

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE VALSARTAN, : MDL No. 19-2875(RBK/KW)
LOSARTAN, AND IRBESARTAN : :
PRODUCTS LIABILITY : :
LITIGATION : :

This Order Relates to all Cases

SPECIAL MASTER ORDER NO. 28

June 21, 2021

THE BACKGROUND OF THIS ORDER IS AS FOLLOWS:

Defendants, Zhejiang Huahai Pharmaceutical Co, Ltd., Huahai U.S., Inc., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively “ZHP” or “Defendants”) have filed a Motion for a Protective Order Precluding the Deposition of ZHP President Baohua Chen. (Doc. 1247.) Counsel for Defendants and Plaintiffs have addressed this matter in briefs filed on the docket. (See Docs. 1247-2, 1295, 1298 and 1307.)

Pursuant to Fed. R. Civ. P. 26(c), “[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense[.]” Fed. R. Civ. P. 26(c)(1). In moving for a protective order, the party seeking the order “must show good cause by demonstrating a particular need for protection.” *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986). Establishing “good cause” requires the movant to “specifically

demonstrate [] that disclosure will cause a clearly defined and serious injury. Broad allegations of harm, unsubstantiated by specific examples, however, will not suffice.” *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995) (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994)).

In support of their motion for a protective order precluding Mr. Chen’s deposition, Defendants invoke the “apex doctrine,” “an analytical framework used by courts in assessing whether to permit the depositions of individuals at the ‘apex’ of corporations and other entities.” *U.S. ex rel. Galmines v. Novartis Pharm. Corp.*, CV 06-3213, 2015 WL 4973626, at *1 (E.D. Pa. Aug. 20, 2015). This “doctrine recognizes that depositions of high-level officers severely burdens those officers and the entities they represent, and that adversaries might use this severe burden to their unfair advantage.” *Id.* “Simply stated, the apex doctrine applies when those at the top of the company, *i.e.* men and women at the ‘apex,’ really don’t have personal knowledge about what is going on with the product, or its marketing, or its financing or really anything else that might be of interest to the plaintiffs, or the attorneys, or the jury, or the court.” *In re Tylenol (Acetaminophen) Mktg., Sales Practices and Products Liab. Litig.*, 2:13-MD-02436, 2014 WL 3035791, at *2 (E.D. Pa. July 1, 2014).

Defendants argue that, as President of ZHP, a large, multinational corporation, Mr. Chen qualifies as an “apex” witness. They further argue that Plaintiffs have not

rebutted the presumption that his deposition would impose an undue burden.¹ In support of their argument, Defendants point to the voluminous discovery record compiled to date and assert that Plaintiffs have failed to establish that Mr. Chen possesses any unique superior knowledge as to the development, manufacture, sale, contamination, and recall of Valsartan, issues central to this litigation, which cannot be otherwise obtained from his subordinates. (Doc. 1247 at 2.) Defendants maintain, based on the documentary evidence and testimony provided thus far, that Mr. Chen functions in a managerial capacity only, receiving reports and accepting decisions from employees more knowledgeable on these topics, whom Plaintiffs have already deposed. (*Id.* at 19.) Defendants contend that Mr. Chen was not involved in the manufacture of Valsartan, the discovery of nitrosamine contamination, and the recall of the product. (*Id.*) As such, Defendants argue, Mr. Chen's testimony would be duplicative of other witnesses and unduly burdensome.

In opposition to the motion, Plaintiffs argue that Mr. Chen serves a central role at ZHP, and had direct involvement, and thus unique knowledge concerning the development, manufacture, sale, and recall of Valsartan, which cannot, and has not been obtained from other witnesses. (Doc. 1298 at 2.) Specifically, Plaintiffs point

¹ Some courts have applied a “rebuttable presumption that a high-level official's deposition represents a significant burden upon the deponent and that this burden is undue absent the . . . the lack of a more convenient, less burdensome, and less expensive alternative.” *Novartis Pharm. Corp.*, 2015 WL 4973626, at *2.

out that Mr. Chen is a Chemical Engineer with a Master of Science degree in Chemical Engineering. He is described in ZHP documents as having “wide experience in the product development and quality management of bulk drugs.” (Ex. C to Plaintiffs’ Brief in Opp. to ZHP Mot. for Protective Order, ZHP01662344.) Mr. Chen headed ZHP’s Quality department, “covering all functions and actions necessary to provide adequate confidence that the finished product manufactured by the company will perform the intended purpose with regard to safety, purity and effectiveness.” (*Id.* ZHP01662359.) Plaintiffs have also pointed to evidence that Mr. Chen was heavily involved with the pricing of Valsartan to increase the company’s market share. (*See* Ex. O to Plaintiffs’ Brief in Opp. to ZHP Mot. for Protective Order, SOLCO00189499 (“Mr. Chen is not satisfied with our [Valsartan market] share and wants us to target 40%! Mr. Chen has promised . . . that he would lower our COGS.”).) In this regard, ZHP informed the FDA that it implemented the manufacturing process that Plaintiffs suspect caused nitrosamine contamination “to save money,” and the resulting “cost reduction was so significant it is what made it possible for the firm to dominate the world market share.” (Ex. U to Plaintiffs’ Brief in Opp. to ZHP Mot. for Protective Order, PRINSTON00162373.)

Shortly, after the June 2018 disclosure of the contamination, Mr. Chen communicated directly with the FDA, participated in a number of FDA inspections,

and organized, attended and participated in multiple meetings at ZHP regarding the contamination. (*Id.* at 2-4.) Additionally, Plaintiffs claim that Mr. Chen, as the first member of ZHP's "Recall Group," was "intimately involved" in ZHIP's recall of Valsartan, and even handled customer complaints regarding the same. (*Id.* at 4-7.) In communications with the FDA, Mr. Chen stated that he "has the ultimate authority at the firm and takes full responsibility for the company's operations." (Ex. G to Plaintiffs' Brief in Opp. to ZHP Mot. for Protective Order, PRINSTON00083647.) Plaintiffs also point to evidence that Mr. Chen dealt directly with the European Directorate for the Quality of Medicines regarding the nitrosamine contamination and ZHP's corrective actions. (Ex. W to Plaintiffs' Brief in Opp. to ZHP Mot. for Protective Order, ZHP01423197.)

"At bottom, the question of whether the 'Apex Doctrine' should be applied to preclude a deposition is within the Court's sound discretion and is, axiomatically, an extremely fact-sensitive determination." *In re Lincoln Nat'l COI Litig.*, 16-CV-6605-GJP, 2019 WL 7581176, at *2 (E.D. Pa. Dec. 5, 2019). For instance, "where the subject matter of the deposition would involve merely the company's 'day to day operations' or something manifestly immaterial in view of the total scope of the company's overall operations, such as slip-and-fall cases or a routine claim of trademark infringement, such facts might be said to tend to favor the application of the "Apex Doctrine" to preclude the requested deposition." *Id.*

But this is not a case that involves the routine day-to-day operations of ZHP. Nor does this case present a garden-variety tort claim. It is a case that concerns the alleged contamination of a popular blood pressure pharmaceutical produced by a leading player in the world-wide market. And it is not a case that raises a claim of an isolated instance of contamination; it concerns the manufacturing process that may have resulted in wholesale contamination of the product. This is the kind of case that one would expect a company's leader would be playing a leading role, and Plaintiffs have adduced evidence of such a role being played by Mr. Chen. The evidence cited by Plaintiffs is indeed sufficient to rebut the presumption that, as an "apex" witness, Mr. Chen lacks unique knowledge of the nitrosamine contamination and ZHP's response to it. Plaintiffs, at a minimum, have adequately shown that Mr. Chen's involvement and authority with respect to the development, manufacture, sale and recall of Valsartan was substantial and that it is likely that Mr. Chen has personal or unique firsthand knowledge regarding the matters at issue in this case. Plaintiffs have also made a meaningful showing that they are unable to obtain some or all of the information they are seeking through depositions of Mr. Chen's subordinates.

Undoubtedly, Mr. Chen will be inconvenienced by having to travel and sit for a multi-day deposition. This decision to deny the motion for a protective order is

not made lightly, but is made with a recognition of the costs and burdens to be sustained in requiring Mr. Chen to be deposed.

There is, however, no *per se* rule barring depositions of senior executives, and “[i]t is rare for a court to issue a protective order that prohibits a deposition.” *In re Tylenol*, 2:13-MD-02436, 2014 WL 3035791, at *2 (quoting *U.S. v. Mariani*, 178 F.R.D. 447, 449 (M.D. Pa. 1998)). In *Novartis Pharm. Corp.*, on which ZHP relies, the Court refused to require the deposition of a former CEO based upon “generic assertions” regarding the would-be deponent’s connection to the subject matter of the case premised upon a single power-point presentation and email. 2015 WL 4973626, at *2. Here, by way of contrast, Plaintiffs have made much more than a “generic” showing of Mr. Chen’s involvement with the contamination and product recall at the heart of this case. Mr. Chen has technical knowledge and is held out by ZHP as having “wide experience in the product development and quality management of bulk drugs.” (Ex. C to Plaintiffs’ Brief in Opp. to ZHP Mot. for Protective Order, ZHP01662344.) He communicated directly with the FDA and European authorities after the contamination was discovered. He called meetings at ZHP to respond to the contamination. The evidence suggests that Mr. Chen was not a detached manager, but an active participant in matters at the core of this case.

“The apex doctrine is merely a tool for guiding the Court's analysis in determining whether to limit discovery under Rule 26(b)(2)(C) because the

discovery can be obtained from some other source that is more convenient, less burdensome, or less expensive.” *Novartis Pharm. Corp.*, 2015 WL 4973626, at *2. In this case, Plaintiffs have shown that Mr. Chen may have unique knowledge that they have been unable to obtain from the numerous witnesses deposed thus far. Accordingly, Defendants’ motion for a protective order precluding the deposition of Mr. Chen will be denied.

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

1. Defendants’ Motion for Protective Order (Doc. 1247) is **DENIED**.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master