IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In Re: Tepezza Marketing, Sales Practices, and Products Liability Litigation **THIS DOCUMENT RELATES TO: ALL CASES**	Case No. 1:23-cv-03568 MDL No. 3079 Judge Thomas M. Durkin

Horizon's Submission Regarding Bellwether Dispositive Motion Briefing Protocol[1]

At the hearing before the Judicial Panel on Multidistrict Litigation prior to the centralization of the cases into MDL No. 3079, Plaintiffs argued that preemption was one of the common issues that "cuts across every case." (JPML Transcript of 5/25/23 Hearing, Dkt. No. 61, MDL No. 3079, p. 4, line 22). Plaintiffs asserted that "the issue of when newly acquired information was present was a factual issue that's going to apply – it can be sort of set in stone and applied to all of the cases." (*Id.* at lines 22-25). With respect to newly acquired information and preemption, Plaintiffs claimed that it was "a bright line issue" and the "most efficient way to draw that is having one judge in one court do so." (*Id.* at p. 13, lines 10, 13-14).

Further, in their briefing to the Panel, Plaintiffs argued "the 'date' Defendant obtained 'newly acquired information' requiring it effectuate a CBE *is uniform for all cases*. In other words, that 'fact' (i.e., the date) is a fixed moment in time." (*Weibel, et al.* Response and Memorandum in Support of Consolidation, Dkt. No. 15, April 7, 2023, p. 3) (emphasis in original). Plaintiffs confirmed that briefing this issue was important so "*that one* Court can identify the moment in time Horizon obtained "newly acquired information." (*Id.*). Plaintiffs have also agreed that the

[1] As this Court previously ruled that resolution of the design defect preemption arguments should be determined based upon the *Williams* briefing, dismissal of Plaintiffs' design defect claims based on preemption is not addressed in this submission.

only variation in the application of the preemption principles is the Plaintiffs' respective infusion dates. (*Pledger, et al.* Response and Memorandum in Support of Consolidation, Dkt. No. 16, April 12, 2023, p. 7). Preemption was one of the main catalysts in establishing MDL No. 3079; the Panel cited concern regarding potential inefficiencies and inconsistent rulings in having multiple judges resolve Horizon's cross-cutting, common preemption arguments regarding TEPEZZA®. (June 2, 2023 Transfer Order, Dkt. No. 1). Nothing has changed.

Resolution of Preemption Issues

Deciding the threshold issue of preemption is consistent with the statutory framework, as one of the benefits of the MDL process is resolution of common issues centralized in coordinated proceedings. *See* 28 U.S.C. § 1407(a) (2012). The importance of identifying and resolving common legal issues is reiterated in the Manual for Complex Litigation. The Manual counsels that "[i]dentifying the issues—and the governing statutory or decisional law—is critical to developing a plan for efficiently resolving complex tort litigation." Manual for Complex Litigation § 22.634. And MDL judges have significant discretion in crafting procedures to decide issues of law that can be decided by motions to dismiss on the legal insufficiencies of the claim. *Id.* §11.32.

For example, Judge Rosenstengel in the Southern District of Illinois concluded that resolution of Rule 12 motions at the outset of MDL No. 3036, rather than at the bellwether stage as the Plaintiffs argued, was the appropriate path. Plaintiffs in MDL 3036 alleged that they developed Parkinson's Disease as a result of exposure to Paraquat, the active ingredient in herbicide products sold in the United States since the 1960s. Defendants filed motions to dismiss Plaintiffs' complaints based upon statutes of limitation and repose, failure to state a public nuisance claim, and state-specific law issues. Plaintiffs argued the motions to dismiss violated the fundamental purpose of an MDL related to "efficient, just, and expeditious" resolution of the cases,

that the motions required a fact-intensive review and, as the Plaintiffs argue here, consideration was more appropriate at the bellwether stage. Judge Rosenstengel held:

> The purpose of an MDL is multifold and includes avoidance of repetitive discovery compliance, elimination of inconsistent pretrial rulings, and conservation of resources of both the judiciary and litigants." *Casey v. Denton*, 2018 WL 4205153, at *1 (S.D. Ill. Sept. 4, 2018). In accomplishing these goals, however, an MDL court must adhere to the Federal Rules of Civil Procedure. As noted by the Sixth Circuit Court of Appeals, which the undersigned finds persuasive, **"Rule 12(b) states that 'a party may assert' the defenses enumerated therein 'by motion,' which means that the district court may not refuse to adjudicate motions properly filed under that Rule."** *In re Nat'l Prescription Opiate Litig*., 956 F. 3d 838, 846 (6th Cir. 2020). In *In re Nat'l Prescription Opiate Litig*., the court held that the district court erred in thinking "it had authority to disregard the Rules' requirements…in favor or enhancing the efficiency of the MDL as a whole." *Id*. at 844.

In re Paraquat Products Liability Litigation, 2021 WL 9793339 (S.D. Ill. Nov. 10, 2021).[2] (emphasis supplied).

Similarly, Judge Cote concluded that Rule 12 Motion practice was appropriate at the outset of MDL No. 2754, *In re: Eliquis (Apixaban) Products Liability Litigation*. Prior to centralization of the cases, the defendants had filed motions to dismiss in various federal courts. Judge Cote, who was overseeing seventeen Eliquis cases in the Southern District of New York, ordered that the parties identify a motion appropriate for early resolution in the event that the JPML denied the petition. She advised that the parties would be given an opportunity to explain why discovery should not commence pending resolution of any remaining motions to dismiss.[3] In December 2016, Judge Cote dismissed Plaintiffs' design defect claims, which alleged defendants had a pre-approval duty to submit a differently designed drug for FDA approval and that defendants should never have sold the FDA-approved formation of Eliquis as preempted, confirming that defendants

[2] Following Rule 12 briefing, Judge Rosenstengel ultimately dismissed Plaintiffs' public nuisance claims. *See In re Paraquat Products Liability Litigation*, 2022 WL 451898 (S.D. Ill. Feb. 14, 2022).
[3] *Utts v. Bristol-Myers Squibb Co*., Case No. 16-CV-05668, November 21, 2016 Order, Dkt. No. 22.

had no ability to alter the composition of Eliquis without prior approval of the FDA.[4] However, Judge Cote permitted Plaintiffs leave to amend the remaining claims, including their failure to warn claims.

Following centralization of the *In re: Eliquis* cases before her in MDL No. 2754 in February 2017, Judge Cote permitted the plaintiffs to amend their complaint for a second time. She determined that the best procedure for the MDL was to allow briefing of the motion to dismiss the second amended complaint and, following that ruling, proceed with discovery if the motion was denied or have the other plaintiffs show cause why their similar complaints should not be dismissed.[5] Ultimately, Judge Cote also dismissed plaintiffs' failure to warn claims as preempted.[6]

Judge Cote's reasoning tracks what this Court has already recognized with respect to addressing preemption of the design defect claims. Following consultation with the parties, the Court concluded at the July 31, 2023 hearing that preemption of design defect claims is a discrete issue, which could be decided by the Court based upon the briefing in the *Williams* case. (MDL No. 3079 Transcript of 7/31/23 Hearing, Dkt. No.19, p. 41, lines 10-24 and p. 46, lines 8-11). Likewise, preemption of Plaintiffs' failure to warn claims and application of that ruling to all Plaintiffs' respective infusion dates is another common legal issue Horizon has been attempting to resolve since Plaintiffs filed the first product liability case over one year ago.

Horizon's Bellwether Dispositive Motion Protocol

To effectuate this common goal of identifying the bright line of when Horizon had "newly acquired information," Horizon has proposed that both sides simultaneously select five Plaintiffs who received treatment across a spectrum of time for Rule 12 briefing. Specifically, both sides

[4] *See Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185-186 (S.D.N.Y. 2016).
[5] *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 702-703. (2nd Cir. 2019).
[6] *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644 (S.D.N.Y. 2017), aff'd by *Gibbons v. Bristol-Myers Squibb Co.*, 919 F. 3d 699 (2nd Cir. 2019).

would select one case with infusion dates during 2020, two cases with infusion dates during 2021, and two cases with infusion dates during 2022.[7] Horizon will then file motions to dismiss in each of these cases addressing both failure to warn as preempted by federal law and failure to properly plead such claims under applicable state product liability law.[8]

If the preemption motions are granted, resulting in dismissal of failure to warn claims of Plaintiffs infused before a date certain, for example, then it will be merely an administrative matter of applying that ruling to other cases with similar, or earlier, infusion dates that are pending before this Court or in Plaintiffs' stable of unfiled cases. The remaining bellwether Plaintiffs will proceed to the bellwether discovery process.

As noted, although the focus of the dispositive motion practice will be preemption of Plaintiffs' failure to warn claims, Horizon also intends to address the viability of Plaintiffs' pleadings under applicable state law. Horizon recognizes that many deficiencies in Plaintiffs' cut and paste complaints could be cured by amendment and does not desire to waste the Court's time or resources. However, Horizon has repeatedly requested that Plaintiffs correct the pleading deficiencies, and Plaintiffs have refused, advising that they intend to stand on the pleadings as filed. The *Williams* briefing reviewed by this Court for resolution of whether the design defect claims are preempted is an example of Horizon's predicament. Specifically, the *Williams* complaint contains inconsistent and presumably inaccurate treatment dates, and an assertion of

[7] If both sides select the same case or cases, that will reduce the total number of cases to be briefed.
[8] MDL judges may dispose of an entire litigation on a motion to dismiss ruling. *See, e.g., In re: Whole Foods Market, Inc.*, 163 F. Supp. 3d 385 (W.D. Tex. 2016) (dismissing all claims as preempted by federal law). *See also In re Zappos.com, Inc.*, 108 F. Supp. 3d 949 (D. Nev. 2015) (dismissing all claims for lack of standing); *In re Fruit Juice Products Marketing and Sales Practices Litig.*, 831 F. Supp. 2d 507, 509 (D. Mass. 2011) (dismissing all claims as Plaintiffs lacked standing for failing to allege an injury-in-fact or an economic injury); *In re Epogen and Aranesp Off-Label Marketing and Sales Pracs. Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) (dismissing all MDL claims because the lawsuits constitute an improper attempt to "shoehorn allegations that Defendants have engaged in off-label promotion in violation of the FDCA into RICO and state consumer fraud causes of action").

strict product liability claims which are not recognized under Virginia law. Despite awareness of these defects, and footnotes reserving the right to cure them through amendment under Rule 15(a), Plaintiffs have failed to do so. As such, Horizon must address similar deficiencies in other Complaints in its Rule 12 motions at the outset of this MDL.

PLC's Bellwether Protocol

Conversely, PLC has proposed a Bellwether Protocol ("PLC Protocol") that does not permit Horizon to file dispositive motions on the threshold preemption issue (or any issue) until late December 2023.[9] Horizon objects to the PLC Protocol for a myriad of reasons, but primarily because it delays and complicates likely dispositive issues by prioritizing potentially unnecessary fact discovery. Horizon has sought dismissal of these cases as preempted since the outset of this litigation in August 2022. It is fundamentally unfair to burden Horizon with expansive and expensive anticipated discovery requests before deciding the "bright line" – which Plaintiffs repeatedly admit exists – triggering the CBE process in relation to Plaintiffs' treatment dates. Moreover, proceeding with discovery for these Plaintiffs, before resolving the viability of their claims, defeats the purposes of efficiency mandated by the MDL statute and the Manual for Complex Litigation as some or all claims could be dismissed.

Further, PLC's assertion at the July 28, 2023 hearing that this Court should adopt a Bellwether Protocol ***before*** Rule 12 motion practice because Judge Pallmeyer did so in *In re: Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation*, MDL No. 3026, N.D. Ill. Case No. 1:22-cv-00071 is flawed. Judge Pallmeyer did not address Rule 12 motions at the outset because two early cases progressed to the dispositive motion stage and had been decided before the MDL was certified. Specifically, the federal district court in Connecticut had previously

[9] Although styled as a discovery bellwether protocol, the different versions sent by Plaintiffs' counsel demonstrate the true intent for the document to serve as a bellwether trial protocol.

considered, and denied as premature, the defendants' preemption argument on a motion to dismiss. *See Ferry v. Mead Johnson & Co., et. al.*, 514 F. Supp. 3d 418 (D. Conn Jan. 25, 2021).[10] The court did so because it was confronting an issue of first impression – not present in this MDL — and even then said it was "a close question":

> At this motion to dismiss stage, it is a close question whether federal law preempts Ferry's claim for design defect based on the presence of cow milk in the Defendants' exempt infant formulas. I am aware of no court that has held that the IFA (Infant Formula Act) impliedly preempts state-law product liability claims regarding infant formula, and it seems that no court has even addressed that precise issue...The most relevant precedent regards impossibility preemption of state law product liability claims against generic and brand-name drug manufacturers. **But the regulatory scheme applicable to drug manufacturers is not the same as the regulatory scheme applicable to manufacturers of infant formulas, which are food**. Thus, I do not have the benefit of prior courts' discussions regarding this issue of apparent first impression…As a result, I am left with several questions regarding the relevant regulatory regime that prevent me from granting the Defendants' motions to dismiss on this ground.[11]

Ferry, 514 F. Supp. 3d at 338, 440 (emphasis supplied).

Thus, in the infant formula cases, the defendants did not ask for a ruling on preemption before the bellwether discovery process began, presumably because they were coming into the MDL with two orders of record denying their Rule 12 motions as premature. In sum, the infant formula cases are distinguishable because they involve an FDA regulatory scheme applicable to food, not drugs; the preemption motions raised issues of first impression concerning application of the Infant Formula Act, and as a result were denied as "premature"; and the parties therefore agreed to proceed with the bellwether process before Rule 12 motion practice. None of those factors are present here, and the PLC's attempt at comparing these MDLs is without merit.

[10] The Court in *Sanchez v. Abbott*, 6:21 cv 00502 RBD EJK (MD Fla Aug. 2, 2021) relied on *Ferry* to hold that dismissal of the complaint base on preemption was "premature."

[11] The Court in *Ferry* granted the defendants' motions to dismiss claims for breach of warranty and intentional and negligent misrepresentation. 514 F. Supp.3d at 451.

Finally, the PLC Protocol requires Horizon to identify bellwether cases for trial based upon six questions in the proposed Plaintiff Profile Form ("PPF") that the Plaintiffs need only "substantially complete" and medical records (assuming such records could even be collected and reviewed within the compressed time parameters suggested). The Manual for Complex Litigation states that if bellwether cases are to "produce reliable information about other mass tort cases, the specific Plaintiffs and their claims should be representative of the range of cases." *See* §22.315. Yet, nothing in the proposed PPF addresses pre-existing medical conditions, other medications prescribed to each Plaintiff, Plaintiff's work history, premorbid hearing loss or risk factors, disability claims, or provides information regarding each Plaintiff's primary care physician. From this limited information, it would be virtually impossible to identify a representative range of cases, which both frustrates the MDL process and creates unfairness to Horizon. Additionally, once the bellwether Plaintiffs are selected, there are no provisions in the PLC's Protocol for discovery on any of these issues, as the only depositions permitted would be of the physician who prescribed TEPEZZA® and the physician who diagnosed the claimed injury.

Should this Court agree with the Plaintiffs that the Bellwether Discovery Protocol must proceed, Horizon agrees to meet and confer with Plaintiffs regarding the limitations of and omissions in the PLC Protocol.[12] Specifically, Horizon will need to address the deficiencies noted above to ensure that the pool of cases is truly representative of the litigation, rather than simply cases that present the best opportunity for success at trial based upon Plaintiffs' investigation of their cases.

[12] By agreeing to participate in the Bellwether Discovery Protocol if ordered by the Court, Horizon specifically preserves and does not waive any rights to file subsequent motions to dismiss or motion to transfer based on improper venue, *forum non conveniens*, lack of personal jurisdiction, the requirements of 28 U.S.C. §1407, *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998), or any defense or objection.

Conclusion

Horizon respectfully requests this Court resolve the cross-cutting preemption motion to dismiss Plaintiffs' failure to warn claims by identifying the bright line moment in time that the Court believes, based upon the allegations in the complaints, that Horizon had "newly acquired information sufficient to trigger the CBE process. And this decision should occur before Horizon is exposed to broad and potentially unwarranted discovery.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on August 21, 2023, a copy of the foregoing Submission Regarding Bellwether Dispositive Motion Briefing Protocol was filed using the CM/ECF filing system, which will send notice of electronic filing to all parties appearing on the Court's ECF service list.

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