the time of Duramed's narrowing amendment. (Paddock Ex. 7, DPI_CENESTIN0074938.)

the field of the invention . . . ." [10] *Festo X*, 493 F.3d at 1380 (emphasis added). Duramed argues that an equivalent must be "generally known" to those skilled in the art in the sense that the relevant knowledge must have in fact been widely disseminated among skilled artisans at the time of the amendment. This definition of the standard allows Duramed to opine that most actual skilled artisans would not have come across an international patent application or have known about certain sales of Opadry AMB, and therefore genuine issues of material fact preclude summary judgment on foreseeability. (*See e.g.* Pl.'s Mem. Opp. Def.'s Mot. Summ. 8-9) ("At best, the only 'publications' Paddock can point to as disclosing Opadry AMB by the relevant time are a handful of questionable abstracts from conferences no one remembers attending and publications no one remembers reading at the relevant time."). Put differently, Duramed argues that the Court should ask what the majority of skilled artisans *in fact* knew and were able to foresee in 1998, while Paddock argues that the Court should ask what a hypothetical skilled artisan *should* have known and been able to foresee in 1998.

However, Duramed's construction of the standard is belied by the Court of Appeals for the Federal Circuit's discussion in the very same *Festo X* opinion. The *Festo X* court went on to state that "an alternative is foreseeable if it is disclosed in the pertinent prior art in the field of the invention," that is, it is foreseeable because it was disclosed in the art and a hypothetical skilled artisan is presumed to be familiar with said disclosure.

[10] That Duramed places undue weight on this phrase can be readily ascertained from an examination of the context in which it is used. The phrase "generally known" appears only once in the *Festo X* opinion. Yet the Court of Appeals for the Federal Circuit restates the standard for foreseeability twice over within the same opinion without repeating the phrase "generally known." *See Festo X*, 493 F.3d at 1379 ("[W]e find that an alternative is foreseeable if it is disclosed in the pertinent prior art in the field of the invention. In other words, an alternative is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment."); *id.* at 1382 ("An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown.").

Festo X, 493 F.3d at 1379. Likewise, in *Pioneer Magnetics*, the court held that because a prior patent disclosed the equivalent in question, it was for that reason alone considered known in the art and foreseeable. *Pioneer Magnetics*, 330 F.3d at 1357 ("As noted, the Carpenter [patent] discloses a non-switching multiplier circuit. Therefore, a non-switching circuit was known in the art and would have been foreseeable at the time of the amendment.").

Rather than actual dispersion of knowledge, the phrase "generally known" as used in *Festo X* refers to the fact that it need not be specifically known that the claimed equivalent "perform the same function in substantially the same way to achieve the same result" at the time of the amendment. *Festo X*, 493 F.3d at 1379 (citation omitted). Foreseeability only requires a less specific kind of knowledge about the claimed equivalent. *See id.* at 1381 ("For example, if a claim before amendment broadly claimed a metal filament for a light bulb but was later amended to avoid prior art and to specify metal A because of its longevity, the equivalent metal B, known in the prior art to function as a bulb filament, is not unforeseeable even though its longevity was unknown at the time of amendment."). In fact, the Court of Appeals for the Federal Circuit would later hold that the equivalent need not even exist at the time of the amendment so long as it would have been reasonably foreseen by skilled artisans based on the state of the art. *Honeywell*, 523 F.3d at 1312 ("Foreseeability does not require that the accused infringing product or process be foreseeable, nor that any equivalent exist at the time; rather foreseeability only requires that one of ordinary skill in the art would have reasonably foreseen the proposed equivalent at the pertinent time.") (citation omitted).

Duramed also argues that even if PVA MBCs were disclosed in the prior art or generally known to exist, serious questions existed as to PVA's effectiveness as a MBC in 1998. In support, Duramed points to the Colorcon PCT, which details the many problems with PVA MBCs and provides only conclusory assertions that the inventors had overcome those problems.[11] However, even if the effectiveness of PVA was unknown in 1998, that would not mean that PVA MBCs were unforeseeable. "An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown." *Festo X*, 493 F.3d at 1382.

Accordingly, the Court finds that there is no genuine issue of material fact with respect to foreseeability. When asked at oral argument what evidence Duramed would present at a bench trial, Duramed's counsel claimed that it would present more testimony from the same expert witnesses that have been deposed, in which the experts would testify that Opadry AMB's existence and suitability were not well known or known to them in 1998, as well as evidence questioning the availability of Paddock's prior art documents. (T. at 66.[12]) But for the reasons stated above, neither a showing that those experts did not know of Opadry AMB, nor that they doubted its efficacy, nor that they would be unlikely to come across the publicly available prior art references could support

[11] Duramed raises similar arguments against Paddock's other prior art evidence, which must suffer the same fate.

[12] All references to "T." refer to the transcript of the oral argument held before this Court on May 4, 2010.

a verdict for Duramed. Accordingly summary judgment is appropriate on the issue of foreseeability.[13]

b. Tangentiality

Turning to the tangentiality prong of the rebuttal of the *Festo* presumption, the Court asks "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo IX*, 344 F.3d at 1369. The tangential prong is a "very narrow" exception to the *Festo* presumption. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1335 (Fed. Cir. 2007). The patentee bears the burden on the tangentiality prong and must make its showing by pointing to evidence in the prosecution history file. *Festo IX*, 344 F.3d at 1369.

The essential question here is whether the reason behind the narrowing amendment implicates the alleged equivalent. *See id.* at 1342 (Fed. Cir. 2007) ("[A]n amendment distinguishing prior art based on *where* the vacuum source was located was only tangentially related to an equivalent directed at the *number* of vacuum sources") (emphases in original); *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005). If the patent holder narrowed claim X but the equivalent only relates to claim Y, which was never narrowed, then no estoppel can arise because the equivalent is only relevant to the non-narrowed claim. Accordingly, we must inquire whether Duramed's narrowing amendment concerned the type of MBC covered by the patent, because the alleged equivalent is another type of MBC. In this case, it is clear that the narrowing amendment is not tangential to the equivalent.

[13] Although we do not question Duramed's good faith in seeking a bench trial, we note that a consequence of conducting such a trial would be to extend significantly the hold which the pendency of these proceedings has placed upon Paddock's entry into the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I); 21 C.F.R. § 314.107(b)(3).

The main case relied on by Duramed, *Regents of the University of California v. Dakocytomation*, 517 F.3d 1364 (Fed. Cir. 2008) is inapposite because in that case, the amendment focused on a method, not the type of chemical that would perform that method. Therefore, the patentee did not surrender other types of chemicals because it had never narrowed its claim as regards the type of chemical used. *Id.* at 1378 ("[T]he focus of the patentees' arguments centered on the method of blocking—not on the particular type of nucleic acid that could be used for blocking. Indeed, the "nucleic acid" limitation was never narrowed during prosecution . . . ."). In this case, the narrowing amendment related only to the type of moisture barrier coating used, and the alleged equivalent is a different type of moisture barrier coating.

Duramed's contends that the ethylcellulose amendment was unnecessary to secure patentability because the patent examiner originally rejected both claim 1, which claimed all types of MBCs, and claim 7, which specifically claimed an ethylcellulose MBC. Duramed argues that although the ethylcellulose limitation was added to claim 1 at the patent examiner's suggestion, neither Duramed nor the patent examiner focused on it, and this amendment "did not improve the patentability of the claimed invention over the prior art." (Pl.'s Mem. Opp. Def.'s Mot. Summ. J. 10.) Essentially, Duramed argues that there was no reason for the amendment. However, even if this were true, it would not suffice to meet Duramed's burden; silence in the record as to the reason for the amendment does not overcome the *Festo* presumption. *Honeywell*, 523 F.3d at 1315; *Festo IX*, 344 F.3d at 1371-72 ("Festo thus argues that the amendment was unnecessary to respond to (and thus only tangential to) the . . . rejection. . . . Because the prosecution history reveals no reason for the . . . amendment, and because Festo still identifies no such reason, Festo has

not shown that the reason for the . . . amendment was only tangential to the accused equivalent.").

Because Duramed's amendment concerned the type of MBC to be used, and the alleged equivalent is another type of moisture barrier coating, Duramed's narrowing amendment was not tangential to the alleged equivalent.

IV. Conclusion

Based on the foregoing, Duramed is unable to rebut the *Festo* presumption, and prosecution history estoppel applies. Duramed is therefore precluded from relying on the doctrine of equivalents in its patent infringement action. Because Duramed cannot succeed on its patent infringement action without resorting to the doctrine of equivalents for the ethylcellulose MBC limitation, Duramed's patent infringement claim fails. *See, e.g.*, *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1321 (Fed. Cir. 2003).

Accordingly, Paddock's motion for summary judgment of non-infringement is granted solely on prosecution history estoppel grounds. This holding moots all remaining claims and arguments, including Paddock's argument-based estoppel and claim vitiation arguments. Because our prosecution history estoppel ruling entails a holding of non-infringement, there is no indication that a live case or controversy is presented by Paddock's further claims that the '638 patent is invalid; indeed, Paddock itself claims that a prosecution history estoppel holding "would end the case." (Def.'s Mem. Opp. Pl.'s Mot. Partial Summ. J. 4.) Consequently, we forego consideration of Duramed's motion for partial summary judgment, and both parties' claim construction arguments.

As the Hatch-Waxman Act automatic stay of FDA approval for Paddock's proposed generic tablets will end on the date judgment is entered, the Clerk of Court is directed to enter judgment forthwith and close the case.

SO ORDERED.

Dated: June 1, 2010
New York, NY

U.S.D.J.