IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION	:	CIVIL ACTION
	:	
v.	:	
	:	
ABBVIE INC., et al.	:	NO. 14-5151

MEMORANDUM

Bartle, J. September 15, 2017

The Federal Trade Commission ("FTC") has filed this action against defendants AbbVie Inc., Abbott Laboratories, and Unimed Pharmaceuticals LLC (collectively "AbbVie"),[1] as well as against Besins Healthcare Inc. The FTC alleges that the defendants engaged in monopolistic conduct in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). Section 45(a)(1) states that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."

As part of its claim for relief, the FTC asserts that the defendants filed sham patent infringement lawsuits against two competitors, Teva Pharmaceuticals USA, Inc. and Perrigo Company, which were seeking approval from the U.S. Food and Drug

1. AbbVie came into existence in January 2013 when it separated from Abbott Laboratories. Unimed is a wholly-owned, indirect subsidiary of AbbVie. Solvay is a wholly-owned subsidiary of AbbVie.

Administration ("FDA") for generic versions of AndroGel 1%, the defendants' brand-name product.[2] AndroGel 1% is a transdermal testosterone replacement therapy gel. It has been approved by the FDA for the treatment of conditions in men associated with a deficiency or absence of endogenous testosterone and is protected by U.S. Patent No. 6,503,894 ("the '894 patent"). The FTC further alleges that the defendants possessed monopoly power with respect to AndroGel 1% at the time of the filing of the underlying lawsuits.

The court has before it the motions[3] of the defendants for summary judgment on Count One of the complaint and the motion of the plaintiff FTC for partial summary judgment on the objective baselessness element of the sham litigation prong of their illegal monopolization claim.[4]

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2. Those lawsuits were Abbott Products, Inc. v. Teva Pharmaceuticals USA, Inc., Civil Action No. 11-384 (D. Del.), and Abbott Products, Inc. v. Perrigo Co., Civil Action No. 11-6357 (D.N.J.), respectively.

3. The defendants originally moved for summary judgment in February 2015 before discovery had been conducted in this case. These motions are now ripe for the court's review.

4. The court previously dismissed Count Two, which was the only other claim for relief, wherein the FTC asserted that AbbVie had entered into an anticompetitive settlement with Teva of their underlying patent infringement litigation against Teva. See FTC v. AbbVie Inc., 107 F. Supp. 3d 428, 438 (E.D. Pa. 2015). Although Teva was named as a defendant in this action, as result of the dismissal of Count Two, Teva is no longer a party.

I.

We first turn to the undisputed facts from the prosecution history record of the '894 patent, which issued on January 7, 2003 from U.S. Patent Application Serial No. 09/651,777 ("the '777 application").

The patent application process began in August 2000 when AbbVie and Besins filed an application for a "pharmaceutical composition comprising testosterone in a gel formulation, and to methods of using the same." Claim 1 of the '777 application read:

> A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, comprising:
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> (a) a C1-C4 alcohol;
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> (b) a penetration enhancer;
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> (c) the active pharmaceutical ingredient; and
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> (d) water.

(Emphasis added). Claim 1 encompassed all penetration enhancers without limitation.[5] The '777 application explained that "[a] 'penetration enhancer' is an agent known to accelerate the delivery of the drug through the skin." The invention description in the '777 application stated:

5. On page thirty-three of their brief in support of their motion for summary judgment, the defendants state that there are at least 30,000,000 penetration enhancers. (Doc. # 241).

> Non-limiting examples of penetration enhancers include C8-C22 fatty acids such as isostearic acid, octanoic acid, and oleic acid; C8-C22 fatty alcohols such as oleyl alcohol and lauryl alcohol; lower alkyl esters of C8-C22 fatty acids such as ethyl oleate, isopropyl myristate, butyl stearate, and methyl laurate; di(lower)alkyl esters of C6-C8 diacids such as diisopropyl adipate; monoglycerides of C8-C22 fatty acids such as glyceryl monolaurate; tetrahydrofurfuryl alcohol polyethylene glycol ether; polyethylene glycol, propylene glycol; 2-(2-ethoxyethoxy)ethanol; diethylene glycol monomethyl ether; alkylaryl ethers of polyethylene oxide; polyethylene oxide monomethyl ethers; polyethylene oxide dimethyl ethers; dimethyl sulfoxide; glycerol; ethyl acetate; acetoacetic ester; N-alkylpyrrolidone; and terpenes.

(Emphasis added). Isopropyl myristate is the penetration enhancer actually used in AndroGel 1%.

In June 2001, the patent examiner at the U.S. Patent and Trademark Office ("PTO") rejected claims 1-9 and 35-36[6] of the '777 application as obvious over prior art references Mak in view of Allen, among others. Allen is an international patent application published in September 1996, which discloses the use of isopropyl myristate, isopropyl palmitate, and three other penetration enhancers in a nitroglycerin cream. Mak is an international patent application published in May 1999, which discloses a transdermal testosterone gel that uses the

6. Claims 10-34 already had been withdrawn by the applicants by the time that the PTO issued its June 2001 office action.

penetration enhancer oleic acid. In rejecting the claims of the '777 application, the examiner stated "[s]ince all composition components herein are known to be useful for the percutaneous delivery of pharmaceuticals, it is considered prima facie obvious to combine them into a single composition useful for the very same purpose."

In response to the June 2001 office action rejecting the claim of all penetration enhancers, AbbVie and Besins submitted their first amendment to their '777 application in October 2001. Claim 1 of the amended '777 application now read:

> A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, consisting essentially of:
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> (a) at least one penetration enhancer selected from the group consisting of isostearic acid, octanoic acid, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol, polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy) ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, terpene, and combinations of any of the foregoing; and
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> (b) testosterone.

(Emphasis added). In this amendment, AbbVie and Besins narrowed their claim from one encompassing all penetration enhancers to a claim naming only twenty-four penetration enhancers, including isopropyl myristate. They also added several new claims. In new claim 47, AbbVie and Besins claimed "a penetration enhancer selected from the group consisting of isopropyl myristate and lauryl alcohol." In new claims 61 and 62, they identified only isopropyl myristate as the penetration enhancer.

In support of the October 2001 amendment, the defendants argued to the examiner that "[a]pplicants' invention is not obvious because of secondary considerations recognized by the courts as indicia of non-obviousness." They submitted the declaration of Jean-Louis Anspach, the chief executive officer of Unimed Pharmaceuticals, Inc., stating that "Unimed launched AndroGel® in June 2000, and it has met with substantial commercial success as shown below." The AndroGel product used only isopropyl myristate as the penetration enhancer.

On December 6, 2001, attorneys for AbbVie and Besins met with the patent examiner to discuss the October 2001 amendment. In her interview summary, the examiner noted that claims 61 and 62, which identified only isopropyl myristate as the penetration enhancer, "are seen to be allowable over the prior art." The interview summary also stated that "applicants argued claim 47 is novel [and] nonobvious over the prior art

because the prior art does not teach the composition with particular concentration." As previously stated, claim 47 identified isopropyl myristate and lauryl alcohol as penetration enhancers.

Two weeks later, on December 21, 2001, AbbVie and Besins submitted a supplemental amendment to their patent application. They cancelled the October 2001 amended claim 1 in its entirety and amended claim 47 to specify only isopropyl myristate as the penetration enhancer. As a result, they reduced the number of penetration enhancers in the '777 application from twenty-four to one. AbbVie and Besins also modified the concentration ranges for isopropyl myristate in claim 61. In support of their amended application, AbbVie and Besins stated:

> With entry of the above amendments and in view of the foregoing remarks, it is respectfully submitted that claims 47, 48, 51, 52, 54-62, 66-96 are in condition for allowance. . . . Accordingly, reconsideration and withdrawal of the outstanding rejections and allowance of the present claim is respectfully solicited.

They further asserted that "[t]he prior art does not teach the claimed combination; therefore, it is patentable."

AbbVie and Besins submitted additional amendments in February 2002, July 2002, and August 2002. The February 2002 amendment narrowed the concentration range for isopropyl

myristate in claims 47 and 61 and cancelled claim 62. AbbVie and Besins stated in the February 2002 that they sought "reconsideration and withdrawal of the outstanding rejections and allowance of the present claims." The July 2002 and August 2002 amendments contained additional changes not relevant here.

The patent examiner finally issued a Notice of Allowability in August 2002 as to claims 47-48, 51-52, 54-57, 61, 78-81, 83, 87-89, and 97-121. The examiner wrote that "[t]he claimed pharmaceutical composition consisting essentially of the particular ingredients herein in the specific amounts, is not seen to be taught or fairly suggested by the prior art as discussed below." The examiner then distinguished the most recent version of the '777 application from the previous versions of the application and from the prior art references Mak and Allen, among others, that were the bases for her rejections in her June 2001 office action. The examiner approved the application because "the prior art [including Allen] does not teach or fairly suggest the instant claimed pharmaceutical composition consisting essentially of the specific ingredients herein in the particular amounts."

In January 2003, the '894 patent issued. Isopropyl myristate was now the only claimed penetration enhancer. The '894 patent expires in 2020.

Thereafter, Perrigo and Teva, two competitors of AbbVie and Besins, developed generic versions of AndroGel 1%. In order to be able to market their generic products, Perrigo and Teva sought approval from the FDA. Perrigo's product was similar to AndroGel 1% in most respects, except that it used isostearic acid, rather than isopropyl myristate, as the penetration enhancer. Teva's product used isopropyl palmitate rather than isopropyl myristate as its penetration enhancer.

In April 2011 and October 2011, AbbVie and Besins filed lawsuits against Teva and Perrigo. In those lawsuits, AbbVie and Besins maintained that Teva's and Perrigo's generic products infringed the '894 patent under the doctrine of equivalents. They did not allege literal infringement.

At the time the lawsuits were filed, Teva and Perrigo were still in the process of obtaining approval of their generic products from the FDA. By filing the lawsuits, AbbVie and Besins automatically triggered a thirty-month stay of FDA approval of those generic products. See 21 U.S.C. § 355(c)(3)(C). This step delayed entry of the Teva and Perrigo generic products into the market where they would compete with AndroGel 1%. Perrigo began selling its generic product in December 2014 while Teva has not launched its generic product.

II.

In Count One, the only remaining claim in this action, the FTC asserts that AbbVie and Besins engaged in illegal monopolization by filing sham patent litigation against Perrigo and Teva so as to delay entry of their generic products into the testosterone gel market where those generic products would compete with the defendants' AndroGel 1%. In order to prove a claim of illegal monopolization, the FTC must establish both: "(1) the possession of monopoly power [by the defendants] in the relevant market and (2) the willful acquisition or maintenance [by the defendants] of that power."[7] Broadcom Corp. v. Qualcomm, Inc., 501 F.3d 297, 306-07 (3d Cir. 2007) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966)).

As noted above, the defendants have filed a motion for summary judgment, and the FTC has filed a motion for partial summary judgment. Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R.

7. Although this standard for illegal monopolization comes from cases interpreting the Sherman Act, 15 U.S.C. § 2, it is well-settled that § 45(a) of the FTC Act, the relevant statutory provision here, contemplates a range of conduct that includes, but is not limited to, conduct that violates the Sherman Act. See, e.g., FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 454 (1986).

Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the nonmoving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Summary judgment is granted where there is insufficient record evidence for a reasonable factfinder to find for the nonmovant. See id. When ruling on a motion for summary judgment, we view the facts and draw all inferences in favor of the nonmoving party. See In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004).

The FTC seeks partial summary judgment as to only the willful acquisition or maintenance of monopoly power prong of the illegal monopolization claim. In particular, the FTC alleges that the defendants willfully acquired or maintained monopoly power by filing sham patent infringement litigation against Teva and Perrigo. Although parties generally may not be held liable for violating the antitrust laws for petitioning the government for redress, this immunity does not extend to sham litigation. See Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc. ("PRE"), 508 U.S. 49, 57 (1993) (citing United Workers of Am. v. Pennington, 381 U.S. 657, 670 (1965); E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961)); In re Wellbutrin XL Antitrust Litig., ___ F.3d ___, 2017 WL 3531069, at *6 (3d Cir. Aug. 9, 2017).

To prove that the infringement actions filed by AbbVie and Besins against Teva and Perrigo were shams, the FTC must establish that: (1) those lawsuits were objectively baseless; and (2) those filing the lawsuits subjectively intended to interfere directly with a competitor's business interests using government process as an anticompetitive weapon. See PRE, 508 U.S. at 60-61. The second element concerning the subjective intent of the defendants is not now before the court.

The defendants argue that they are entitled to summary judgment because the FTC cannot make out as a matter of law either the objective baselessness element of the sham litigation prong or the monopoly power prong of the illegal monopolization claim.

III.

We begin with the objective baselessness element of the sham litigation prong of the monopolization claim. Litigation is objectively baseless if "no reasonable litigant could realistically expect success on the merits." See PRE, 508 U.S. at 60. To demonstrate that litigation is objectively baseless, "the plaintiff [must] prove that the defendant lacked probable cause" in filing the underlying lawsuit. See id. at 62. Probable cause "requires no more than a 'reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid

upon adjudication.'" Id. at 62-63 (quoting Hubbard v. Beatty & Hyde, Inc., 178 N.E.2d 485, 488 (Ma. 1961)).

In the two underlying lawsuits at issue here, AbbVie and Besins alleged that Teva's use of the isopropyl palmitate as a penetration enhancer and Perrigo's use of isostearic acid for that same purpose in their respective generic products infringed the '894 patent under the doctrine of equivalents. AbbVie and Besins did not assert that Teva and Perrigo engaged in literal infringement since the '894 patent disclosed the use of only isopropyl myristate, a different penetration enhancer. Instead, AbbVie and Besins claimed that isopropyl palmitate and isostearic acid were the equivalents of isopropyl myristate.

The doctrine of equivalents provides that "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. ("Festo VIII"), 535 U.S. 722, 732 (2002)[8]; see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations

8. There were numerous opinions written by the Federal Circuit, Supreme Court, and other federal courts during the course of litigation between Festo Corporation and Shoketsu Kinzoku Kogyo Kabushiki Company. Although this Memorandum does not mention many of the related cases, we will refer to the cases that are mentioned by their place in the litigation series, as has been done by other courts.

that were not captured in drafting the original patent claim but which could be created through trivial changes." Festo VIII, 535 U.S. at 733. An element of the alleged infringing product is equivalent to an element of the patented invention if the alleged equivalent is insubstantially different. See Dawn Equip. Co. v. Ky. Farms, Inc., 140 F.3d 1009, 1015-16 (Fed. Cir. 1998) (citing Warner-Jenkinson Co., 520 U.S. at 40).

The FTC does not dispute that the penetration enhancers used by Perrigo and Teva are insubstantially different from the isopropyl myristate penetration enhancer used in AndroGel 1% and disclosed in the '894 patent. Rather, the FTC maintains that the lawsuits against Teva and Perrigo were objectively baseless under the doctrine of prosecution history estoppel. This doctrine with certain exceptions precludes a patentee from claiming equivalents if the patentee surrendered the equivalents for reasons of patentability during the patent prosecution process. See Festo VIII, 535 U.S. at 733-34. The FTC argues that the defendants are estopped from claiming that the isostearic acid used in the Perrigo product or the isopropyl palmitate used in the Teva product are equivalents of the isopropyl myristate claimed in the '894 patent because, in the FTC's view, the defendants clearly and affirmatively surrendered those penetration enhancers during the patent prosecution.

As the Supreme Court has explained, prosecution history estoppel balances the rights of patentees with the interest of the public in understanding the limits of the patent so that the public may "be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." See id. at 731-32. It also "ensures that the doctrine of equivalents remains tied to its underlying purpose" of acknowledging "language's inability to capture the essence of innovation." Id. at 734. When the prosecution history record demonstrates that the patentee "turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter," the patentee is not entitled to the protections of the doctrine of equivalents as to that subject matter. Id. at 734-35. "[T]he purpose of applying the estoppel in the first place [is] to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment." Id. at 737-38. For the patentee to prevail against the defense of prosecution history estoppel, "[t]he patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." See id. at 741. The Supreme Court has placed the

burden on the patentee to establish that any amendment is not for the purpose of patentability. Id. at 739.

The Federal Circuit has set forth a well-established three-step inquiry for determining whether prosecution history estoppel bars the defendants from claiming the doctrine of equivalents. First, estoppel applies only if the court determines that "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. ("Festo IX"), 344 F.3d 1359, 1366 (Fed. Cir. 2003) (citing Festo VIII, 535 U.S. at 740; Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352, 1356 (Fed Cir. 2003)).

This first step requires us to identify the relevant amendments in the '777 application. The case law is clear that we must consider the entire prosecution history in determining whether estoppel applies. See Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 867 (Fed. Cir. 1993); Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n, 988 F.2d 1165, 1174 (Fed. Cir. 1993). Yet, with respect to the Teva patent infringement litigation, the defendants argue that only the October 2001 amendment is relevant. In the October 2001 amendment, the defendants narrowed their original claim encompassing all penetration enhancers to a claim limited to twenty-four identified penetration enhancers. This amendment did not name

and thus excluded isopropyl palmitate, the penetration enhancer in Teva's generic product. The amendment, however, specifically included isostearic acid, the penetration enhancer in Perrigo's generic product, among the twenty-four penetration enhancers that the defendants claimed. Thus, for the patent infringement litigation against Perrigo, the defendants ask us to look only to the December 2001 amendment which eliminated isostearic acid from the scope of the '777 application.

While we agree with the defendants that the prosecution history estoppel inquiry takes into account only the relevant amendments in the prosecution history, we disagree with the defendants' characterization of what is relevant. The examiner, we note, rejected in June 2001 claim 1 which claimed all penetration enhancers. In light of this rejection, over the course of their October 2001, December 2001, and February 2002 amendments, the defendants without question narrowed the claimed penetration enhancers in the '777 application from all penetration enhancers including those used in the Teva and Perrigo products to only isopropyl myristate at a particular concentration.[9] We must focus on the above history in its entirety to obtain an accurate understanding of what occurred.

9. In July 2002 and August 2002, the defendants made additional amendments to other aspects of the claimed invention that are not at issue here.

Having determined that the October 2001, December 2001, and February 2002 amendments narrowed the relevant claims after the examiner's rejection in June 2001, "the second question [for determining prosecution history estoppel] is whether the reason for that amendment was a substantial one relating to patentability." See Festo IX, 344 F.3d at 1366-67. Prosecution history estoppel applies to amendments made for a substantial reason relating to patentability -- whether to address an earlier rejection or for some other reason that satisfies a requirement of the Patent Act, 35 U.S.C. §§ 101, et seq. See id. at 1366 (citing Festo VIII, 535 U.S. at 727). As noted above, the patentee "bear[s] the burden of showing that the amendment does not surrender the particular equivalent in question." Festo VIII, 535 U.S. at 740; Festo IX, 344 F.3d at 1368. In doing so, the patentee "is restricted to the evidence in the prosecution history record." Festo IX, 344 F.3d at 1367 (citing Warner-Jenkinson Co., 520 U.S. at 33)).

Even if the amendment was for purposes of patentability, the patentee can rebut the presumption of surrender by demonstrating: (1) the alleged equivalent was "unforeseeable at the time of the application;" (2) "the rationale underlying the amendment [ ] bear[s] no more than a tangential relation to the equivalent in question;" or (3) there

is "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." See Festo VIII, 535 U.S. at 740-41 (emphasis added). In this case, the defendants rely only on the tangential relation exception. "The tangential relation criterion for overcoming the Festo presumption is very narrow." Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp., 523 F.3d 1304, 1315 (Fed. Cir. 2008). It "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. This inquiry "focuses on the patentee's objectively apparent reason for the narrowing amendment." See id.

The question whether the patentee demonstrated a tangential relation is a matter of law for the court to decide. The court limits its review to "the prosecution history record without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record." Id. at 1370. This analysis "is an objective one that depends on what a competitor would reasonably conclude from the patent's prosecution history." See Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995).

Turning first to the underlying patent infringement litigation filed by AbbVie and Besins against Teva, the

defendants concede that they excluded isopropyl palmitate, the penetration enhancer used by Teva, from the scope of the '777 application for purposes of patentability. Nevertheless, they argue that it was objectively reasonable to bring that lawsuit against Teva because the October 2001 amendment excluding isopropyl palmitate was tangential to isopropyl palmitate. Relying on expert testimony,[10] the defendants contend that the sole purpose of the October 2001 amendment was to exclude oleic acid, which is the penetration enhancer disclosed in the Mak prior art reference. Oleic acid, like isopropyl palmitate, was not one of the twenty-four penetration enhancers claimed in the October 2001 amendment.

It is undisputed that the October 2001 amendment did not simply eliminate oleic acid or its components. The examiner, it must be remembered, had rejected the original claim 1 encompassing all penetration enhancers in June 2001. The October 2001 amendment sought to overcome the rejection by narrowing the original claim 1 for all penetration enhancers to only twenty-four. It thereby excluded not only oleic acid but

10. Testimony from a person skilled in the art is not necessary to interpret the prosecution history record in this case. See Festo IX, 344 F.3d at 1370. Yet, even if we were to take into account the rationale offered by the expert witness for the October 2001 amendment, the defendants are nevertheless estopped from asserting the doctrine of equivalents with respect to isopropyl palmitate for the reasons explained below.

also isopropyl palmitate and countless other penetration enhancers previously rejected. If AbbVie and Besins merely sought to relinquish oleic acid and no other penetration enhancer in October 2001, they easily could have said so. The defendants' latter-day explanation for the October 2001 amendment is groundless. It fails the reasonableness test in light of the examiner's June 2001 broad-based rejection to say that the abandonment of isopropyl palmitate and many other penetration enhancers was incidental to abandoning only oleic acid. See Felix v. Am. Honda Motor Co., 562 F.3d 1167, 1184 (Fed. Cir. 2009); Amgen, Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1314-15 (Fed. Cir. 2006).

In addition, the Mak prior art, which disclosed the use of oleic acid, was not the only prior art that AbbVie and Besins had to address to overcome the examiner's rejection. In June 2001, the examiner had found the '777 application obvious in light of the Allen prior art, among others. The Allen prior art listed isopropyl palmitate as one of five penetration enhancers and used isopropyl palmitate in six of its nine composition examples. It cannot be doubted from reading the prosecution history record that the defendants sought to address the examiner's June 2001 obviousness rejection based on the Allen prior art when they relinquished the isopropyl palmitate penetration enhancer in filing their October 2001 amendment.

The surrender of isopropyl palmitate in the October 2001 amendment to avoid prior art is "the classic basis for the application of prosecution history estoppel."[11] See Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352, 1357 (Fed Cir. 2003); Festo IX, 344 F.3d at 1369.

The defendants further argue that the October 2001 amendment could not have intended to overcome the Allen prior art with its disclosure of isopropyl palmitate because Allen also disclosed isopropyl myristate, which was included in the '894 patent. The defendants' argument is without any merit.

The defendants, during the patent prosecution, cited to evidence of secondary considerations of non-obviousness to support their inclusion of isopropyl myristate at a particular

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11. Moreover, as the Federal Circuit has explained:

> [T]here is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art reference that was the basis for an examiner's rejection. To the contrary, it frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art. In such cases, we have held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to.

Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1361-62 (Fed. Cir. 2005).

concentration in the October 2001 amendment and to overcome Allen. A patent applicant may rely on secondary considerations of commercial success, long felt but unmet needs, and the failure of others, among other factors, to overcome an obviousness rejection. See KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 399 (2007) (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966)). In their remarks in connection with the October 2001 amendment, the defendants argued to the examiner that "[a]pplicants' invention is not obvious because of secondary considerations recognized by the courts as indicia of non-obviousness." In support of their position, they submitted the declaration of Jean-Louis Anspach, the chief executive officer of Unimed Pharmaceuticals, Inc. Anspach stated that "Unimed launched AndroGel® in June 2000, and it has met with substantial commercial success as shown below." Isopropyl myristate, at a concentration within the range disclosed in the '894 patent, is the sole penetration enhancer in AndroGel 1%. The defendants singled out isopropyl myristate on the ground of its commercial success from the other penetration enhancers disclosed in Allen. The defendants made no effort based on commercial success or otherwise to save isopropyl palmitate or the other penetration enhancers disclosed in the Allen prior art and found to be obvious by the examiner in June 2001.

In sum, the defendants have cited no evidence in the prosecution history record to rebut the presumption of surrender of isopropyl palmitate. As the Supreme Court teaches in Festo VIII, to avoid prosecution history estoppel, the patentee must establish that it could not reasonably be expected to have drafted the October 2001 amendment to include isopropyl palmitate. See Festo VIII, 535 U.S. at 741. There is no way that the defendants can avoid prosecution history estoppel by arguing that it was reasonable for them not to include isopropyl palmitate in the October 2001 amendment. Accordingly, the surrender of isopropyl palmitate in the October 2001 amendment was not tangential or peripheral to the isopropyl palmitate in Teva's generic product. See Festo IX, 344 F.3d at 1369.

We next turn to the isostearic acid penetration enhancer at issue in the Perrigo infringement action. The defendants contend that it was objectively reasonable to file infringement litigation against Perrigo because the December 2001 amendment excluding isostearic acid was not for purposes of patentability and was tangential to isostearic acid. In the December 2001 amendment, the defendants disavowed twenty-three of the penetration enhancers listed in the October 2001 amendment, including isostearic acid, when they narrowed the claimed penetration enhancer to isopropyl myristate.

The defendants contend that their exclusion of isostearic acid in December 2001 was not for a substantial reason related to patentability because it was not in response to a rejection by the examiner. They note that the only office action rejecting the '777 application was issued by the examiner in June 2001 and that they had since amended the application in October 2001 to address that office action. According to defendants, none of their pending claims stood rejected by the examiner when they voluntarily submitted another amendment in December 2001. The defendants are incorrect. They would have the court ignore a significant event in the prosecution history, that is the examiner's rejection of all penetration enhancers including isostearic acid in June 2001. This we will not do.

Moreover, in the interview summary from the December 6, 2001 interview, the examiner stated that claim 61, which included only isopropyl myristate as the penetration enhancer, is "seen to be allowable over the prior art." The examiner's earlier rejection in June 2001 and her position at the December 6, 2001 interview constituted a telling signal to any reasonable person that patentability required the narrowing of any claim so that it disclosed isopropyl myristate at a particular concentration as the sole penetration enhancer.

The December 2001 amendment also explicitly aimed to overcome the prior art cited by the examiner in her June 2001

office action. The defendants argued in their December 2001 amendment that "reconsideration and withdrawal of the outstanding rejections and allowance of the present claims is respectfully solicited." They also asserted that "[t]he prior art does not teach the claimed combination; therefore, it is patentable."

The defendants' statements in their various briefs are also telling. On page three of their brief in opposition to the motion of the FTC for partial summary judgment (Doc. # 256), the defendants state that the December 2001 amendment "simplified the pending claims to accord with subject matter that the examiner already indicated was allowable over the prior art at a time when the objective public facts showed that prompt issuance of at least some claims was of pressing concern." The defendants admit at page thirty-nine of their brief filed in support of their summary judgment motion (Doc. # 241) that they dropped their claim to isostearic acid and the other penetration enhancers "immediately follow[ing] an interview in which the examiner stated that a claim reciting isopropyl myristate would be allowable." Thus, as the defendants argued in the prosecution history record and reiterated in their summary judgment briefs, their December 2001 amendment specifically aimed to address in pursuit of patentability the examiner's prior art objections in the June 2001 office action.

The defendants' reliance on a so-called voluntary claim-amendment theory is spurious. A voluntary claim amendment is one that the patent examiner does not require or that is not made based on a specific rejection by the examiner. Such an amendment does not preclude prosecution history estoppel. Festo IX, 344 F.3d at 1364, 1366; Pioneer Magnetics, Inc., 330 F.3d at 1357. Otherwise a patent applicant could simply release its claims to subject matter that it believes the examiner is unlikely to approve before the examiner has issued an office action and then recapture that material under the doctrine of equivalents after the patent issues. If the defendants are correct, they could recapture the twenty-three penetration enhancers that they surrendered in December 2001 or potentially the more than 30,000,000 penetration enhancers that were encompassed in the original claim 1 and relinquished in October 2001.

The defendants further contend that by filing the December 2001 amendment they simply sought to expedite their patent application in anticipation of the end of the three-year FDA marketing exclusivity period for AndroGel 1% in February 2003. An amendment narrowing the scope of the patent application in order to expedite the patent prosecution process is necessarily for the purpose of patentability unless it falls in a narrow exception. See Regents of the Univ. of Cal. v.

Dakocytomation Cal., Inc., 517 F.3d 1364, 1378 (Fed. Cir. 2008); Biogen, Inc. v. Berlex Labs., Inc., 318 F.3d 1132, 1142 (Fed. Cir. 2003). Furthermore, the defendants' extrinsic reasons for seeking expedited approval of their application are not contained in the prosecution history record and therefore are not relevant to vitiate prosecution history estoppel. See Festo IX, 344 F.3d at 1367 (citing Pioneer Magnetics, 330 F.3d at 1356); Tex. Instruments, Inc., 988 F.2d at 1174; Wang Labs., Inc., 993 F.2d at 867.

As with the isopropyl palmitate in the Teva product, the defendants have no credible argument to rebut the presumption of disavowal of isostearic acid in the Perrigo product. The December 2001 amendment surrendering isostearic acid was not peripheral or tangential to isostearic acid. See Festo IX, 344 F.3d at 1369. Again, the defendants cannot overcome prosecution history estoppel because they cannot establish that it was reasonable for them not to have been expected to draft the December 2001 amendment to include isostearic acid. The clear language of the Supreme Court in Festo VIII is decisive. See Festo VIII, 535 U.S. at 741.

Finally, "the third question in a prosecution history estoppel analysis addresses the scope of the subject matter surrendered by the narrowing amendment." Festo IX, 344 F.3d at 1367. "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." Festo VIII, 535 U.S. at 740. The Supreme Court explained that when a patentee narrows "a prior application describing the precise element at issue . . . . the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter." See id. at 734-35. Consequently, there is a presumption that the patentee has "surrendered all subject matter between the broader and the narrower language." See id. at 740; Pioneer Magnetics, Inc., 330 F.3d at 1356 (citing Warner-Jenkinson, 520 U.S. at 33).

Again, the defendants originally claimed all penetration enhancers in claim 1. The examiner rejected the claim as obvious. Over the course of the patent application process, they narrowed their claim to isopropyl myristate at a particular concentration. In so doing, the defendants relinquished their claims to isopropyl palmitate and isostearic acid. The defendants cannot now "avoid the PTO's gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." See Festo VIII, 535 U.S. at 740. Prosecution history estoppel without question prevents the defendants from claiming

that the doctrine of equivalents encompasses the penetration enhancers that they abandoned during the application process, including isopropyl palmitate and isostearic acid. See id. at 736. The defendants clearly surrendered broader language for narrower language. See id. at 740. There is no plausible argument to overcome the presumption in favor of the application of prosecution history estoppel.

In sum, the law with respect to sham litigation, the doctrine of equivalents, and prosecution history estoppel was well-settled at the time that defendants filed their lawsuits against Teva and Perrigo in 2011.[12] See PRE, 508 U.S. at 60-61; Festo VIII, 535 U.S. at 739; Festo IX, 344 F.3d at 1369. In the final analysis, it must not be forgotten that the purpose of prosecution history estoppel is to protect the patentees' competitors from patent infringement litigation based on the doctrine of equivalents if the prosecution history demonstrates that an equivalent not specifically disclosed in the patent has been purposefully and not tangentially excluded from its scope. The patentee has the burden to overcome the presumption of surrender. Here, any reasonable person who reads the

12. The Supreme Court has "made it clear that the doctrine of equivalents and the rule of prosecution history estoppel are settled law. The responsibility for changing them rests with Congress." See Festo VIII, 535 U.S. at 739 (citing Warner-Jenkinson Co., 520 U.S. at 28).

prosecution history of the '894 patent can reach no other conclusion than that the defendants have purposefully and not tangentially excluded isopropyl palmitate and isostearic acid as penetration enhancers equivalent to isopropyl myristate.

The patent lawsuits against Teva and Perrigo were without question objectively baseless. AbbVie and Besins could not realistically have expected success on the merits of this issue or have had a reasonable belief that they had a chance to prevail. See PRE, 508 U.S. at 60, 62–63. The FTC is entitled to partial summary judgment on the objective baselessness element of the sham litigation prong of their illegal monopolization claim.[13] To the extent that the defendants move for summary judgment on objective baselessness, their motion will be denied.

IV.

The defendants also seek summary judgment on the monopoly power prong of the FTC's illegal monopolization claim under Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which, as previously noted, provides that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or

13. The defendants raise a number of other arguments in opposition to the FTC's motion for partial summary judgment and in support of their own motion for summary judgment on the issue of objective baselessness. Those arguments are without merit and do not warrant further discussion.

practices in or affecting commerce, are hereby declared unlawful." In order to commit illegal monopolization, the defendants must have had "monopoly power in the relevant market." Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 433 (3d Cir. 2016). "[M]onopoly power is 'the ability to control prices and exclude competition in a given market.'" Id. at 434 (quoting Broadcom Corp., 501 F.3d at 307). This is a fact-intensive inquiry. See Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 482 (1992). The plaintiff has the burden of proof with respect to these questions of fact. See Mylan Pharm., Inc., 838 F.3d at 435.

A plaintiff may prove "[t]he existence of monopoly power . . . through direct evidence of supracompetitive prices and restricted output." See Mylan Pharm., Inc., 838 F.3d at 434 (quoting Broadcom Corp., 501 F.3d at 307). In demonstrating monopoly power by direct evidence, "a plaintiff must often provide an analysis of the defendant's costs, showing both that the defendant had an 'abnormally high price-cost margin' and that the defendant 'restricted output.'" See id.

In addition, a plaintiff may prove monopoly power by indirect evidence. "To support a claim of monopoly power through indirect evidence, [the plaintiff] must show that (1) Defendants had market power in the relevant market and (2) that there were barriers to entry into the market."

Id. at 435. Products are in the same market if there is reasonable interchangeability of use and cross-elasticity of demand. See id. Cross-elasticity of demand is "[a] relationship between two products, usually substitutes for each other, in which a price change for one product affects the price of the other." Id. at 435-36 (quoting Black's Law Dictionary 458 (10th ed. 2014)).

Here, there are genuine disputes of material fact concerning defendants' monopoly power. At this stage, the defendants are not entitled to judgment as a matter of law as to the monopoly power prong of the illegal monopolization claim. See Fed. R. Civ. P. 56(a). This complex issue will have to await a trial.

V.

Accordingly, we will grant the motion of the plaintiff Federal Trade Commission for partial summary judgment on the objective baselessness element of the sham litigation prong of its monopolization claim and deny the motions of defendants AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare Inc. for summary judgment.