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	No. 23 C 3568 MDL No. 3079 Judge Thomas M. Durkin Magistrate Judge M. David Weisman

THE PLC'S NARRATIVE SUBMISSION FOR THE DECEMBER 4, 2023, DISCOVERY CONFERENCE

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On October 19, 2023, the Parties appeared before this Court for an initial Case Management Discovery Conference following Judge Durkin's referral. Following the hearing, this Court entered a Minute Order directing the parties to: "[m]eet and confer and conduct preliminary runs of search terms based on proposed search terms." ECF No. 66. Before that conference, the PLC requested that Horizon provide hit reports for the proposed search terms, but Horizon would not agree. Instead of complying with the Court's directive, Horizon deemed more than two dozen terms "not relevant" and did not run hit reports for them. For the terms it *did* run, it refused to eliminate email "footers" or produce hit reports that included email threading, leading to hit reports that were artificially inflated making any analysis essentially useless.[1] As a result, the hit reports Horizon supplied (as detailed below) provided limited guidance on the actual number of documents the PLC's proposed search terms might produce.

In its October 19, 2023, Minute Order, the Court further directed the Parties to supply, "a narrative from each side regarding status of discussions on ESI search terms and protocols, hit reports, and any proposed modification of search terms based on hit reports, among other issues the parties wish to raise." *Id.* The PLC now supplies this narrative submission in advance of the December 4 Discovery

[1] On November 13, 2023, after numerous email exchanges, Horizon finally agreed to conduct email threading; a request that is rudimentary to determining an accurate hit report. *See Email from Lori Hammond to Tim Becker* (attached as Ex. 1). And during the final meet and confer before this filing was due, Horizon *finally* agreed to run all proposed search terms. Horizon anticipates the results will be available the week of November 20, 2023. The PLC anticipates the resulting data will provide the information it needs to narrow the search terms.

Conference outlining issues that remain unresolved. In addition to the issues addressed in the PLC's submission on ESI Discovery (ECF No. 34), the PLC intends to discuss: 1) the methodology Defendant intends to employ to collect custodial and non-custodial files (along with an overview of the data Defendant supplied to date); 2) establishing a presumptive custodial cap for current and former Horizon employees with relevant information; and 3) implementing a production protocol to facilitate the timely and efficient production of documents in this case.

BACKGROUND

From the beginning of this MDL, the PLC advocated for the timely initiation and completion of discovery, including obtaining ESI from Defendant's current and former employees. Over the past several months, the PLC attempted to negotiate with Defendant to reach agreement on an ESI search-term protocol, proposed search terms, the total number of ESI custodians, and a schedule governing the production of documents. Those negotiations were largely unsuccessful.

A. A host of ESI issues require resolution by this Court.

1. General outstanding ESI issues

On August 21, 2023, the PLC filed *Plaintiffs' Positions Regarding the Protocol for Electronically Stored Information*. ECF No. 34 (ESI Brief). The PLC's ESI Brief outlined four areas of dispute: 1) transparency of the discovery process (*i.e.*, the methodology Defendant intends to employ to collect and review documents); 2) production of hyper-linked documents embedded in emails; 3) proportionality of discovery directed to individual plaintiffs; and 4) Defendant's intention to conduct multiple culling methods of documents (*i.e.*, its intention to perform a

"responsiveness" review after culling the documents through agreed search terms). Given the PLC anticipates discussing these issues at the Discovery Conference, the PLC incorporates the ESI Brief by reference. *Id.*

Given the efforts to reach an agreed-to search protocol, the issue regarding multiple culling methods requires additional discussion. Specifically, Horizon seeks to use search terms to limit the scope of the production, and then re-review the documents to assess whether any individual document is "relevant." The PLC, in turn, requested Horizon run negotiated search terms and produce all documents that "hit" on a term. This is because search terms, by their very nature, subsume "relevant" words targeted towards "relevant" documents.

Stated differently, search terms are expressly designed to identify "relevant" documents. Beyond that, search terms *benefit* a defendant. Specifically, search terms allow a defendant to run searches across a database as opposed to conducting a document-by-document review. Invariably, search terms reflect a trade-off between the parties to efficiently advance the litigation—*i.e.*, the plaintiff agrees to a subset of documents that encompass the universe of *all* potentially relevant documents in exchange for the receipt of *all* documents that land upon a "hit" document.[2] *See generally Shumway v. Wright,* No. 4:19-cv-00058-DN-PK, 2019 WL 8137128, at * 3, (D. Utah, Oct. 25, 2019) (recognizing search terms are both over- and underinclusive); *William A. Gross Const. Assoc., Inc. v. Am. Mfg. Mut. Ins. Co.,* 256 F.R.D. 134, 135–

[2] The PLC informed Horizon that its request did not preclude Horizon from removing documents subsumed within the attorney-client or work product privileges. To date, Horizon has refused to run search terms without a secondary "relevance" review.

36 (S.D.N.Y 2009) (noting because search terms invariably miss relevant documents, parties must work collaboratively to create ESI protocol).

It is for this reason that courts view search terms differently than traditional document-by-document Rule 34 productions. *Outzen v. Kapsch Trafficcom USA, Inc.,* is instructive. In *Outzen*, the defendant utilized search terms to produce "hundreds of thousands of documents." No. 1:20-cv-01286-TWP-MJD, 2021 WL 3673786, at *6 (Aug. 19, 2012, S.D. Ind.). Upon receipt, the plaintiff argued Rule 34 required the defendant to identify which documents were responsive to which request. The court disagreed, holding:

> [The search term process] is almost certainly not perfect, in that there are likely some relevant documents that were not captured by the searches and clearly some irrelevant documents that were, but the alternative would be for Plaintiffs—not Kapsch—to cull through *all* of the numerous custodians' files in search of the relevant files, as they would have had to have done if the files had only been maintained on paper.

Id. at *7 (emphasis in original). Although the case arose in the context of a party *seeking* to compel a responsiveness review—as opposed to the PLC's position seeking to preclude a responsiveness review—the underlying analysis is relevant in that it outlines the choice Horizon faces: namely, Horizon, like the *Outzen* plaintiffs, may either take the benefit of a search-term process, recognizing the process will be simultaneously over- and underinclusive, or alternatively, review each-and-every document in each-and-every custodians' file for their "responsiveness" to future Rule 34 document requests. Given Horizon *elected* to utilize search terms, it is compelled to produce the non-privileged documents identified by the search terms. *See Raab v.*

Wendel, No. 16-CV-1396, 2018 WL 11408277 at *5 (Feb. 15, 2018, E.D. Wis.) (holding plaintiff not required to conduct responsiveness review where parties agreed to use search terms).

2. Horizon failed to run search terms against all terms the PLC proposed, broke the terms into separate buckets of "agreed-to" and "overly broad," and supplied "hit reports" that provide little insight into the actual number of documents.

On August 27, 2023, the PLC supplied Horizon with its initial search-term list. The list included 278 individual terms, many of which were appended to modifiers. *See* PLC Proposed Search Terms (attached as Ex. 2). Horizon immediately balked at the list contending the number of terms was unreasonable. To put this in perspective, the number of terms the PLC supplied (278) is well below that agreed to in other MDLs in this District. For example, in *In re: Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation,* MDL No. 3026, No. 1:22-cv-00071 (N.D. Ill.) (*In re: NEC*), the parties agreed to 478 search terms. Here, the PLC's proposal was roughly half that. Nonetheless, Horizon balked at the proposal, declaring 28 terms as "not relevant;" 118 terms as "agreed to;" and 117 as "overly broad." *See* Horizon Hit Reports for "Agreed to" Terms and "Overly Broad" Terms (attached as Exs. 3–4).[3] Despite numerous conferences, Horizon has not budged since.

a. Terms Horizon declared "not relevant" are, in fact, relevant.

Following the initial conference with this Court on October 19, the Court directed the "Parties . . . to meet and confer and conduct preliminary run of search

[3] Horizon also identified 17 terms as "unclear."

terms based on proposed search terms." ECF No. 66. Horizon did not do so. Specifically, a brief comparison of Exhibit 2 (the PLC's proposed terms) and Exhibits 3–4 (Horizon's hit reports for "agreed to" and "overly broad" terms) provided on November 9, 2023, establishes that Horizon did not run hit reports across most of the terms Horizon deemed "not relevant," or for that matter the totality of the "agreed to" terms.

The problem with this approach, beyond the fact it ignored this Court's directive, is that many of the terms Horizon deemed "not relevant" are, in fact, directly relevant to pharmaceutical litigation. For example, the PLC's original list included terms like "EMA" (an acronym for the term "European Medical Agency.") and "Health /3 Canada" (the Canadian agency responsible for regulation of pharmaceuticals distributed in Canada). Horizon informed the PLC it will not produce foreign-regulatory documents absent a court order compelling them to do so. But courts overseeing pharmaceutical litigation routinely recognize the relevance of these types of documents because they may evidence the defendant had notice its products were harmful.[4] For example, in *In re Davol, Inc./C.R. Bard, Inc.,*

[4] The reason for this is that all Parties desire to run search terms once, absent discovery of unforeseen terms. As such, the PLC anticipates that any agreement reached at the Discovery Conference will include a "presumptive set" of search terms that will be run across all custodial and non-custodial data sources. As noted below, in those cases where the defendant refuses to produce foreign-regulatory documents (which are few and far between), most MDL courts require their production. *See, e.g.*, *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, No. 3:16-MD-2734, 2017 WL 4399198, at *10 (N.D. Fla. Sept. 29, 2017) (ordering the defendants to certify in writing "that there are no other responsive documents to any label changes in any other foreign countries relating to impulse control disorders or pathological gambling" and to produce "any regulatory documents related to label changes in Europe, Canada, France, and Switzerland . . . that have not already been produced" and to "provide written assurance that there are no other regulatory documents related to label changes in other countries that have not been provided to Plaintiffs"); *Hodges v. Pfizer, Inc.*, No. CV 14-4855,

Polypropylene Hernia Mesh Products Liability Litigation, the court reasoned that "foreign regulatory materials may therefore be relevant to the extent they contain information about what Defendants knew about the alleged risks associated with their hernia mesh products, when they knew about those alleged risks, and whether those alleged risks were communicated to physicians and patients." No. 2:18-MD-2846, 2019 WL 341909, at *2 (S.D. Ohio Jan. 28, 2019). Because foreign-regulatory documents may establish notice—a fact that is relevant under any measure—they are discoverable. Nonetheless, Horizon not only refuses to produce them, but it also refused for months to run hit reports on those terms as this Court directed. Horizon advised the PLC yesterday, for the first time, that it will actually run hit reports for all proposed terms, including the foreign-regulatory terms.

Similarly, Horizon also refused to run the term "heterogeneous." Heterogeneous or heterogeneity is a key concept in the field of epidemiology. Epidemiological studies often evaluate the risk of a given product to a control (typically a placebo). The "risk" is typically reported as an Odds-Ratio or Hazard-Ratio that reports the likelihood (or lack thereof) that a given product causes an increased risk in a stated harm. Heterogeneity, in turn, is a concept that analyzes differences or variability of epidemiological study results. Variation in heterogeneity (*i.e.*, variation of individual study results) may support a conclusion the outcome is

2016 WL 1222229, at *2–3 (D. Minn. Mar. 28, 2016) (affirming magistrate's order that the defendants produce foreign-regulatory documents from France, United Kingdom, Netherlands, Germany, Japan, Australia, or Taiwan pertaining to product labeling and packaging, adverse events, and regulatory agency correspondence, and regulatory actions, including restrictions or withdrawals from the market where the plaintiff asserted claims for failure to warn and defective design, among others).

not reliable. Conversely, an absence of heterogeneity (or homogeneity) of study results tends to establish the outcome is legitimate. In the context of pharmaceutical litigation, companies often conduct internal epidemiological analysis in connection with ongoing pharmacovigilance. Given Horizon did, in fact, reanalyze certain clinical trial data (and/or conducted an internal meta-analysis of adverse events) related to hearing loss, the outcome of that analysis is directly relevant to the litigation, particularly if the data establish the analysis was, in fact, *not* heterogenous. This is likely the case given that analysis led to the July 2023 label change to warn of the very danger—hearing impairment—Plaintiffs allege. Not only has Horizon refused to agree to this search term, it was not until November 16 that it agreed to run hit reports for this and other terms it insists are "not relevant."[5]

These are but two examples of search terms directly relevant to this litigation that Horizon declared not relevant and for which it has not provided any hit reports.

b. Horizon did run hit reports for certain terms it agreed to or declared "overly broad," but they were artificially inflated through the absence of standard threading and the failure to eliminate email footers from the counts.

The Manual for Complex Litigation provides guidance for complex litigation, in general, and MDL practice in particular. A fundamental theme endorsed by the Manual is that discovery is an iterative process that requires cooperation and candor amongst the parties. Specifically, it notes that "[t]he responding parties should be

[5] The PLC will be prepared to discuss all of the terms subsumed within Horizon's "not relevant" and "overly broad" designations at the Discovery Conference. The terms noted above are merely for illustrative purposes.

forthcoming and explicit in identifying what data are available from what sources, to allow for formulation of a realistic computer-based discovery plan." MANUAL FOR COMPLEX LITIGATION(FOURTH), § 11.446 at 79. The Manual is buttressed by the Guidelines and Best Practices for Large and Mass-Tort MDLs (Second) (Duke Guidelines), which counsels the transferee judge to adopt an *efficient* discovery plan noting: "The discovery plan should synchronize the production of information with other phases of the litigation and *otherwise facilitate the efficient flow of information*." *Id.* at 6, 1C(i) (emphasis supplied). Unfortunately, Horizon's approach veers far from these tenets.

At the outset, the hit reports Horizon provided to date are fundamentally flawed. Specifically, Horizon informed the PLC it ran search terms across the total number of documents contained within the 35 custodians' files it originally disclosed to the PLC.[6] Horizon reported the total number of documents subsumed in the 35 custodial files was 5,241,550. *See e.g.,* Ex. 7. Horizon also informed the PLC that it "de-duped" the documents while running the hit reports—*i.e.*, that the document count *does not* include duplicate documents contained in multiple custodians' files. Simple math establishes that the reported number is grossly out of whack and that something in Horizon's search methodology is amiss.

Assuming the total number of documents was, in fact, de-duped and emanates from the 35 custodians' custodial files, it means that average size of each custodial file is 149,758 documents (5,241,550/35 = 149,758). Horizon filed its BLA application

[6] In doing so, Horizon did not run search terms across all agreed-to terms. It omitted dozens of terms without disclosing this fact to the PLC or providing any explanation for this failure.

with FDA in July of 2019—four-and-a-half years ago. Assuming Horizon's search went back seven years,[7] and that every custodian worked exclusively on Tepezza throughout the entire period (a proposition that seems highly unlikely given many of the custodians work in Regulatory and Marketing—positions that have nothing to do with the actual development of Tepezza—*and* that Horizon told the PLC many, if not all, of the custodians work on multiple products), it means *each* custodian drafted 21,394 *Tepezza-related* documents *per year* (149,758/7 = 21,394), or 89 *Tepezza related* documents *per day* (21,392/240 days = 89 documents/day).[8] That is simply not a realistic result.

So, what went wrong? Two things spring to mind: First, Horizon did not thread email conversations in its hit reports. An email "thread" is a stream of connected emails relating to one conversation. For example, if Joe, Sally, and Sue email each other regarding a given discussion that encompasses 10 separate emails, *each of those emails* is counted as a separate document *unless* the email conversation is "threaded"

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[7] The PLC specifically asked Horizon to identify the time frame it used to collect documents. Instead of providing an actual date that Horizon began to generate Tepezza-related documents, or for that matter whether it limited the search to a time frame when Tepezza-related conduct was performed, the following exchange occurred: Mr. Becker: "We're trying to get our hands around the scope of the hit list you ran. Can you tell us the date ranges for your search?" Ms. Hammond: "The searches were performed exactly as presented and listed in the reports, with no date limiters as indicated by the absence of a date limiter in the search and cell A3 . . ." *See* email exchange between T. Becker and L. Hammond (Nov. 16, 2023) (attached as Ex. 5). The exchange, and lack of a fulsome answer, underscores Horizon's unwillingness to "be forthcoming and explicit in identifying what data are available from what sources . . ." Based on the lack of a forthcoming answer the PLC used a seven-year time frame to analyze the document count by custodian (*i.e*, two years for product development and five years since submission of the BLA).

[8] The 240 number stems from an assumption that the average Horizon employee works 48 weeks per year—a number that is artificially high given most of these employees are senior level employees who likely possess more than four weeks of time off during any calendar year. 48 week * 5 days/week = 240 days).

into one email (or document) that contains the entire conversation. As a result, email threading provides a far more accurate number of the actual documents because it *counts* a continuously read conversation as one document. Second, and equally important, Horizon's vendor likely counted "footers" from email signature blocks (such as company logos) in its hits reports. Hit reports "count" footers as separate documents, even though they contain no actual data and are approximately 1 kilobyte (1kb) in size. In other words, if Horizon's email signature blocks include a company logo, the hit report counts that as a separate "document" thereby artificially inflating the actual count (by a factor of two or more). The PLC asked Horizon to remove these documents from the document tally. Horizon responded it was not technically feasible to do so. *See* Email from L. Hammond to T. Becker (Nov. 15, 2023) (attached as Ex. 6). That position is dubious given Horizon could have eliminated from its count documents under a certain file size (e.g., > 5kb), as is customary when a party is attempting to provide useful data to further a cooperative discovery conference.

The problem with Horizon's approach, and in turn the data it supplied, is that it is effectively no data at all. Specifically, if the reported number of documents grossly exceeds the real count, then the PLC is not able to evaluate whether the request is, in fact, overly broad. To put this in perspective, Horizon reported the total number of hits for "agreed to" and "overly broad" terms as 2,844,647 documents. But that number includes emails that are not threaded, along with footers that are not removed. Put another way, given the bulk of the documents are likely email, the count may be off by a factor of two or more because each email likely includes *at least* one

footer. The PLC remains committed to the position of utilizing targeted searches. But until Horizon discloses an actual number (*i.e.*, it threads emails and eliminates footers from its count), the PLC is effectively evaluating data that are not real. As such, the blanket contention that a term is "overly broad" because Horizon says so is meaningless.

This is particularly true when one considers that Horizon agreed to use the term OPTIC (which rendered over 292,000 hits (*see* Ex. 3)), while claiming terms with far less "hits" are overly broad. By way of example, the PLC sought the following term with the following agreed-to modifier (which Horizon contends is "overly broad"):

> (Advisory w/15 committee) AND (TEPEZZA OR teprotumumab OR (teprotumumab w/3 trbw) OR trb OR ttrb OR trb* OR TZZ OR TPZ OR RV001 OR R04858696 OR CHO OR huMAb OR HZN-001 OR HZN OR HZN* OR Tepro OR Tep OR Tep* OR RG-1507 OR R-1507 OR VUBEZZA OR VUB* OR IGF-1R OR "IGFR" OR (I w/5 R) OR "IGF" OR "IGF1" OR "IGF1R" OR "IGF-1" OR "IGFR-1" OR (IGF w/5 receptor) OR (Insulin* w/10 recepto*) OR ((Insulin w/3 like) w/10 recepto*) OR (Insulin* w/5 grow*) OR (Insulin* w/5 GF) OR Infus* OR IV).

See Overly Broad Spread Sheet with TEP Modifier (attached as Ex. 7). The term "Advisory w/15 committee" clearly relates to FDA's Advisory Committee—a key step in the approval process of any pharmaceutical. It strains credulity to argue that documents discussing Horizon's interaction with, analysis of, or preparation for the FDA Advisory Committee meeting is not relevant to this case. And Horizon makes no effort to do so. Instead, it claims the terms resulted in an "overly broad" number of documents. But even with the likely inflated numbers (due to the failure to thread emails or eliminate footers) the hit report established the term hit on the following number of documents:

> 29,044 Document with Hits;
>
> 49,090 Document with Hits, including Family; and
>
> 259 Documents with Unique Hits (*i.e.*, documents where the term appears alone).

Id.

Or consider the PLC's attempt to obtain Horizon's communication with healthcare providers *related to Tepezza*. The PLC proposed the following term and modifier:

> (Dear w/10 (doctor OR dr OR DO OR Health OR Provider)) AND (TEPEZZA OR teprotumumab OR (teprotumumab w/3 trbw) OR trb OR ttrb OR trb* OR TZZ OR TPZ OR RV001 OR R04858696 OR CHO OR huMAb OR HZN-001 OR HZN OR HZN* OR Tepro OR Tep OR Tep* OR RG-1507 OR R-1507 OR VUBEZZA OR VUB* OR IGF-1R OR "IGFR" OR (I w/5 R) OR "IGF" OR "IGF1" OR "IGF1R" OR "IGF-1" OR "IGFR-1" OR (IGF w/5 receptor) OR (Insulin* w/10 recepto*) OR ((Insulin w/3 like) w/10 recepto*) OR (Insulin* w/5 grow*) OR (Insulin* w/5 GF) OR Infus* OR IV).

Id. Given a manufacturer is *required* to provide accurate labels to the medical community,[9] there is no real argument that such information is not directly relevant to this case. Nor is there a credible argument the number of documents is "overly broad." Like the term set forth above, the hit report established the term hit on the following number of documents:

> 35,369 Document with Hits;
>
> 55,235 Document with Hits, including Family; and
>
> 2537 Documents with Unique Hits (*i.e.*, documents where the term appears alone).

[9] *See generally Wyeth v. Levine*, 555 U.S. 555 (2009) (holding manufacturer is responsible for the contents of its label at all times); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1669, 1673, 203 L.Ed.2d 822 (2019) (same).

Id.

Given Horizon *agreed* to produce documents including the term OPTIC—with its 292,051 hits—one is hard pressed to explain how terms with nearly 600% less hits are "overly broad." Horizon's "overly broad" hit report identifies dozens and dozens of documents that fall within this fact pattern. *Id.* Ultimately, the PLC remains willing to narrow the scope of the terms but requires clarification from Horizon regarding the basis for concluding terms like "Advisory w/15 committee" are overly broad.

Nor is this an indication the PLC is unwilling to negotiate terms down. For example, the "overly broad" list includes the following term:

> (Approv*) AND (TEPEZZA OR teprotumumab OR (teprotumumab w/3 trbw) OR trb OR ttrb OR trb* OR TZZ OR TPZ OR RV001 OR R04858696 OR CHO OR huMAb OR HZN-001 OR HZN OR HZN* OR Tepro OR Tep OR Tep* OR RG-1507 OR R-1507 OR VUBEZZA OR VUB* OR IGF-1R OR "IGFR" OR (I w/5 R) OR "IGF" OR "IGF1" OR "IGF1R" OR "IGF-1" OR "IGFR-1" OR (IGF w/5 receptor) OR (Insulin* w/10 recepto*) OR ((Insulin w/3 like) w/10 recepto*) OR (Insulin* w/5 grow*) OR (Insulin* w/5 GF) OR Infus* OR IV)

See Ex. 7. Horizon's hit report sets forth the following:

> 602,902 Document with Hits;
>
> 779,374 Document with Hits, including Family; and
>
> 35,974 Documents with Unique Hits (*i.e.*, documents where the term appears alone).

Id. While these numbers appear superficially overbroad, a deeper dive into the data underscores that they may or may not be. For example, because Horizon did not thread email or eliminate footers, the eye-popping number of hits are largely meaningless. The reason for this is because Horizon reported the term *only* appears as a unique term (*i.e.*, as a stand-alone term in a document) in 35,974 documents.

This means the balance of the hits are from documents that include *additional search terms*. Put another way, eliminating this term from the list effectively takes the total document count from 2,326,623 to 2,290,649. This underscores the problem Horizon's lack of fulsome disclosure creates when negotiating (and in turn culling) search terms.

B. The PLC's request for 85 custodians falls well within the guidelines MDL courts adopt in setting presumptive caps.

ESI custodial caps are commonplace in MDLs because they provide certainty for the parties and compel the plaintiffs to exercise restraint in selecting potential witnesses. Because products-liability litigation often involves complex scientific and liability issues (as this case does), coupled with the fact that discovery will occur only once, courts routinely set custodial caps. The PLC's request for 85 ESI custodians is reasonable under the Rule 26 factors.[10] This litigation involves more than 50 filed

[10] District courts enjoy broad discretion over discovery. *Equal Emp. Opportunity Comm'n v. Wal-Mart Stores E., L.P.*, 46 F.4th 587, 601 (7th Cir. 2022). Because parties generally cooperate in reaching agreement on ESI issues, caselaw governing the standard to apply when parties are unable to agree upon ESI custodians is "sparse." *Houston v. Papa John's Int'l, Inc.*, No. 3:18-CV-00825-CHB, 2020 WL 6588505, at *2 (W.D. Ky. Oct. 30, 2020) (noting lack of authority within the Sixth Circuit); *see also In re EpiPen Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2018 WL 1440923, at *2 (D. Kan. Mar. 15, 2018) (noting the same in the Tenth Circuit).

Federal Rule of Civil Procedure 26(b)(1) limits discovery to "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]" Fed. R. Civ. P. 26(b)(1). Relevance is to be construed broadly to include "any matter that bears on, or that reasonably could lead to other matter that could bear on" any party's claim or defense. *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (citation omitted). Presuming a party has made the requisite showing of undue burden, in analyzing proportionality, the trial court must consider the need for the information sought based upon "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). A request for 85 additional custodians clearly is "proportional" in the context of an MDL.

claims (with hundreds of unfiled cases) for significant personal injuries. Defendant has exclusive control of its employees' ESI. In 2023, Amgen purchased Horizon for $27.8 billion,[11] so there is no argument that this Defendant lacks resources to provide this discovery. The importance of having access to relevant ESI cannot be understated. And Horizon has not made *any* showing of undue burden to substantiate this objection.[12]

Indeed, it is commonplace for parties to produce ESI for hundreds of custodians in multidistrict litigation.[13] As set forth below, MDL courts, given the gravity of the

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[11] *See* Amgen Press Release (Oct. 6, 2023) (available at https://www.amgen.com/newsroom/press-releases/2023/10/amgen-completes-acquisition-of-horizon-therapeutics-plc) (last accessed Nov. 16, 2023).

[12] *Papst Licensing GmbH & Co. KG v. Apple, Inc.*, No. 17 C 1853, 2017 WL 1233047, at *3 (N.D. Ill. Apr. 4, 2017) ("The party asserting undue burden must present an affidavit or other evidentiary proof of the time or expense involved in responding to the discovery request. Phrased differently, one claiming undue burden must do more than intone the phrase. Undue burden or expense, actual or potential, must be shown by a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements. What the Seventh Circuit said . . . applies equally here: 'unfortunately ... saying so doesn't make it so....' 'Lawyers' talk is no substitute for data.'") (internal quotations and citations omitted) (cleaned up).

[13] *See, e.g.*, *In re: Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, MDL No. 2272, No. 11-cv-5468, at ECF No. 879 (N.D. Ill.) (noting that the Court had previously authorized Plaintiffs to obtain custodial files from 100 current and former Zimmer employees. Subsequently, the PLC removed six names from the list but added an additional 18 for a total of 112 custodians); *In re Ethicon Physiomesh Flexible Composite Hernia Mesh Prod. Liab. Litig.*, No. 1:17-MD-02782, 2022 WL 17687425, at *3 (N.D. Ga. Nov. 14, 2022) (noting that the defendants produced ESI from 846 different custodians or non-custodial sources in MDL); *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 982 F.3d 113, 125 (2d Cir. 2020) (holding that lower court did not abuse its discretion in allowing plaintiffs to obtain documents from 52 custodians); *In re: Benicar (Olmesartan) Prods. Liab. Litig.*, No. 15-md-2606-RBK-JS, CMO 13, ECF No. 170 at PageID: 4976–78 (D.N.J. Oct. 20, 2015) (permitting plaintiffs to identify additional custodians in addition to the 141 custodians who had been identified for two defendants); *In re: Libor-Based Fin. Instruments Antitrust Litig.*, MDL 2662 (S.D.N.Y.), Defs.' Resp. to Pls.' Mot. to Compel, 2022 WL 17885113 (Oct. 13, 2022) (stating the defendants produced documents from more than 500 custodians); *In re Actos Prod. Liab. Litig.*, No. 6:11-md-2299, Defs.' Supp. Br. in Support of Mot. for Prot. Ord., 2013 WL 5329450 (W.D. La. Sept. 5, 2013) (stating that MDL defendants produced ESI "from more than 300 custodians/sources"); *Santiago v. C.R. Bard, Inc.*, No. 8:20-cv-01212, Pl's. Opp. to Def's. Mot.

claims *and* recognizing discovery is being conducted *once*, routinely reject claims—like Horizon will make here—that the production of *hundreds* of custodial files is not proportional. This is particularly true in a case like this where the harm involves catastrophic life-long injuries, and the Defendant is a multinational company with billions in annual revenue and thousands of employees. Under any measure, affording the PLC 85 total custodians is clearly "proportional."

Caps exist so that the parties in general, and plaintiffs in particular, can make targeted inquiries. Caps thus encourage plaintiffs to selectively identify custodians so as not to exceed the cap. A presumptive cap within which Plaintiffs can designate custodians as discovery proceeds will avoid the need to raise disputes with the Court over each individual employee the PLC identifies as having relevant information. Accordingly, the PLC's request for 85 custodians is eminently reasonable.

C. The Court should impose a Production Protocol that identifies clear timelines to produce documents and commence deposition practice.

Finally, given the pace at which this litigation is proceeding, the PLC intends to ask the Court to implement a production schedule to avoid further delay in commencing and completing discovery. The JPML transferred this case to Judge Durkin on June 2, 2023—nearly six months ago. *In re: Tepezza Mktg., Sales Pracs.,*

for Prot. Ord., 2020 WL 7017174, n.1 (M.D. Fla. Sept. 18, 2020) (referencing "more than 110 custodians" originally produced in the related MDL); *Segura v. Astrazeneca Pharm., LP*, No. 5:06-cv-5071, Def's. Resp. to Pl's. Mot. to Compel, 2013 WL 9792224 (D.S.D. June 27, 2013) (stating the defendant produced ESI "from more than 100 individual custodians" in MDL before remand); *Lyons v. Boehringer Ingelheim Pharm., Inc.*, No. 1:18-cv-04624, Def's. Mot. for Entry of Conf. Ord., 2019 WL 8108431 (N.D. Ga. July 24, 2019) (stating the defendant produced 150 custodial files in related MDL).

and Prods. Liab. Litig., 2023 WL 3829248 (J.P.M.L. June 2, 2023). Since that time, the *only* documents Defendant produced were the BLA and Supplemental BLA—which this Court ordered be produced last month. In short, during the past six months, Horizon has not produced a single custodial file, agreed to a production methodology (let alone the search terms governing it), provided any hint as to when documents might be forthcoming, or even informed the PLC which non-custodial data sources might include relevant information. By contrast, the PLC agreed to an aggressive production schedule *for plaintiffs* to produce a completed Plaintiff Profile Form, executed medical authorizations, and all medical records in their counsel's possession by December 1. Discovery is not a one-way street. Yet, that appears to be the road Horizon intends to travel. To ensure discovery proceeds smoothly and without further delay, the PLC intends to ask this Court to impose a Production Protocol governing the production of custodial and non-custodial data sources.

Production schedules are commonplace in MDLs. They exist, much like search terms, to ensure the litigation will proceed smoothly. The PLC proposed adopting a concrete schedule that sets benchmarks for production of custodial files and non-custodial data sources. *See* Email from Tim Becker to Lori Hammond (Nov. 13, 2023) and attached proposed Stipulation for Entry of Custodial Production and Production Protocol (Production Protocol) (attached as Ex. 8). Specifically, the Production Protocol contemplated the PLC identify, and Horizon in turn produce, 15 custodial files (along with a certification of substantial completeness) every 30 days commencing on January 15, 2024. *Id.* at B(1)–(2). The Production Protocol further

contemplated deposition practice open 30 days after Horizon certifies a custodian's production as substantially complete. Such a protocol is hardly a novel proposition. For example, in *In re: NEC*, the parties *stipulated* to a Production Protocol that imposed production obligations and corresponding certification of custodial files. *See In re: NEC*, ECF No. 365, PageID: 4415–16 (attached as Ex. 9). Similarly, MDL courts routinely require certification prior to commencing deposition practice. Commenting on the certification requirement, Judge Pallmeyer made the following observation:

> THE COURT: With respect to certification of completeness of witnesses' custodial production, I think, to the extent Abbott believes that's a vague request, I guess I think it's pretty straightforward that before depositions are scheduled, the plaintiffs are entitled to know that the relevant documents are available to them.

Hr'g Trans. 24 (Dec. 13, 2022) at 24–32 (attached as Ex. 10). That is exactly what the PLC seeks here; namely a production schedule of custodial and non-custodial files where Defendant certifies that the production is complete so that depositions may begin and be conducted once.

Instead of engaging in negotiations over a schedule, or for that matter even agreeing to meet and confer, Horizon informed the PLC that, "We believe that this schedule seems impossibly aggressive, but will be in a better position to address scheduling following the discovery hearing." *See* Email from Tim Becker to Lori Hammond (Nov. 10, 2023) (attached as Ex. 10). When pressed by the PLC to actually discuss the parameters of a schedule, Horizon responded, "Once the discovery parameters are set, we anticipate being able to provide rolling productions every thirty days." *Id.* But even this response is devoid of meaning. For example, who will

be produced, how many documents will be produced, will there be a floor related to the number of custodians produced every 30 days? Put another way, vague assurances of future cooperation are no assurances at all. More important, it is not entirely clear to the PLC that Horizon's 35 custodians are either relevant or impactful. As such, the PLC may not seek the custodial files of each custodian Horizon identified, and likely will not depose all of them. The PLC's proposal affords it (and in turn Defendant) an opportunity to proceed with discovery in a manner that is certain; Defendant's approach does not. Accordingly, the PLC intends to ask the Court to enter the proposed Production Protocol.

CONCLUSION

The PLC looks forward to the December 4, 2023, Discovery Conference and will be prepared to discuss all the issues set forth herein.

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Respectfully submitted,

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