

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

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

MEMORANDUM

Bartle, J.

July 20, 2023

Plaintiffs¹ have moved this court to compel defendants to produce certain privileged and work-product documents on the ground that the crime-fraud exception applies (Doc. #248).

Plaintiffs 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 and Besins.² Plaintiffs allege that they were denied the opportunity to purchase lower-priced generic

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

versions of the pharmaceutical product AndroGel 1%, a transdermal testosterone replacement therapy gel, due to AbbVie and Besins' anticompetitive conduct. The allegations include the assertion that defendants filed a sham patent infringement action against Perrigo Company, one of defendants' competitors. Our Court of Appeals, in a previous action against defendants, has affirmed this court's finding that the action against Perrigo was indeed a sham. See FTC v. AbbVie Inc. (FTC II), 976 F.3d 327, 366 (3d Cir. 2020).

Plaintiffs filed a motion for in camera review of 211 of defendants privileged or work-product documents related to the Perrigo lawsuit. After briefing and oral argument on the issue, the court held that the filing of a sham patent infringement action constitutes fraud for the purposes of the crime-fraud exception to the attorney-client privilege and the work product doctrine. See King Drug Co. of Florence, Inc. v. Abbott Lab'ys, No. CV 19-3565, 2023 WL 2646926, at *5 (E.D. Pa. Mar. 27, 2023). The court initially ordered defendants to produce for the court's review 100 of the 211 documents to be selected by plaintiffs. Id. at *6. The court explained that:

for the Court to engage in an in camera inspection of documents to determine whether the exception applies, the party opposing the privilege . . . must present evidence sufficient to support a reasonable belief that in camera review may yield evidence that established the exception's applicability.

Id. at *5 (quoting U.S. v. Zolin, 491 U.S. 554, 574-75 (1989)). The court reiterated that “[t]he standard for undertaking such a review is much more lenient than for a finding that the veil of secrecy no longer applies.” Id.

Defendants submitted to the court the 100 documents as well as declarations from three of AbbVie’s in-house patent attorneys who were involved in the filing of the action against Perrigo. After reviewing these materials, the court ordered defendants to submit all remaining documents in which any of the declarants was an author or recipient. The court has reviewed a total of 161 documents.

I

Some history is necessary to understand the pending motion. In August 2000, AbbVie and Besins filed U.S. Patent Application Serial No. 09/651,777 (“the ‘777 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.

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. In response to this rejection, AbbVie and Besins amended their '777 application in October 2001 to cover only twenty-four penetration enhancers, including isopropyl myristate. During a meeting to discuss this amendment, the examiner determined that the claims which identified only isopropyl myristate as the penetration enhancer were allowable. AbbVie and Besins submitted a supplemental amendment two weeks later in which they reduced the number of penetration enhancers in the '777 application from twenty-four to one. The examiner approved the application and the '894 patent was issued with isopropyl myristate as the only claimed penetration enhancer.

After the '894 patent was issued, Perrigo--another pharmaceutical company--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. See 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 30-month stay of the approval process and delayed Perrigo's entry into the market for that

period. Perrigo did not begin to sell its generic product until 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. See FTC v. AbbVie Inc. (FTC I), No. CV 14-5151, 2017 WL 4098688 (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. The court granted partial summary judgment in favor of the FTC on the grounds that "[t]he patent lawsuits against Teva and Perrigo were without question objectively baseless." Id. at *32.

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. See 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. It stated that “[n]o reasonable litigant in AbbVie and Besins’ position would believe it had a chance of winning” FTC v. AbbVie Inc. (FTC II), 976 F.3d at 366. The Court, however, determined that Section 13(b) of the Federal Trade Commission Act did not give courts 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 was ultimately dismissed. Id.

Consistent with what this court and our Court of Appeals had previously decided in the earlier action, this court here granted partial summary judgment in favor of the plaintiffs on the ground that AbbVie and Besins’ lawsuit against Perrigo was objectively baseless. See King Drug Co. of Florence v. Abbott Lab'ys, No. CV 19-3565, 2023 WL 324505, at *6 (E.D. Pa. Jan. 19, 2023).

II

The attorney-client privilege allows for the “full and frank communication between attorneys and their clients and thereby promote[s] broader public interests in the observance of law and administration of justice.” U.S. v. Zolin, 491 U.S. 554, 562 (1989) (quoting Upjohn Co. v. United States, 449 U.S. 383, 389 (1981)). Although this privilege protects a client who

discusses past wrongdoings with his or her attorney, it does not apply to discussions of future wrongdoings. The crime-fraud exception to the privilege authorizes disclosure of communications between an attorney and client made in furtherance of a future crime or future fraud. See In re Grand Jury, 705 F.3d 133, 153 (3d Cir. 2012).

"The work-product doctrine . . . protects from discovery materials prepared or collected by an attorney 'in the course of preparation for possible litigation.'" In re Grand Jury Investigation, 599 F.2d 1224, 1228 (3d Cir. 1979) (quoting Hickman v. Taylor, 329 U.S. 495, 505 (1947)). Work product, however, is not protected when it is used in furtherance of an alleged crime or fraud. See In re Grand Jury, 705 F.3d at 153. It is treated in the same way as the attorney-client privilege for purposes of the crime-fraud exception. See id.

To determine whether the disclosure of documents is warranted under the crime-fraud exception, the party seeking to overcome the privilege "must make a prima facie showing that (1) the client was committing or intending to commit a fraud or crime, and (2) the attorney-client communications were in furtherance of that alleged crime or fraud." Id. at 151. Our Court of Appeals explained:

where there is a reasonable basis to suspect that the privilege holder was committing or intending to commit a crime or fraud and that the attorney-client communications or

attorney work product were used in furtherance of the alleged crime or fraud, this is enough to break the privilege.

Id. at 153 (*italics added*).

The first prong of the test--whether "there is a reasonable basis to suspect that the privilege holder was committing or intending to commit a crime or fraud"--clearly has been met here. As discussed above, this court has twice found--and our Court of Appeals once affirmed--that AbbVie and Besins' suit against Perrigo was objectively baseless. See FTC I, No. CV 14-5151, 2017 WL 4098688 at *11; FTC II, 976 F.3d at 366; King Drug Co., No. CV 19-3565, 2023 WL 324505 at *6. The court reiterates its previous findings that AbbVie and Besins: (1) had no objective basis to assert that Perrigo infringed the '894 patent; and (2) illegally and willfully maintained their monopoly power through the filing of sham litigation. In the context of the crime-fraud exception, these holdings provide a reasonable basis to suspect that AbbVie and Besins committed or were intending to commit a crime or fraud.

The second prong of the test is whether there is a reasonable basis to suspect "that the attorney-client communications or attorney work product were used in furtherance of the alleged crime or fraud." For this prong to be met:

All that is necessary is that the client misuse or intend to misuse the attorney's advice in furtherance of an improper purpose. When this occurs, the purpose of

the privilege, to promote the fair administration of justice, has been undermined and the privilege no longer applies.

In re Grand Jury, 705 F.3d at 157. The party opposing the privilege must present "evidence which, if believed by the factfinder, would be sufficient to support a finding that the elements of the crime-fraud exception were met." In re Grand Jury Subpoena, 223 F.3d 213, 217 (3d Cir. 2000) (quoting Haines v. Liggett Grp. Inc., 975 F.2d 81, 95-96 (3d Cir. 1992)).

Defendants argue that the "in furtherance" prong is not met where "attorneys merely opine[] on the lawfulness of a particular course of conduct." In re Grand Jury Subpoena, 745 F.3d 681, 693 (3d Cir. 2014). Our Court of Appeals explained that the crime-fraud exception does not apply when an attorney "merely informs the client of the criminality of a proposed action." Id. Instead, there must be a reasonable basis to conclude that the client could use the attorney's advice in furtherance of a crime or fraud. Id.

For example, in In re Grand Jury Subpoena, a client told his attorney that he was planning to pay a banker to speed up the approval process for a financing project. Id. at 685. The banker worked for a financial institution that was headquartered in the United Kingdom and owned by several foreign countries. After conducting some research, the attorney suspected that the payment could violate the Foreign Corrupt

Practices Act ("FCPA"). The FCPA prohibits a United States resident from paying a bribe to a foreign official for the purpose of inducing that official to act unlawfully. See 15 U.S.C. § 78dd-2(a)(3), (h)(3)(a).

The attorney asked the client "whether the [b]ank was a government entity and whether [b]anker was a government official." Id. at 693. He ultimately advised the client not to make the payment. The client, however, decided to route the payment through the banker's sister to circumvent any government connection. The Court affirmed the district court's decision that the crime-fraud exception applied. It stated that:

Specifically, Attorney's questions about whether or not the Bank was a governmental entity and whether Banker was a government official would have informed Client that the governmental connection was key to violating the FCPA. This would lead logically to the idea of routing the payment through Banker's sister, who was not connected to the Bank, in order to avoid the reaches of the FCPA or detection of the violation.

Id. The attorney's conduct went beyond merely opining on the lawfulness of the client's proposed conduct because the client could reasonably infer how to commit a crime based on the attorney's questions.

The court finds that the attorneys here did more than opine on the lawfulness of conduct. The attorneys were key decisionmakers who directed the filing of sham litigation

against Perrigo.³ Thus, the distinction between attorney and client is conflated in this case. These attorneys were not opining to their employer-client on whether the proposed lawsuit would be fraudulent. Rather, it is reasonable to infer from their legal research and analysis that they knew the filing of the litigation would be a sham. As a result, it is reasonable to conclude that the attorneys used their own legal research and analysis--the documents at issue here--in furtherance of fraud.

III

Having decided that the "in furtherance" prong applies here, the court must next determine which of the documents reviewed were used in furtherance of the sham litigation against Perrigo. Our Court of Appeals has broadly interpreted the scope of communications or work product that implicate the crime-fraud exception. For example, in In Re Grand Jury, ABC Corp. and two individuals were investigated for allegedly engaging in a tax fraud scheme comprised of two stages. 705 F.3d at 139. First, ABC Corp., under the direction of the two individuals, acquired companies with significant tax liabilities. The company would then transfer the stock of the acquired companies to two limited

3. The parties dispute which attorneys bore the ultimate responsibility for filing the Perrigo litigation. Regardless, the court finds that all the declarants played an essential role in assessing whether and how to file sham litigation against Perrigo.

liability companies and complete transactions that fraudulently eliminated the acquired companies' tax liability.

This court found that the evidence submitted by the Government provided a reasonable basis to suspect that ABC Corp. willfully avoided paying federal income taxes and engaged in a conspiracy to defraud the government of federal income taxes. See id. at 155. Therefore, it found that the crime-fraud exception applied. This court ordered in-house counsel for ABC Corp. to answer questions about both stages of the scheme, even though the fraudulent tax transactions occurred during the second stage of the scheme. Our Court of Appeals affirmed this court's findings because the court had "a reasonable basis to suspect that ABC Corp. was engaged in a large-scale criminal scheme that consisted of multiple phases." Id.

Here, the court finds that there is a reasonable basis to suspect that AbbVie and Besins intended to file sham litigation for the purpose of preventing or delaying Perrigo from entering the testosterone replacement market. In the context of sham-litigation, intent is defined as the defendants' "subjective motivation" for filing the action, "not its subjective belief about the merits of its claims." FTC II, 976 F.3d at 369.

On October 4, 2010, the FDA granted AbbVie and Besins' citizen petition requesting that Perrigo file a Paragraph IV

certification. This certification is required when a company is seeking FDA approval to market a generic product. On September 21, 2011, AbbVie and Besins received Perrigo's letter notifying them of the Paragraph IV certification. A patent holder can file an infringement suit within 45 days of receiving a Paragraph IV notice letter. Such a lawsuit automatically stays the generic competitor's entry into the market for 30 months. The stay only expires if the patent expires, or a court determines that the patent is invalid or has not been infringed by the competitor. As demonstrated by four documents, the attorneys were well-aware that they had a 45-day period after receiving Perrigo's letter to file a lawsuit before the 30-month stay expired. See Exhibits 2, 15, 30, 39. If they received the 30-month stay, Perrigo would not be able to enter the market until late March 2014.

It is reasonable to infer that a number of the documents which defendants produced for in camera review show an improper motive in filing the lawsuit against Perrigo. In two documents, the attorneys examined statistics about the typical length for patent cases to be resolved in various district courts. See Exhibits 21, 61. They expressed a preference for filing in New Jersey where they knew the length of time it takes to resolve patent cases is notably longer than in other district courts in the country. Specifically, they stated that the

District of New Jersey was not known for being a "rocket docket" and that Judges in the district generally took significant time to resolve summary judgment motions. By filing in a district in which the action would likely take longer to resolve, AbbVie and Besins could delay receiving an adverse judgment that would terminate the automatic 30-month stay of any sale of a generic AndroGel. See 21 U.S.C. § 355(c)(3)(C)(i). As a result, there is a reasonable basis to suspect that the attorney's venue analysis under the overall circumstances was in furtherance of the filing of sham litigation.

In another document, dated October 14, 2011, the AbbVie attorneys began discussing internally their settlement proposal, not about what Perrigo might pay them but instead what they might pay Perrigo. See Exhibit 49. That discussion began over 15 days before the infringement action against Perrigo was filed on October 31, 2011 in the District of New Jersey. Two months later, during December 2011, AbbVie and Besins agreed to pay Perrigo \$2,000,000 for "reasonable litigation expenses" and provide Perrigo a royalty-free license in return for refraining from competition until January 1, 2015. From this document, a factfinder could reasonably infer that AbbVie and Besins were not planning to litigate what they believed to be a meritorious action. Rather, this document suggests that the attorneys were simply eager to use a sham lawsuit to prevent or delay Perrigo

from entering the testosterone replacement market. They did so by first triggering the 30-month stay and then quickly settling the action on the condition that Perrigo not enter the market for nearly 10 additional months beyond the expiration in March 2014 of the 30-month stay.

In addition, a number of the documents reveal that the attorneys doubted the merits of the action against Perrigo. In support of their litigation against Perrigo, AbbVie and Besins asserted 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., 535 U.S. 722, 732 (2002). It "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." Id. at 733.

In the prior action brought by the FTC against AbbVie and Besins, the FTC argued that the prosecution history estoppel doctrine prevented the application of the doctrine of equivalents. See FTC I, No. CV 14-5151, 2017 WL 4098688 at *6. Under the prosecution history estoppel doctrine, a patentee is

precluded from claiming equivalents if the patentee surrendered the equivalents for reasons of patentability during the patent prosecution process. See id. at 733-34. AbbVie and Besins, however, claimed that their amendments to the '777 application-- which reduced the number of claimed penetration enhancers from twenty-four to only isopropyl myristate--were not made for the purpose of patentability and therefore the prosecution history estoppel doctrine did not apply. In addition, they claimed that they had a good faith basis to advocate for changes in the law.

This court previously found AbbVie and Besins' argument for prosecution history estoppel to be objectively baseless. See FTC I, No. CV 14-5151, 2017 WL 4098688, at *32; King Drug Co., No. CV 19-3565, 2023 WL 324505, at *6. In some of the documents at issue here, the attorneys parrot their objectively baseless arguments on prosecution history estoppel that they ultimately presented to this court. See Exhibits 1, 24, 30, 32, 62, 86, 91, 93, 96, 99, 160. In fact, they acknowledge that they would have more difficulty addressing prosecution history estoppel arguments in their action against Perrigo than in the Teva litigation. The court reiterates its finding that "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." FTC I, No. CV 14-5151, 2017 WL 4098688, at *11. Thus, there is a

reasonable basis to suspect that the content of these documents furthered the filing of an action against Perrigo for an improper motive and as a sham.

In other documents, the attorneys delve extensively into their concerns that the lawsuit against Perrigo would result in sanctions under Rule 11 of the Federal Rules of Civil Procedure. See Exhibits 24, 29, 30, 31, 32, 66, 160. The Rule requires attorneys to affirm that: (1) the action "is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; and (2) "the claims, defenses, and other legal contentions are warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law." Fed. R. Civ. P. 11(b).

The attorneys feared that they did not have viable arguments under the disclosure-dedication doctrine. In Johnson & Johnston Associates, Inc. v. R.E. Service Co., the Federal Circuit sitting en banc established that "when a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public." 285 F.3d 1046, 1054 (Fed. Cir. 2002). Thus, the doctrine of equivalents cannot be used to "recapture subject matter deliberately left unclaimed." Id. In the documents, the attorneys admit that an action against Perrigo would be nearly

indistinguishable from Johnson & Johnston.⁴ The '894 patent expressly describes isosteric acid as a penetration enhancer that can be used as an alternative to isopropyl myristate. As a result, isosteric acid--which Perrigo used as a penetration enhancer--was disclosed and therefore dedicated to the public.

Ultimately, the attorneys acknowledged in one document that the action against Perrigo presented another hurdle--the disclosure-dedication doctrine--in addition to the challenges they faced under the prosecution history estoppel doctrine. See Exhibit 24. As noted above, this court already found that "AbbVie and Besins could not realistically have expected success on the merits of [prosecution history estoppel] or have had a reasonable belief that they had a chance to prevail." FTC I, No. CV 14-5151, 2017 WL 4098688, at *11. Yet, AbbVie's attorneys were concerned that their arguments under the disclosure-dedication doctrine, not prosecution history estoppel, could result in Rule 11 sanctions. From this, a

4. AbbVie's in-house counsel decided to argue that Johnson should be interpreted narrowly or that Johnson conflicts with existing Supreme Court precedent. AbbVie claims that the holding in Janssen Products, L.P., v. Lupin Ltd., 109 F. Supp. 3d 650, 655 (D.N.J. 2014), demonstrates that AbbVie's position was reasonable. Regardless of whether AbbVie would have prevailed under Janssen, the case was decided in 2014 and is therefore irrelevant to AbbVie and Besins' state of mind in 2011 when the patent infringement lawsuit against Perrigo was filed. In addition, it must be emphasized that Johnson was a decision of the Federal Circuit while Janssen was a decision of the District Court.

factfinder could reasonably infer that the attorneys thought their arguments under the disclosure-dedication doctrine were even weaker than their arguments under prosecution history estoppel. There is a reasonable basis for a factfinder to suspect from the documents that AbbVie and Besins filed the action against Perrigo for an improper purpose and as a sham.

The court finds that there is a reasonable basis to suspect that a number of the documents provided by the defendants for in camera review show that defendants knew they were filing a sham litigation against Perrigo. See In re Grand Jury, 705 F.3d at 153. Accordingly, the court will order defendants to disclose Exhibits 1, 2, 15, 21, 24, 29, 30, 31, 32, 39, 61, 62, 66, 86, 91, 93, 96, 99, and 160 to the plaintiffs.