

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

IN RE: PRADAXA (DABIGATRAN
ETEXILATE) PRODUCTS LIABILITY
LITIGATION

) 3:12-md-02385-DRH-SCW
) MDL No. 2385
)
)

This Document Relates to: All Cases

**DEFENDANT BII's MOTION FOR A PROTECTIVE ORDER BARRING THE
DEPOSITIONS OF DR. BARNER AND MR. HILLGROVE**

Pursuant to Federal Rules of Civil Procedure 26(b)(2) and (c)(1), Defendant Boehringer Ingelheim International GmbH (“BII”) seeks a protective order prohibiting the depositions of Dr. Andreas Barner, the Chairman of the Board of Managing Directors of BII, and Allan Hillgrove, a member of the Board of Managing Directors (“BMD”). BII’s BMD is responsible for running the global corporate entities, and its members have responsibility for tens of thousands of employees and broad oversight of BII’s global operations. Dr. Barner, who as Chairman of the BMD effectively serves as the CEO of the global entities, plays a particularly central role in the corporate entities’ overall operations.

Numerous other executives and employees that have been or will be deposed possess the same or superior knowledge regarding the facts at issue in this litigation. Further, as the Seventh Circuit has explained, deposing a “high ranking executive in a multinational corporation” is “quite costly and burdensome.” *Patterson v. Avery Dennison Corp.*, 281 F.3d 676, 682 (7th Cir. 2002). Therefore, considering the “totality of the circumstances,” the depositions of these BMD members, and particularly of Dr. Barner, should not be permitted because the information they possess “can be obtained from some other source that is more convenient, less burdensome, [and] less expensive.” Fed. R. Civ. Proc. 26(b)(2); *see also Patterson*, 281 F.3d at 681 (7th Cir.

2002) (affirming a district court's decision to prohibit the deposition of a high ranking executive); *In re Yasmin and Yaz Mktg., Sales Practices and Relevant Prods. Liab. Litig.*, 2011 WL 3759699, at *2 (S.D. Ill. Aug. 18, 2011) (prohibiting the deposition of two senior executives of Bayer).

BACKGROUND

I. Facts

Plaintiffs seek to depose the Chairman of the Board of Managing Directors of BII, Dr. Andreas Barner, and a member of the Board, Mr. Allan Hillgrove. The Board of Managing Directors oversees Boehringer Ingelheim's entire global organization, which is comprised of BI's global corporate function in Ingelheim, Germany and its affiliates around the world, including Boehringer Ingelheim Pharmaceuticals International, Inc. ("BIPI"). As Chairman of the BMD, Dr. Barner serves in a functionally equivalent role to a global CEO, making him the highest ranking officer in the entire organization. Mr. Hillgrove and the other members of the BMD rank second highest. Both officers are based in Ingelheim, Germany.

If Dr. Barner and Mr. Hillgrove are deposed, that will place a great burden on the officers themselves and on the corporation as a whole. This is particularly true for Dr. Barner, who has ultimate responsibility for oversight of every aspect of a major multinational pharmaceutical organization. Both men sit on numerous boards within the corporation and are constantly travelling among BI's various worldwide entities. Finding time to prepare and sit for a deposition will require taking time away from these important corporate oversight responsibilities. And in the particular case of Dr. Barner, there is no peer who can assume his oversight burdens when he is occupied with deposition-related tasks.

Further, Plaintiffs have already deposed--or will soon depose--approximately 40 witnesses from both BII and BIPI (collectively "BI"). These witnesses include several very high

ranking executives on both the science/medical side as well as the commercial/marketing side. On the science/medical side, these witnesses include: Dr. Christopher Corsico, the Global Head of Quality, Regulatory, Pharmacovigilance and Epidemiology and Medicine, who reports exclusively to the BMD; Dr. Klaus Dugi, the Global Head of Medicine; Dr. Klaus Viel, the Global Head of Regional Medicine and Scientific Affairs; and Dr. Jeffrey Friedman, the Global Therapeutic Head of Cardiovascular Products. On the commercial side, these senior executives include Raj Kannan and Tim Schmidt, both of whom served as the Global Brand Leader for Pradaxa; and Robert Johnson, who served as the Vice President of Sales for the entire United States. Apart from these senior executives, Plaintiffs have also deposed or will be deposing a wide range of employees who were most directly involved, on a day to day basis, in the development, safety, and marketing of Pradaxa. In addition, Defendants have produced the custodial files of each of these witnesses, as well as the files of numerous other custodians, providing Plaintiffs with tens of millions of pages of information relevant to this case.

Dr. Barner and Mr. Hillgrove are responsible for oversight of the entire organization. As such, they have been involved in Pradaxa-related issues. For example, Dr. Barner is Chair of the Pradaxa Steering Committee and Mr. Hillgrove--who was the Head of Established Markets before assuming his BMD position at the beginning of this year--has been involved in Pradaxa marketing. Their involvement, however, has not been as extensive as that of the BI executives and employees whose sole or primary responsibilities are Pradaxa-related. Thus, the many other executives and employees that have been and will be deposed in this litigation possess the same and greater knowledge about the facts underlying this litigation, and Plaintiffs will have more than ample opportunity to obtain the information necessary and relevant to this litigation from that wide swath of existing designated witnesses. For example, Plaintiffs are already scheduled

to depose at least four other members of the Pradaxa Steering Committee: Dr. Christopher Corsico, Dr. Rischke, Dr. Dugi, and Dr. Heinrich-Nols, all of whom have held a more day-to-day role with respect to Pradaxa issues than Dr. Barner.

II. Procedural Background

Defendants have not objected to any of Plaintiffs' previous requests to depose senior BI executives, willingly facilitating the depositions of witnesses like Drs. Corsico, Dugi, Viel, and Friedman, and Messrs. Kannan, Schmidt, and Johnson. Defendants have, however, informed Plaintiffs that they oppose the depositions of BMD members, and particularly of Dr. Barner. They have explained to Plaintiffs that the relevant information BMD members possess can also be obtained from the numerous BI witnesses that Defendants have already agreed to produce. They have also explained the extreme burdens that will be placed on the organization as a whole and Dr. Barner and Mr. Hillgrove as individuals if they must sit for depositions, and the great disruption that such depositions will cause given these officers' abundant and various responsibilities with respect to the corporation as a whole. Plaintiffs have been unreceptive to this position.

Both parties have attempted to reach compromise on this issue. On Defendants' side, they have offered to make Mr. Hillgrove available for deposition if Plaintiffs forgo the deposition of Dr. Barner. Defendants did not make this offer because they believe that Mr. Hillgrove possesses any unique or specialized knowledge that cannot be provided by another employee. Rather, they made the offer in the spirit of cooperation and because the deposition of Dr. Barner would be particularly disruptive to BI's overall business. Plaintiffs have made their own counter-proposals, but Plaintiffs have been unwilling to accept an agreement that does not allow them to depose both Dr. Barner and Mr. Hillgrove. After further attempts at negotiation failed, and after discussions with Plaintiffs' counsel about this motion being the appropriate

means of resolving this question, Defendants now seek a protective order. Because Defendants believe that Plaintiffs have failed to supply adequate justification for deposing either Dr. Barner or Mr. Hillgrove, Defendants seeks an order barring both depositions.

ARGUMENT

Federal Rule of Civil Procedure 26(b)(2) states that a court “must limit” discovery if a party seeks information that is “unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive.” In deciding whether discovery is appropriately restricted under this rule, the court must consider “the totality of the circumstances, weighing the value of the material sought against the burden of providing it.” *Patterson*, 281 F.3d at 681. Thus, the Seventh Circuit has affirmed a district court’s authority to deny the deposition of a high-ranking executive in a multinational corporation where the added “value of the material sought” is minimal, and “the burden of providing” the deposition is great. *Id.*; *see also Thomas v. International Business Machines*, 48 F.3d 478, 483 (10th Cir. 1995) (affirming district court’s issuance of a protective order barring the deposition of IBM’s chairman). Indeed, because a company’s most senior corporate officers typically do not “possess unique or specialized knowledge” that is unavailable from other deponents, and because the depositions of corporate officers place a tremendous burden on the company, district courts routinely deny such depositions. *In re Yasmin and Yaz*, 2011 WL 3759699, at *2; *Craig & Landreth, Inc. v. Mazda Motor of Am., Inc.*, No. 4:07-cv-134-SEB-WGH, 2009 WL 103650, at *2 (S.D.Ind. Jan. 12, 2009) (declining to compel deposition of high-ranking corporate official); *Berning*, 242 F.R.D. 510, 513 (N.D. Ind. 2007) (same).¹

¹ *See also, e.g., Zouroufie v. Lance, Inc.*, No. 07-2016-B/P, 2008 WL 1767729, at *2 (W.D. Tenn. Apr. 15, 2008) (granting protective order barring CEO’s deposition where plaintiff “ha[d] not sufficiently demonstrated that the CEO] has unique personal knowledge of the matters in this (continued...)”).

Accordingly, the depositions of BMD members, and in particular Dr. Barner, should be prohibited because the information they can provide is obtainable from other witnesses, while the burden of their depositions would be great. At a minimum, Plaintiffs should not be permitted to depose either of the officers until they have completed the depositions of the other BI employee witnesses, and pointed to specific information that they have been unable to obtain from these depositions and other less intrusive means of discovery. See *Baine v. General Motors Corp.*, 141 F.R.D. 332, 335 (M.D. Ala. 1991). At that point, any deposition of either officer should be subject to more limited time and expressly restricted to those issues concerning which Dr. Barner or Mr. Hillgrove has information beyond that which has been supplied during the depositions of the other BI employees.

I. Dr. Barner and Mr. Hillgrove do not possess “unique or specialized knowledge” because other employees possess the same or better information regarding Pradaxa.

As this Court has explained, district courts “may preclude the depositions of high-ranking executives if the witness does not possess unique or specialized knowledge relevant to the litigation.” *In re Yazmin and Yaz*, 2011 WL 3759699, at *2. Rule 26(b) specifically contemplates that discovery must be limited where the same information is “obtainable from some other source that is more convenient, less burdensome, or less expensive.” For that reason, a key consideration in determining whether a high ranking executive possesses “unique or specialized knowledge” is whether the same or better information may be provided by other

lawsuit . . . nor ha[d] he demonstrated that he ha[d] attempted to first obtain this information through less burdensome means, such as by taking depositions of lower level employees”); *Reif v. CNA*, 248 F.R.D. 448, 451 (E.D. Pa. 2008) (refusing to permit CEO’s deposition); *Simon v. Pronational Ins. Co.*, No. 07-60757, 2007 WL 4893478, at *1--2 (S.D. Fla. Dec. 13, 2007) (same); *Evans v. Allstate Ins. Co.*, 216 F.R.D. 515, 519 (N.D. Okla. 2003) (same); *Filetech, S.A v. France Telecom, S.A.*, No. 95 CIV 1848(CSH), 1999 WL 92517, at *2 (S.D.N.Y. Feb. 17, 1999) (refusing to permit the deposition of corporation’s foreign chairman); *Baine v. General Motors Corp.*, 141 F.R.D. 332, 335 (M.D. Ala. 1991) (same).

employee witnesses. For example, the Tenth Circuit, in affirming the issuance of a protective order blocking the deposition of IBM's chairman, observed that plaintiff had failed "to demonstrate that the information she seeks to obtain from [the CEO] could not be gathered from other IBM personnel, for whom a deposition might have been less burdensome." *Thomas*, 48 F.3d at 483; *see also, e.g., Reif v. CNA*, 248 F.R.D. 448, 453 (E.D. Pa. 2008) (finding that, in order to depose a CEO, plaintiffs "must demonstrate the information [they seek] can only be obtained from [the CEO]," rather than from other employee witnesses); *Evans v. Allstate Ins. Co.*, 216 F.R.D. 515, 519 (N.D. Okla. 2003) (denying depositions of senior corporate officers where "the information can alternately be obtained from other sources without deposing these 'apex' officers"); *Filetech, S.A v. France Telecom, S.A.*, No. 95 CIV 1848(CSH), 1999 WL 92517, at *2 (S.D.N.Y. Feb. 17, 1999) (granting protective order against deposition of French company chairman where "lesser France Telecom employees are available to furnish information" on the "narrow" matter at issue).

Thus, in *Yaz*, this Court denied a motion to compel the depositions of two of defendants' senior executives after finding that "the plaintiffs have already deposed (and are scheduled to depose) numerous senior-level employees intimately familiar with the design, development, safety, marketing, and distribution of the subject drugs." *In re Yazmin and Yaz*, 2011 WL 3759699 at *2; *see also Patterson*, 281 F.3d at 681 (observing that "the district judge allowed [plaintiff] to depose" a director and "two additional employees" with intimate knowledge of plaintiff's claims, before upholding the court's decision to preclude the deposition of a high ranking official). In this case, too, Plaintiffs have already deposed or will depose numerous senior-level employees that are intimately familiar with--among other things--the "design, development, safety, marketing, and distribution" of Pradaxa. The following are the some of the

most notable examples:

Medical/Clinical/Safety: Plaintiffs have deposed or will be deposing a broad range of BI employees with direct knowledge about the scientific issues surrounding the medical, clinical, regulatory, and safety aspects of Pradaxa. In addition to the senior medical executives discussed above (Dr. Corsico, Dr. Dugi, Dr. Viel, and Dr. Friedman), these employees include:

- **Paul Reilly**: Dr. Reilly is the Clinical Program Leader for Cardiovascular Medicine with primary day to day responsibility for overseeing the pivotal clinical trial for Pradaxa, the RE-LY trial.
- **Jeanne Varrone**: Dr. Varrone is now the Vice President for Clinical Research. She was previously the Trial Clinical Monitor for the RE-LY trial, and had responsibility for its oversight and monitoring.
- **Susan Wang**: Dr. Wang is a Senior Associate Director in Statistics, she served as the lead statistician for the RE-LY trial and had primary responsibility for the trial's statistical design and analyses.
- **John Smith**: Dr. Smith is the Senior Vice President for Clinical Development and Medical Affairs with primary responsibility for oversight of the global strategy for Pradaxa, including the determination of what clinical studies should be undertaken to manage the drug throughout its patent life.
- **Janet Schnee**: Dr. Schnee is the Executive Director of Cardiovascular Medical Affairs with primary responsibility for facilitating physician information and education regarding Pradaxa and Pradaxa-related issues.
- **Andreas Clemens**: Dr. Clemens is the Medical Team Leader for Pradaxa. He is involved in analyzing RE-LY results and advising Marketing with respect to all medical issues.
- **Martina Brückmann**: Dr. Brückmann is the Medical Advisor for Pradaxa who is responsible for analyzing RE-LY results and publications regarding dabigatran.
- **Jutta Heinrich-Nols**: Dr. Heinrich-Nols is the former International Project Manager for Pradaxa, with direct involvement in the coordination of Pradaxa efforts between all departments of BI.
- **Peter Zilles**: Dr. Zilles is the Senior Risk Management Physician for Pradaxa. He has direct responsibility for handling post-marketing safety evaluation for Pradaxa.
- **Sonny Cornejo**: Dr. Cornejo is U.S. Risk Management Physician for Pradaxa and has a similar post-marketing safety evaluation role for Pradaxa.

- **James Kotsanos**: Dr. Kotsanos was the former Global Vice President of Pharmacovigilance and has responsibility for the processing of post-marketing safety reports.
- **Michelle Kliewer**: Ms. Kliewer, the Director of Drug Regulatory Affairs, possesses comprehensive information with respect to BI's interactions with the Food and Drug Administration concerning safety, as she was the FDA's primary contact.
- **Ralf Rischke**: Dr. Rischke is the head of a product group within the Global Regulatory Affairs department, with responsibility for various regulatory issues concerning Pradaxa.

Commercial/Marketing: Numerous BII and BIPI witnesses also possess intimate familiarity with the issues surrounding the marketing, sales, and promotion of Pradaxa. Besides the senior marketing executives described above (Mr. Kannan, Mr. Schmidt, and Mr. Johnson), such witnesses include:

- **Wa'el Hashad**: Mr. Hashad served as the Head of U.S. Cardiovascular Marketing, supervising Pradaxa's launch in the United States.
- **William Ragatz**: Mr. Ragatz was the Pradaxa brand team leader in the United States until September of 2012, with day to day responsibility for the drug's marketing in the United States.
- **Timothy Ryan**: Mr. Ryan was the Executive Director of Prescription Medicines Training and Development with direct responsibility for aspects of Pradaxa's sales efforts.
- **Timothy King**: Mr. King, the Director of Marketing on the United States Pradaxa brand team, with direct responsibility for marketing Pradaxa to institutions and insurers.
- **Laszlo Szanka**: Mr. Szanka is a former Director of Marketing who was responsible for all marketing materials used with health care providers.
- **Dan deLannoy**: Mr. deLannoy is an Associate Director on the Pradaxa Brand Team, with direct responsibility for marketing Pradaxa to health care providers.
- **Paula Palmer**: Ms. Palmer is an Associate Director of Marketing for Pradaxa. She is responsible for direct-to-consumer marketing for Pradaxa.
- **Mary Sullivan**: Ms. Sullivan is the Executive Director of Advertising and Promotion within the Drug Regulatory Affairs department. She oversees BI's compliance with FDA regulations relating to advertising and promotions.

As these lists indicate, Defendants have worked with Plaintiffs to ensure that they have

access to the BII and BIPI witnesses with the greatest familiarity and understanding of the facts underlying this case. For this reason, relevant information provided through the depositions of the Chairman and Members of the BMD will inevitably be duplicative and cumulative of the information that is already available to Plaintiffs through other means. *See, e.g., Reif v. CNA*, 248 F.R.D. 448 (denying deposition of CEO where plaintiff had not demonstrated that information was unavailable from other employees).

Indeed, in the discussions leading up to this motion, Plaintiffs have alleged that they need to take the depositions of Dr. Barner and Mr. Hillgrove primarily because Dr. Barner chaired a Pradaxa Steering Committee that oversaw RE-LY, and because Mr. Hillgrove was involved in marketing oversight for Pradaxa. But, as detailed above, BII and BIPI have already produced or agreed to produce numerous witnesses--such as Paul Reilly and Jeanne Varrone--who are more familiar with the clinical trials in general and RE-LY issues in particular. Plaintiffs are also scheduled to depose four other participants in the Pradaxa Steering Committee who, in addition to their strategy and leadership roles, are more acquainted with the day to day issues involving Pradaxa. Similarly, while Mr. Hillgrove had involvement in Pradaxa marketing, the many marketing witnesses BII has produced or agreed to produce possess the same or better information with respect to Pradaxa's marketing efforts. It therefore cannot be said that either Dr. Barner or Mr. Hillgrove have "unique or specialized knowledge" that can justify their depositions. *See In re Yazmin and Yaz*, 2011 WL 3759699 at *2. By very definition, knowledge is not "unique" or "special" when it is also held by other deponents.

II. Deposing Dr. Barner and Mr. Hillgrove would be unduly burdensome.

As the Seventh Circuit has explained, requiring the deposition of a "high ranking executive in a multinational corporation" is "quite costly and burdensome." *Patterson*, 281 F.3d at 682. It is well-established that "permitting unfettered discovery of corporate executives would

threaten disruption of their business and could serve as a potent tool for harassment in litigation.” *Consol. Rail Corp. v. Primary Indus. Corp.*, 92 CIV. 4927 (PNL), 1993 WL 364471 (S.D.N.Y. Sept. 10, 1993); *see also, e.g., Berning v. UAW Local 2209*, 242 F.R.D. 510, 513 (N.D. Ind. 2007) (quoting same); *Mulvey v. Chrysler Corp.*, 106 F.R.D. 364, 366 (D.R.I. 1985) (the CEO of Chrysler, Lee Iacocca, “is a singularly unique and important individual who can be easily subjected to unwarranted harassment and abuse. He has a right to be protected, and the courts have a duty to recognize his vulnerability.”).

For example, in *Berning*, the court denied the deposition of the head of the United Auto Workers, citing the great burden such a deposition would entail. The *Berning* court explained that “[a]s the international president of the UAW, an organization representing 1.3 million members, [the president] oversees more than six hundred full-time UAW staff members who bargain contracts, handle grievances, and conduct business with nearly one thousand different employers in a variety of industries across the United States, Canada, and Puerto Rico.” 242 F.R.D. at 513. The burden with respect to Dr. Barner and Mr. Hillgrove is on a much greater scale: As the officers of a global pharmaceutical corporation, Dr. Barner and Mr. Hillgrove oversee more than 46,000 BI employees (with approximately 24,000 in Germany and the United States alone) involved in every aspect of the development, testing, safety, regulation, and marketing of pharmaceuticals in Europe, the United States, Asia, and many other areas of the world. Fulfilling their oversight responsibilities requires, among other things, sitting on multiple boards and engaging in constant international travel. Given these duties, it would be extremely demanding for Dr. Barner and Mr. Hillgrove to set aside sufficient time to prepare for and participate in a deposition in this litigation, and a requirement that they do so would almost certainly disrupt BI’s business. In Dr. Barner’s case, these difficulties are even greater as he is

“a singularly unique and important individual” at the head of the corporation, which both enhances the burden of being deposed and enhances the risk that he will be subjected to “unwarranted harassment and abuse.” *See Mulvey*, 106 F.R.D. at 366.

III. The totality of the circumstances dictates that the depositions of Dr. Barner and Mr. Hillgrove should be barred.

Consideration of the “totality of the circumstances” leads to the inevitable conclusion that Plaintiffs’ deposition requests are unwarranted. The miniscule chance that the depositions of Dr. Barner or Mr. Hillgrove will produce new information is clearly outweighed by the indisputable fact that the depositions will impose a tremendous burden on the Defendants *See Patterson*, 281 F.3d at 681. Given Rule 26(b)(2)’s explicit restriction on discovery that is “unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive,” the depositions of Dr. Barner and Mr. Hillgrove cannot be permitted.

At a minimum, Plaintiffs should be required to withdraw their deposition requests until they have exhausted other less intrusive means of discovery. *See Baine v. General Motors Corp.*, 141 F.R.D. 332, 335 (M.D. Ala. 1991) (granting protective order against deposition of one of General Motor’s vice presidents when other discovery devices, including depositions of knowledgeable lower level employees, and corporate designee “ha[d] not yet been exhausted”). Specifically, because the depositions of the other BI employees are virtually certain to produce the relevant information that Plaintiffs seek, those depositions should be completed before the court entertains a request to depose Dr. Barner or Mr. Hillgrove . *Id.* Further, given the extreme burden that preparing and sitting for a deposition will impose, Plaintiffs should also be required to use interrogatories to solicit any information they claim to need from Dr. Barner and Mr. Hillgrove. *See Mulvey*, 106 F.R.D. at 366 (requiring that Plaintiffs propound written

interrogatories to a CEO, and permitting a deposition request only if “the answers are shown to be insufficient”). In the extremely unlikely event that these other means of discovery ultimately prove insufficient, any future deposition of either officer should be tightly restricted in time and strictly limited to those particular issues concerning which Plaintiffs have not already secured information.

CONCLUSION

For the foregoing reasons, BII respectfully requests that the Court enter an order prohibiting the deposition of Dr. Barner and Mr. Hillgrove.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 26(c)(1)

Pursuant to Federal Rule of Civil Procedure 26(c)(1), I hereby certify that I have in good faith conferred with Plaintiffs' counsel in an effort to resolve this dispute without court action.

/s/ Beth Rose _____
Beth Rose

CERTIFICATE OF SERVICE

Pursuant to Local Rule 5.1 and Case Management Order No. 1, Paragraph 5, I hereby certify that, on October 22, 2013, a copy of the foregoing document was filed through the Court's ECF system. Notice of this filing will be sent electronically to registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Beth Rose _____
Beth Rose