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

APOTEX, INC.	:	CIVIL ACTION
	:	
v.	:	NO. 2:06-cv-2768
	:	
CEPHALON, INC., et al.	:	

MEMORANDUM OPINION

DAVID R. STRAWBRIDGE
UNITED STATES MAGISTRATE JUDGE October 1, 2014

Presently before the Court is "Defendants' Joint Motion to Exclude Testimony of Plaintiff Apotex, Inc.'s Fed. R. Evid. 701 Witness, Gordon Fahner," filed by Cephalon, Inc., Barr Laboratories, Inc., Mylan, Inc., Mylan Pharmaceuticals, Inc., Ranbaxy Laboratories, Ltd., Ranbaxy Pharmaceuticals, Inc., Teva Pharmaceutical Industries, Limited and Teva Pharmaceuticals USA, Inc. (Doc. 683) ("Defs' Mot.") and "Memorandum, Declaration and Exhibits in Support of Defendants' Joint Motion to Exclude Testimony of Plaintiff Apotex Inc.'s Fed. R. Evid. 701 Witness Gordon Fahner, by Cephalon, Inc." (Doc. 707) ("Defendants' Memo"). By its motion, the defendants seek the entry of an order to preclude what they characterize as the lay opinion testimony of Gordon Fahner, a 25 year Apotex employee, on the question of the re-launch of the Apotex Modafinil in a but-for world (see Doc. 707 at Memo p. 2). In response, Apotex has filed "Plaintiff Apotex's Memorandum in Opposition to Defendants' Joint Motion to Exclude Testimony of Gordon Fahner" (Doc. 754) ("Apotex Opp.") together with the Declaration of Thomas J. Maas (Doc. 756) in support. Defendants then filed "Defendants' Reply Memorandum in Support of Their Joint Motion to Exclude Testimony of Plaintiff Apotex Inc.'s Fed. R. Evid. 701 Witness Gordon Fahner" (Doc. 781).

BACKGROUND

Apotex seeks to exlude the Fed. R. Evid. 701 opinion of Fahner that the "FDA issues which purportedly prevented Apotex from entering the market would not have impeded the launch, re-launch or sale of modanifil at any time in the but-for world" and that "modafinil would have ranked among the company's top five commercial priorities for a re-launch in the but-for world." The defendants argue that Mr. Fahner has no FDA regulatory experience and therefore lacks the personal knowledge and background required by Fed. R. Evid. 701 and 602 to render the opinion with respect to the impact of the FDA and, secondly, that he had no involvement or experience with the commercial ranking or prioritizing of the Apotex products for re-launch, precluding him from rendering even a lay opinion under Fed. R. Evid. 701 on this topic. (Doc. 707, p. 2).

As the defendants set out, Apotex, in the real world, was precluded from launching its modifinal product in December 2006 by what it alleges to be Cephalon's anti-competitive acts despite having received tentative approval for a launch from the FDA. (*Id.* at 4). For the purpose of demonstrating its economic loss, Apotex has modeled a but-for world that approximates the profits it says it would have made if the Apotex modifinal were not kept off the market by the actions of the defendants. (*Id*. at 1). The parties acknowledge that the but-for world must take into account the real world circumstance that the FDA placed an import alert banning the sale of products in the United States that were manufactured at two Canadian sites, Etobiocoke and Signet Drive, where Apotex manufactured its modifinal product between August 2009 and July 2011. (*Id.*, p. 1).

In anticipation of its re-launch after July 2011, Apotex organized a steering committee to plan the re-launch at the two facilities. (*Id.* at 4). Fahner, who is the Vice President of Business

Operations and Finance, had previously taken on "the responsibilities of the Vice President of Supply Chain" and was a member of the committee responsible for managing, ranking, and prioritizing the re-launch of Apotex's products after the import ban. (Doc. 707, Ex. 1, Fahner Decl. ¶¶ 9, 17). The committee evaluated its products considering a number of factors, and then prioritized the order in which they would re-launch these products. (*Id*. at ¶¶ 8-9). The factors considered in coming to its prioritization decision included: sales of the product before the import alert, the potential opportunity in the marketplace after re-launch, the number of competitors in the market, and the dynamic of the generic market without Apotex in 2010. (Doc. 754 at 5).

In August 2012, the FDA inspected Apotex's Signet facility and identified violations of the current good manufacturing practice regulations. (*Id.* at 6). As a result, it issued a Warning Letter, which, in the real world, precluded Apotex from obtaining final approval for U.S. sales from the FDA until February 2014. (*Id.*)

Since actual sales of modafinil before the import alert are not available, Fahner considered the projections of Apotex's expert witness to opine that modafinil would have been part of the re-launch plan in 2010. (*Id*. at 5). Fahner's challenged testimony further concluded that (1) in the but-for world, modafinil would have ranked among the company's top five commercial priorities for re-launch after the lifting of the import ban, and (2) the FDA issues that have allegedly prevented Apotex's entry over the last two years would not have impeded the launch, re-launch, and sale of modafinil. (Doc. 707 at 2).

DISCUSSION

Defendants argue that, under the Federal Rule of Evidence 701, Fahner should be precluded from testifying on two topics: (1) Apotex's ranking and prioritization of modafinil and

its alleged re-launch in the but-for world, and (2) the impact of the 2013 FDA Warning Letter on Apotex's ability to sell modafinil in the but-for world from re-launch to present. (Doc. 707).

Fed. R. Evid. 701, which governs the admissibility of lay testimony, provides that "[i]f a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is: (a) rationally based on the witness' perception; (b) helpful to clearly understanding the witness' testimony or to determine a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701.[1] *See Hirst v. Inverness Hotel Corp.*, 544 F.3d 221, 225 (3d Cir. 2008). The proponent of the testimony has the burden of production to establish its admissibility. *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005).

The "rational basis" criteria of Rule 701(a) requires that the opinion must be based on facts or information personally known to the witness. *See* Fed. R. Evid. 701 advisory committee note (1972) ("Limitation (a) is the familiar requirement of first-hand knowledge or observation."); *see also Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1175 (3d Cir. 1993) ("Lay opinion testimony may be based on the witness' own perceptions and knowledge and participation in the day-to-day affairs of [the] business"). The 701(a) analysis is informed by reference to the personal knowledge requirement of Fed. R. Evid. 602 which requires that "a witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter." Here, defendants assert that Fahner, even as a member of the steering committee, had no personal knowledge of the workings of the FDA and, to the extent that the delay in the re-launch to February 2014, was based in significant part upon the issuance of the warning letter by the FDA, the matter of dealing with this limitation

[1] Defendants challenge Fahner's testimony only on FRE 701(a) and (b) grounds. Defendants did not raise a FRE 701(c) challenge to Fahner's testimony.

leading him, in part, to his opinion was based upon hearsay information from colleagues "in the regulatory department, from the quality department, from the president and [COO] of the corporation." (Doc. 707, pp. 8-9, citing Fahner Dep. at 313:10-20). This deficiency on the part of Mr. Fahner is amplified by the fact that he had not, by his own admission, ever been "personally involved in regulatory affairs for Apotex," or "personally . . . involved in any interactions with the FDA," and had no oversight responsibilities for quality control or compliance with FDA regulations while at Apotex. (Doc. 707, p. 11).

Similarly, the defendants argue that the "helpfulness" requirement of 701 is not met in this circumstance. Defendants point to the limitations inherent in the lay opinion expressed by Mr. Fahner that if the re-launch had taken place in the but-for world, Apotex would have secured as much as 20% of the modifinal market. (Doc. 707, pp. 14-15). The defendants argue that there are significant contradictory allocations, including the opinion of the Apotex principal damage expert, Dr. Hal Singer, who has opined that after the import alert that Apotex would have obtained a market share of approximately 7.5%. (Doc. 754, p. 11). It is also clear, according to defendants, that the import alert and subsequent warning letter cost considerable goodwill to Apotex among its customer base. Defendants have supported that position with documentation submitted by Apotex in the proceeding it brought against the United States in the Court of Claims arbitration where it alleged that the import alert had a "devastating effect" upon the company. Apotex said in papers it filed in that proceeding that it "suffered a very significant loss of profits, incurred substantial out-of-pocket expenses and suffered harm to 'its good will and reputation vis-à-vis its customers.'" Memorial of Claimants (July 30, 2012) filed in *Apotex Holdings Inc. and Apotex Inc. v. United States*, ICSID Case. No. ARV(AF)/12/1 (as cited in Doc. 707, p.3). Apotex further stated that, as a result for being out of the market for two years, it lost

significant market share dropping it from the fifth largest player in the modifinal generic market to no. 24. (*Id.*).

In this proceeding, Apotex also articulated that it found it difficult "to increase its market share . . . because in the intervening years customers have developed supply relationships with competitors that are not easy to dislodge." *(Id.)*. We appreciate from the defendants' perspective that this evidence would have a substantial impact upon the reliability of the Fahner opinion and, accordingly, impair significantly any potential "helpfulness" it would provide to the jury.

Rule 701(a) also requires that the witness possess experience necessary to ensure that the opinion offered is reliable. *Asplundh Mfg. Div., a Div. of Asplundh Tree Expert Co. v. Benton Harbor Eng'g*, 57 F.3d 1190, 1201 (3d Cir. 1995). (internal quotations omitted). In a corporate context, "[a] witness testifying about business operations may testify about 'inferences that he could draw from his perception' of a business record, or facts or data perceived by him in his corporate capacity." *U.S. v. Polishan*, 336 F.3d 234, 242 (3d Cir. 2003). At the same time, lay opinion based on faulty, invalid assumptions or on facts that do not logically support the opinion, will not meet the Rule 701(b) criteria.

We are persuaded here that Fahner's 701 opinion does not meet the reliability prong – given the limitation in his relevant experience, the contrary indications Apotex presented to the Court of Claims when seeking relief from the United States for the imposition of the alert, as well as the actual experience Apotex had in the real world where the re-launch was delayed until February 2014. Even giving wide berth to his substantial experience at Apotex, including responsibility in the area of finance and supply chain, we cannot overlook Fahner's deficiencies in regulatory affairs which we agree with defendants, given this Rule 701 context, cannot be overcome by the hearsay statements of others. We grant defendants' motion.