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

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

MEMORANDUM

Bartle, J.

April 25, 2022

Plaintiffs are direct-purchase wholesalers of pharmaceutical drugs. They bring this civil antitrust action under the Sherman Act against defendants Abbott Laboratories, AbbVie Inc., AbbVie Products LLC, and Unimed Pharmaceuticals LLC (collectively "AbbVie"),¹ Besins Healthcare Inc. ("Besins"), Actavis Holdco U.S. Inc., Actavis Inc., Paddock Laboratories Inc., Par Pharmaceutical Inc., and Teva Pharmaceuticals USA Inc. who are brand and generic drug manufacturers. <u>See</u> 15 U.S.C. §§ 1-2. This action concerns generic competition for AndroGel 1%, a brand-name transdermal testosterone gel product developed by AbbVie and Besins and approved by the United States Food and Drug Administration ("FDA") in 2000. AbbVie and Besins together own U.S. Patent No. 6,503,894 ("`894 patent") for AndroGel 1%.

^{1.} The court will use "AbbVie" to generally refer to all the subsidiaries and predecessors of AbbVie Inc. including Solvay Pharmaceuticals LLC, Abbott Products LLC, AbbVie Products LLC, Unimed Pharmaceuticals LLC, and Abbott Laboratories.

Plaintiffs have filed a motion to compel defendants AbbVie and Besins to produce documents responsive to request for production No. 52. That request seeks:

> All documents concerning Abbvie's, Unimed's, Besins's or their agents' assessment of the materiality of the 1995 Supply Agreement (or details relating to the shipments of testosterone gel pursuant to the 1995 Supply Agreement) or the 1995 License Agreement, or Abbvie's, Unimed's, Besins's, or their agents' consideration of whether to disclose either of those agreements to the PTO during the prosecution of the AndroGel Patents between August 30, 2000 and September 15, 2015.

AbbVie and Besins object to the extent that the request seeks documents protected by the attorney-client privilege or the work product doctrine. Defendants also object to this request in its entirety based on the limitations on discovery incorporated into a Stipulation which the parties signed and the court approved on December 22, 2020. Plaintiffs assert that the attorney-client privilege and work product doctrine have been waived and that the Stipulation does not prevent the discovery sought here.

In support of waiver, plaintiffs cite the testimony of Joseph Mahoney, the attorney who prosecuted the '894 patent in the United States Patent and Trademark Office ("PTO") on behalf of AbbVie, in a deposition taken in antitrust litigation regarding AndroGel 1% in the Northern District of Georgia. In that deposition, Mahoney was asked about the 1995 Supply

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Agreement between Unimed and Besins which allegedly involved the sale of Androgel 1% and about his decision not to provide it to the examiner in the PTO who was reviewing the application to determine whether a patent should be granted. Plaintiffs cite the following dialogue:

> Q: Mr. Mahoney, during the time which you were [] prosecuting the application that became the '894 patent, were you aware of a Supply Agreement between Unimed and Besins?

A: Yes.

Q: And did you make a decision not to disclose that Supply Agreement to the patent office?

A: Yes.

Q: And can you tell me why you decided not to disclose that Supply Agreement to the patent office?

A: It is non-material to patentability.

Q: And what do you base that conclusion on?

A: The -- what I recall is that we -- and this would have been Tom Stieble and myself -- were made aware of the License and Supply Agreement between Unimed and Besins during the prosecution of the '894 patent, and we -- we looked at those agreements and the joint development nature of those agreements. We also had discussions with our client related to the relationship between Unimed and Besins.

The attorney for AbbVie, Jeffrey Weinberger, then interjected to caution Mahoney that he did not want Mahoney "to get into the substantive conversations with [Mahoney's] client."

Later in the deposition, the following exchange occurred between counsel for plaintiffs and counsel for AbbVie:

Q [to Mahoney]: So where are you drawing the line for attorney-client privilege here? It sounds like you are describing your work product and the analysis of whether or not the Supply Agreement was material; is that correct?

Mr. Weinberger: Well, I think -- I think it's up to us to draw the line, and we are not allowing him to testify as to any specific communications that he had with the client, but I think the work product behind the determinations made with respect to the patent office is discoverable. So that's the line I am trying to draw.

Plaintiffs maintain that the information sought in request No. 52 about the 1995 Supply Agreement is highly relevant to their assertion that the '894 patent is invalid because the invention claimed therein was on sale more than a year before the patent's filing date of August 30, 2000. <u>See</u> 35 U.S.C. § 102.

To decide the pending motion, it is important to review the contours of the attorney-client privilege, the work product doctrine, and the issue of waiver. The attorney-client privilege protects from discovery confidential communications between an attorney and client. <u>Rhone-Poulenc Rorer, Inc. v.</u> Home Indem. Co., 32 F.3d 851, 862 (3d Cir. 1994). The client of

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course may always waive the privilege. <u>Id.</u> at 863-64.² The party seeking to obtain privileged information has the burden of proving that a waiver has occurred. <u>Brigham & Women's Hosp.</u> <u>Inc. v. Teva Pharm. USA, Inc.</u>, 707 F. Supp.2d 463, 469 (D. Del. 2010).

The privilege, however, does not extend so far as to protect the fact that communications between attorney and client took place or the general nature or topics of those communications. <u>GFI, Inc. v. Franklin Corp.</u>, 265 F.3d 1268, 1273 (Fed. Cir. 2004). Rather it protects from disclosure the substance of these conversations unless the privilege is waived. Id.

Here, Mahoney, the attorney representing AbbVie in the patent prosecution, did not cross the line at his deposition. While he disclosed that conversations with the client occurred concerning the relationship between Unimed and Besins, he did not disclose the substance of those conversations. Hence the attorney-client privilege was not waived.

^{2.} Although neither plaintiffs nor defendants have raised the issue of whether the client in this instance was the one to waive any privilege, the court notes that an attorney may waive attorney-client privilege when acting on behalf of the client. <u>See e.g., Shaffer v. Pennsbury Sch. Dist.</u>, 525 F. Supp. 3d 573, 577 (E.D. Pa. 2021) (citing <u>Westinghouse Elec. Corp. v. Republic of the Philippines</u>, 951 F.2d 1414, 1420, 1431 (3d Cir. 1991); <u>Fid. & Deposit Co. of Md. v. McCulloch</u>, 168 F.R.D. 516, 523 (E.D. Pa. 1996)).

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The work product doctrine is distinct from the attorney-client privilege. Westinghouse Elec. Corp. v. Republic of the Philippines, 951 F.2d 1414, 1427-28 (3d Cir. 1991); In re Grand Jury Proceedings, 604 F.2d 798, 801 (3d Cir. 1979); Praxair, Inc. v. ATMI, Inc., 445 F. Supp. 2d 473, 480 n.9 (D. Del. 2006). The work product doctrine is designed to protect the papers prepared by the attorney or on behalf of an attorney in anticipation of litigation. Unlike the waiver of the attorney-client privilege, a waiver related to an attorney's work product extends only to the documents disclosed and not beyond. 6 James Wm. Moore et al., Moore's Federal Practice § 26.70[6][c] (3d ed. 2022). Absent evidence to the contrary, a patent prosecution before the PTO is not litigation or in anticipation of litigation. See FTC v. AbbeVie, Inc., 2015 WL 8623076, at *4 (E.D. Pa. Dec. 14, 2015); see also Burroughs Wellcome Co. v. Barr Labs., Inc., 143 F.R.D. 611, 617-18 (E.D.N.C. 1992). There is nothing before the court that demonstrates there was any protectable attorney work product in connection with the prosecution of the '894 patent. Thus there can be no waiver of the attorney work product doctrine.

Even if there is no waiver here, there are documents subject to the request for production No. 52 that are not confidential communications between attorney and client and are not papers that are an attorney's work product. Defendants, in

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opposing the motion to compel, rely on the Stipulation of the parties putting limits on the voluminous discovery in this action. The Stipulation was designed to avoid duplicative and unnecessary production of documents that were already produced and available from earlier related lawsuits in the federal courts in the Northern District of Georgia and in this court, the Eastern District of Pennsylvania. <u>See In re AndroGel</u> <u>Antitrust Litig. (No. II)</u>, Civil Action No. 09-2084 (N.D. Ga.); FTC v. AbbVie Inc., Civil Action No. 14-5151 (E.D. Pa.).

As previously stated, in their request for production No. 52, plaintiffs seek the following:

> All documents concerning Abbvie's, Unimed's, Besins's or their agents' assessment of the materiality of the 1995 Supply Agreement (or details relating to the shipments of testosterone gel pursuant to the 1995 Supply Agreement) or the 1995 License Agreement, or Abbvie's, Unimed's, Besins's, or their agents' consideration of whether to disclose either of those agreements to the PTO during the prosecution of the AndroGel Patents between August 30, 2000 and September 15, 2015.

The plaintiffs in the Georgia litigation previously sought in July 2010 from Unimed and Solvay, now AbbVie, the following:

> All documents relating to communications with counsel (both in-house and outside) regarding: (a) your basis for any belief held at any time that the '894 patent was or was not valid, enforceable and/or infringed; (b) your investigation of any Paragraph IV certification made with respect to the '894

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patent; (c) your decision to initiate the AndroGel Patent Litigation; (d) the reasons for settling the AndroGel Patent Litigation; (e) your consideration of whether any of the Generic Defendants would seek to market a generic "at risk" at any time while the AndroGel Patent Litigation was pending; (f) the likely outcome(s) of the AndroGel Patent Litigation.

In that same request for production, the plaintiffs sought from Unimed and Solvay "[f]or the period starting in August 30, 2000, all documents relating to any discussion, communication, or question relating to disclosure of information to the U.S. Patent and Trademark Office during prosecution of the '777 Application or any related application."³ Similarly, the plaintiffs in the Georgia litigation subpoenaed Besins in August 2010 for "[a]ll documents relating to any discussion, communication, or question relating to disclosure of information to the U.S. Patent and Trademark Office during prosecution of the '777 Application or any related application."

Plaintiffs' present request for production No. 52 to AbbVie and Besins is duplicative of the production sought in 2010 in the Georgia litigation and therefore is barred by the Stipulation. The Stipulation signed by the parties in this action states that "[t]he parties agree that all documents . . . produced in the Georgia Action by any Defendant in the Pennsylvania Action (or by any affiliate or predecessor of any

^{3.} The application number for the `894 patent was 09/651,777.

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Defendant) shall be deemed produced in the Pennsylvania Action." The Stipulation further provides that "Plaintiffs agree that AbbVie, Actavis, Inc., Par and Paddock, and Besins ("Georgia Entities") will not be required to conduct a re-search of their files for categories of documents related to the 2006 Agreements or otherwise duplicative of discovery already produced in the Georgia Action."

Plaintiffs argue that Judge Thomas W. Thrash in the Georgia litigation denied plaintiffs' February 2016 request for production which sought from AbbVie:

> Describe any good faith justifications for (1) Dr. Dudley's and Mr. Mahoney's failure to disclose to the USPTO during the prosecution of the '894 Patent (a) the Supply Agreement, and (b) the Pre-Critical Date Transfers of testosterone gel pursuant to the Supply Agreement; (2) Mr. Mahoney's statement to the USPTO during the prosecution of the '894 Patent that "the claimed invention was not sold, offered for sale, or used publicly before the critical date" . . . and (3) Dr. Dudley's statement to the USPTO during the prosecution of the '894 Patent that "at no time before AndroGel's approval by the FDA did Unimed or Besins sell or offer to sell the AndroGel formulation to any third party.

Plaintiffs in the Georgia litigation, however, had already sought this information from both AbbVie and Besins in their 2010 requests for production. Plaintiffs argue that defendants did not produce the information sought in those 2010 requests. There is no evidence before the court, however, that

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plaintiffs moved within a reasonable time to compel the requested information. The fact that they later sought the information in 2016 and were denied as out of time does not change the fact that they previously sought this information in 2010 in the Georgia litigation.

For the foregoing reasons, the court will deny plaintiffs' motion to compel production of documents responsive to request for production No. 52.