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

KING DRUG CO. OF FLORENCE, INC., et al.	:	CIVIL ACTION
v.	:	NO. 19-3565
ABBOTT LABORATORIES, et al.	:	

MEMORANDUM

Bartle, J. January 19, 2023

Plaintiffs[1] are direct-purchase wholesalers of pharmaceutical drugs. They bring this civil antitrust action under the Sherman Act, 15 U.S.C. §§ 1 et seq., against drug manufacturers AbbVie[2] and Besins[3]. Plaintiffs allege that they were denied the opportunity to purchase lower-priced generic versions of the pharmaceutical product AndroGel 1%, transdermal

1. Plaintiffs are King Drug Company of Florence, Inc., AmerisourceBergen Corp., AmerisourceBergen Drug Corp., Bellco Drug Co., H.D. Smith, LLC, Cardinal Health, Inc., The Harvard Drug Group, LLC, McKesson Corp., J.M. Smith Corp. (d/b/a Smith Drug Co.), Burlington Drug Co., Inc., The North Carolina Mutual Wholesale Drug Co., Dakota Drug Inc., Value Drug Co., and FWK Holdings, LLC.

2. "AbbVie" is used here to refer to defendants AbbVie Inc., AbbVie Products LLC (f/k/a Abbott Products LLC f/k/a Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc.), Unimed Pharmaceuticals, LLC (f/k/a Unimed Pharmaceuticals, Inc.) and Abbott Laboratories.

3. "Besins" is used here to refer to defendant Besins Healthcare, Inc. (f/k/a Laboratoires Besins Iscovesco and Besins-Iscovesco U.S., Inc.).

testosterone replacement therapy gel, due to AbbVie and Besins's anticompetitive conduct.

Before the court is the motion of the plaintiffs for partial summary judgment on the grounds that the lawsuit Abbott Products, Inc. v. Perrigo Co., Civ. No. 3:11-cv-06357 (D.N.J.), filed by AbbVie and Besins on October 31, 2011, was objectively baseless. In Perrigo, AbbVie and Besins claimed that Perrigo's New Drug Application No. 203098 to market a generic version of their AndroGel 1% infringed U.S. Patent No. 6,503,894 ("the '894 patent").

I

The facts from the prosecution history record of the '894 patent--issued on January 7, 2003 from U.S. Patent Application Serial No. 09/651,777 ("the '777 application")--are undisputed. In August 2000, 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 included "a penetration enhancer" as part of the active pharmaceutical ingredient. The penetration enhancer would "accelerate the delivery of the drug through the skin." Claim 1 encompassed all penetration enhancers without any limitations. The invention description in the application included non-limiting examples of penetration

enhancers including isopropyl myristate, which was ultimately used in AndroGel 1%.

In June 2001, the patent examiner at the U.S. Patent and Trademark Office ("PTO") rejected claims 1-9 and 35-366 of the '777 application as unpatentable over several prior art references, including the Allen and Mak references. 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 penetration enhancer oleic acid. Based on these references, the examiner stated: "Since 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. 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 added claim 47, in which they 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 this amendment, they also submitted a declaration discussing the success of AndroGel, which 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." She also noted that the "applicants argued claim 47," which identified isopropyl myristate and lauryl alcohol as penetration enhancers, "is novel [and] nonobvious over the prior art because the prior art does not teach the composition with particular concentration."

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. They also modified the concentration ranges for isopropyl myristate in claim 61. In

support of their amended application, they requested the "reconsideration and withdrawal of the outstanding rejections and allowance of the present claim."

AbbVie and Besins submitted three additional amendments in February, July, and August of 2022. The February 2002 amendment narrowed the concentration range for isopropyl myristate in claims 47 and 61 and cancelled claim 62. They again requested "reconsideration and withdrawal of the outstanding rejections and allowance of the present claims." The remaining two amendments did not contain relevant changes.

The examiner 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 approved the application because "the prior art does not teach or fairly suggest the instant claimed pharmaceutical composition consisting essentially of the specific ingredients herein in the particular amounts." The '894 patent was issued in January 2003, with isopropyl myristate as the only claimed penetration enhancer.

II

After the '894 patent was issued, Perrigo developed a generic version of AndroGel 1% that used isostearic acid, rather than isopropyl myristate, as the penetration enhancer. In response, AbbVie and Besins filed a lawsuit on October 31, 2011 against Perrigo alleging that Perrigo's generic product

infringed the '894 patent under the doctrine of equivalents. Abbott Products, Inc., Civ. No. 3:11-cv-06357 (D.N.J.). Because Perrigo's product was still in the process of obtaining Food and Drug Administration ("FDA") approval, the lawsuit triggered a thirty-month stay of the approval process and delayed Perrigo's entry into the market. Perrigo began selling its generic product in December 2014.

After AbbVie and Besins filed patent infringement lawsuits against Perrigo and Teva, another competitor, the Federal Trade Commission ("FTC") filed an action against them in this court. FTC v. AbbVie Inc. (FTC I), 2017 U.S. Dist. LEXIS 149824 (E.D. Pa. Sept. 15, 2017). The FTC alleged that AbbVie and Besins had violated Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), by filing "sham patent infringement lawsuits" against Perrigo and Teva. Id. at *2. As part of the FTC's claim that AbbVie and Besins "willfully acquired or maintained monopoly power by filing sham patent infringement litigation," the FTC had to establish that the lawsuits were objectively baseless. Id. at *12. AbbVie and Besins claimed that their exclusion of isostearic acid in December 2001 was not for a substantial reason related to patentability. Id. at *25-*26. They argued that the exclusion was not in response to a rejection by the examiner because the

examiner only rejected the application in June 2001, and they had voluntarily amended the application in December 2001. Id.

The court, however, refused to "ignore a significant event in the prosecution history, that is the examiner's rejection of all penetration enhancers including isostearic acid in June 2001." Id. at *26. Furthermore, the court noted that the examiner provided "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." Id. Ultimately, the court held that:

> 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. The FTC is entitled to partial summary judgment on the objective baselessness element of the sham litigation prong of their illegal monopolization claim.

Id. at *32 (citations omitted).

After a three-week trial, the court ultimately found that AbbVie and Besins had actual knowledge that these infringement lawsuits were baseless and that they had acted in bad faith. FTC v. AbbVie Inc., 329 F. Supp. 3d 98, 126 (E.D. Pa. 2018). In addition, the court determined that AbbVie and Besins "possessed monopoly power and illegally and willfully maintained that monopoly power through the filing of sham

litigation." Id. at 136. The court ultimately awarded disgorgement but denied the FTC's request for an injunction. Id. at 144-45.

Our Court of Appeals affirmed that the suit against Perrigo was objectively baseless, stating that "[n]o reasonable litigant in AbbVie and Besins's position would believe it had a chance of winning . . . ." FTC v. AbbVie Inc. (FTC II), 976 F.3d 327, 366 (3d Cir. 2020). The Court found that "nothing in the prosecution history supports AbbVie and Besins's claim that the December 2001 amendment's purpose was to expedite prosecution." Id. Rather, the prosecution history demonstrated that the December 2001 amendment was related to patentability. Id. at 367. The Court, however, determined that Section 13(b) of the Federal Trade Commission Act did not give this court the power to order disgorgement. Id. at 374. As a result, the judgment in favor of the FTC was reversed. Id. at 381. The action was remanded on grounds unrelated to the sham litigation claims and ultimately dismissed. Id.

In this case, the court denied plaintiffs' motion to preclude AbbVie and Besins from relitigating certain facts and issues decided in FTC II. The court explained that the plaintiffs could not assert issue preclusion because the FTC did not receive any of its requested relief in the previous lawsuit and therefore could not be considered a prevailing party. This

decision, however, does not preclude plaintiffs from moving for summary judgment on objective baselessness.

III

As discussed in greater detail in FTC I, 2017 U.S. Dist. LEXIS 149824, AbbVie and Besins's suit against Perrigo was objectively baseless. The court's analysis of this issue has not changed.

Litigation is objectively baseless if "no reasonable litigant could realistically expect success on the merits." Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc. (PRE), 508 U.S. 49, 60 (1993). To demonstrate that litigation is objectively baseless, "the plaintiff [must] prove that the defendant lacked probable cause" in filing the underlying lawsuit. 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 underlying lawsuit at issue here, AbbVie and Besins alleged that Perrigo's use of isostearic acid as a penetration enhancer for its generic product was an equivalent of isopropyl myristate and therefore infringed the '894 patent under the doctrine of equivalents. 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). 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 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).

Plaintiffs assert, however, that the doctrine of prosecution history estoppel applies. Under this doctrine, a patentee is precluded 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. 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.

The Federal Circuit has established a three-step inquiry to determine whether prosecution history estoppel applies. A court must determine: (1) whether "an amendment filed in the [PTO] has narrowed the literal scope of a claim"; (2) "whether the reason for that amendment was a substantial one relating to patentability"; and (3) whether the patentee can rebut the presumption that "the patentee has surrendered all territory between the original claim limitation and the amended claim limitation." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. ("Festo IX"), 344 F.3d 1359, 1366-67 (Fed. Cir. 2003).

To answer whether AbbVie and Besins filed an amendment to the '777 application that narrowed the scope of the literal claim, the court must consider the entire prosecution history. 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). The examiner first rejected AbbVie and Besins's claim 1, which claimed all penetration enhancers. As a result, AbbVie and Besins narrowed their claim over the course of their October 2001, December 2001, and February 2002 amendments from all penetration enhancers to only isopropyl myristate at a particular concentration.

Next, the court must determine if whether the reason for the narrowing amendments "was a substantial one relating to patentability." See Festo IX, 344 F.3d at 1366-67. 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).

If an amendment was for purposes of patentability, the patentee can rebut the presumption of surrender by demonstrating that: (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." Festo VIII, 535 U.S. at 740-41 (emphasis added).

As discussed above, the court rejects, as it did in the prior action, AbbVie and Besins's argument that their exclusion of isostearic acid in December 2001 was not for purposes of patentability and was tangential to isostearic acid. They argue that the amendment was not in response to an examiner's rejection. However, the examiners June 2001

rejection of penetration enhancers including isostearic acid was a significant event in the prosecution history. Furthermore, the examiner's comments served as a telling signal to any reasonable person that AbbVie and Besins's claims needed to be narrowed to isopropyl myristate at a particular concentration to be patentable. Accordingly, the court reiterates that AbbVie and Besins's suit against Perrigo was objectively baseless.

IV

AbbVie and Besins argue that their suit against Perrigo was not objectively baseless because it "was based on an objectively 'good faith argument for the extension, modification, or reversal of existing law.'" PRE, 508 U.S. at 65 (quoting Fed. R. Civ. P. 11). The Advisory Committee Notes to the 1993 Amendment states that:

> Arguments for extensions, modifications, or reversals of existing law or for creation of new law do not violate subdivision (b)(2) provided they are "nonfrivolous." This establishes an objective standard, intended to eliminate any "empty-head pure-heart" justification for patently frivolous arguments. However, the extent to which a litigant has researched the issues and found some support for its theories even in minority opinions, in law review articles, or through consultation with other attorneys should certainly be taken into account in determining whether paragraph (2) has been violated. Although arguments for a change of law are not required to be specifically so identified, a contention that is so identified should be viewed with greater tolerance under the rule.

AbbVie and Besins claim they had the right in Perrigo to ask the Federal Circuit or Supreme Court for three changes in the law. First, AbbVie and Besins argue that a court should only determine that "the reason for [an] amendment was a substantial one relating to patentability" if the amendment was made to overcome a statutory defect in patentability. They assert that this position is supported by Warner-Jenkinson, 520 U.S. 17 (1997), and that they would ask the Supreme Court to return to this interpretation. Defendants' complaint in Perrigo does not mention or even suggest this argument.

This court previously rejected, for the reasons stated above, AbbVie and Besins's argument that their December 2001 amendment was not made for a reason relating to patentability because it was not made to comply with a provision of the Patent Act. The court determined that the amendment was motivated by the examiner's June 2001 rejection and her signal that patentability required claiming only isopropyl myristate at a particular concentration. Our Court of Appeals agreed. It ruled that "[t]o the extent the prosecution history reveals the December 2001 amendment's purpose, it shows the amendment related to patentability." FTC II, 976 F.3d at 367.

Furthermore, AbbVie and Besins previously argued that the reason for their December 2001 amendment was "to expedite prosecution," even if that purpose "did not appear in the

prosecution history." Our Court of Appeals rejected this "even as an argument for the extension, modification, or reversal of existing law," because the existing approach is "fundamental" to protecting "the needs of would-be competitors for adequate notice of the scope of [patent] protection." FTC II, 976 F.3d at 362 (quotation marks omitted).

Second, AbbVie and Besins claim they could have asked for Honeywell International Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131 (Fed. Cir. 2004) (en banc), to be reversed. The Honeywell rule treats the cancellation of an independent claim as a narrowing amendment when one of its formerly dependent claims is then pursued as an independent claim. AbbVie and Besins argue that they are facing litigation because this rule applied to their cancellation of claim 1 and subsequent pursuit of separate, narrower claims. Finally, AbbVie and Besins state that they could have asked for the abolishment of the prosecution history estoppel doctrine altogether. Neither of these arguments was mentioned or even hinted at in the Perrigo complaint, nor was any of them raised in prior briefing on the issue of objective baselessness.

Regardless, AbbVie and Besins's suit against Perrigo was not based on objectively good faith arguments for seeking these three changes in the law. The Supreme Court, in Festo VIII, reiterated that it had "made it clear that the doctrine of

equivalents and the rule of prosecution history estoppel are settled law" and that "[t]he responsibility for changing them rests with Congress." 535 U.S. at 739. AbbVie and Besins have not provided any basis that the Supreme Court has changed its position or that Congress has passed any legislation related to the prosecution history estoppel doctrine. Consequently, no reasonable litigant could have expected that filing this patent infringement suit against Perrigo would have led to these proposed changes in the law.

V

AbbVie and Besins filed an objectively baseless suit against Perrigo. Accordingly, the court will grant the motion of the plaintiffs for summary judgment in their favor and against defendants AbbVie and Besins.