UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

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THIS DOCUMENT RELATES TO: ALL CASES

PLAINTIFFS' MOTION TO MODIFY PRETRIAL ORDER NO. 30 AND INCORPORATED MEMORANDUM OF LAW

Pursuant to Fed. R. Civ. P. 16(b)(4), Plaintiffs respectfully move to modify Pretrial Order No. 30 in accordance with the proposed schedule set forth in the attached Exhibit A.

INTRODUCTION

PTO No. 30 imposed an 18-month discovery timeline. It was premised on all parties working together to conduct full, non-bifurcated discovery based on a series of events and deadlines heavily negotiated by the parties and adopted by the Court. Defendants have not kept their end of the bargain. Consistent and widespread production delays of *critical* non-custodial and custodial documents have handicapped Plaintiffs' ability to: (i) efficiently and timely review crucial documents; (ii) prepare for and schedule depositions of key witnesses; and (iii) prepare experts for the submission of general causation expert reports. As a result, the schedule mandated by PTO 30 is no longer viable and must be modified.

Defendants agree that the schedule mandated by PTO 30 must be modified. For that reason, the Court vacated all future PTO 30 deadlines at the April 20, 2021 Case Management Conference, to be reset following consideration of this motion. This motion details why the

schedule attached as Exhibit A is warranted and *essential* to enable Plaintiffs to effectively and properly prosecute one of the largest and most complex multidistrict proceedings in history.[1]

This relief is necessary, principally because the Brand Manufacturing Defendants ("Brands") have persistently violated this Court's PTOs governing the progress of discovery in this litigation. In particular, the Brands have delayed or attempted to avoid their discovery obligations and failed to timely make crucial custodial and non-custodial productions that are routine in most every pharmaceutical MDL. Their litany of explanations - whether Covid-related delays or "forgetting" to run key search terms - are neither here nor there for purposes of this motion. Whatever the reasons, Plaintiffs cannot properly prosecute this litigation and prepare their general causation experts without timely access to the complete production of crucial categories of documents that include Defendants' regulatory files, pre-approval and post-approval, non-clinical, clinical and preclinical studies, tests and investigations of ranitidine, NDMA and potential carcinogenicity, mutagenicity and oncogenicity, and the analytical testing (stability, degradation, impurity and residual solvents) of Defendants' finished dose products and API, as well as manufacturing, storage and transport. Without the timely production of these documents, depositions of key witnesses cannot effectively be taken. Without deposition testimony of key witnesses, Plaintiffs cannot adequately consult their experts, let alone expect them to prepare expert reports.

[1] The deadlines set forth in Exhibit A – which are different from those proposed by Plaintiffs on March 17, 2021 [DE 3062], and those briefly discussed during the April 20, 2021 Case Management Conference –represent a *very aggressive and tight schedule* that leaves no room for error based on the status of discovery and events as Plaintiffs understood them prior to the April 22, 2021 Discovery Conference, which involved GSK's study-related productions. Since then, there have been additional delays with GSK that are the subject of ongoing hearings before Magistrate Judge Reinhart, as well as with the Generics that have caused many of the PTO 60 deposition dates to be postponed. Therefore, based on the status of PTO 54, PTO 60 and the ongoing delays in Defendants' document productions, the proposed schedule attached as Exhibit A may be further adjusted at the time Plaintiffs file their Reply.

The entire schedule set forth in PTO 30 has been derailed, and Plaintiffs are powerless to get back on track. The schedule is dependent on the Brands' (and other Defendants') completion of their productions.[2] Each step of the existing schedule flows from the previous one, and the Brands' noncompliance has stymied Plaintiffs at virtually every step. The Brands acknowledge the existing schedule must change. The only disagreement is the modest amount of extra time Plaintiffs seek beyond the Brands' meager proposal. Remarkably, the Brands do not ground their proposal on what is prudent, fair or even possible. Rather, their unwillingness to appropriately extend the schedule is primarily centered on their wish to win a race to *Daubert* rulings with state-court proceedings.

The Brands' position is inappropriate. The Brands' noncompliance necessitated this motion. The proper schedule is the one that allows Plaintiffs – in light of the Brands' delays – to provide superlative representation to Plaintiffs, who include tens of thousands of cancer victims and, all too often, the next of kin they left behind. Plaintiffs should not be rushed through a truncated discovery and general causation process because the Brands face *other* plaintiffs in other tribunals, with different legal standards and unique schedules, procedures, facts, and circumstances that are not before this Court.

PROCEDURAL BACKGROUND

More than a year ago, the Court entered PTO 16 [DE 557] which directed "Appointed Counsel [to] meet and confer.…regarding the timing and scope of discovery…. [T]he Court instructs the parties to begin earnest discussions about the scope and timing of discovery…. The Court expects Appointed Counsel to meet and confer concerning which categories of relevant

[2] The emphasis on the Brands is because the full, non-bifurcated discovery of them was purposefully the initial focus, designed to triage discovery in a meaningful way by category of Defendant, to meet the deadlines under PTO 30. The Brands' delays have created this problem, although ongoing discovery issues with the Generics have also substantially impacted the schedule.

documents defendants could reasonably produce in the near term…and a timeline for production of documents that it is agreed should be produced but which are not readily obtainable."[3]

At that time, these discussions only included the Brands. Plaintiffs' interim leadership met and conferred with each Brand beginning in early April 2020 and reached an agreement on the production of initial core discovery including, but not limited to, complete regulatory files to be produced in the *near term*. In mid-June 2020, following the formal appointment of Plaintiffs' leadership and consistent with PTO 24 and PTO 30 [DE 767, 875], Plaintiffs served each of the Brands with formal written discovery consisting of substantially similar requests for production, interrogatories, and multiple 30(b)(6) notices on various foundational topics in relevant functional departments.

Amended PTO 24 provided for *full*, *non-bifurcated* discovery that began on June 15, 2020, [DE 1194],[4] and would "continue[s] for 18 months culminating in the filing of Daubert motions relating to general causation, as well as motions for class certification…." *See* APTO 24 at p. 2. During the 18-month discovery period, Plaintiffs were required "to complete all fact discovery of all Defendants, including document discovery and fact depositions, and the parties shall complete expert discovery necessary to prepare general causation Daubert motions within that 18-month period." *Id.* In addition, APTO 24 provides that Plaintiffs' motions for class certification shall also be filed 18 months following the initiation of discovery. *Id.* Implementing these milestones, PTO 30 required the following, specific deadlines:

- fact discovery would begin on June 15, 2020;
- 2) fact discovery of Defendants on issues related to general causation and expert reports would conclude by August 2, 2021;

[3] *See* PTO 16 at pp. 4-5.

[4] Amended PTO 24 was entered on July 22, 2020 [DE 1194], and largely mirrored the original version entered on May 28, 2020 [DE 767].

- 3) all fact discovery of Defendants and fact discovery related to class certification would conclude by December 20, 2021; and
- 4) *Daubert* motions, Plaintiffs' class certification motions, and expert reports would be filed on December 20, 2021.

Id. at pp. 3-4.

Shortly thereafter, Plaintiffs negotiated Core Discovery Agreements with the Generic Manufacturer Defendants ("Generics"), as well as the Retailer and Distributor Defendants, that resulted in the entry of PTOs 34, 35 and 57 [DE 1117, 1206, 2468], designed to obtain key documents in the near term and stage formal discovery for those Defendants in the early months of 2021.

On October 3, 2020, the Court entered Amended PTO 47 [DE 1987], which ordered the Brands to produce the first tranche of custodial files beginning on November 24, 2020, with substantial completion by December 31, 2020, and substantial completion of non-custodial document production on a rolling basis by varying deadlines.[5] The Court noted that its intervention was "necessary to ensure the 18-month discovery schedule is maintained." *See* APTO 47 at p. 1. The Court reaffirmed "the need for ***each Defendant to make substantial rolling productions as quickly as possible***" and that "Defendants should ***provide all documents as soon as practically possible***." *Id*. at pp. 3 - 4 (emphasis added).

On February 25, 2021, following extensive negotiations with the Generics, the Court entered PTO 60 [DE 2877], which set forth parameters for Rule 30(b)(6) deposition scheduling, relevant custodial discovery, and required substantive responses to Plaintiffs' formal written discovery by March 11, 2021.

[5] The Brands' non-custodial document production was ordered to be substantially completed by: October 30, 2020 for Pfizer; December 20, 2020 for BI; December 31, 2020 for Sanofi; and March 15, 2021 for GSK.

On April 8, 2021, the Court entered PTO 63, which extended the deadlines for each of the Brands to substantially complete their respective document productions. [DE 3164].[6] The extension of these PTO 47 deadlines did not provide for a corresponding modification of PTO 30 deadlines, as requested by Plaintiffs, although the Court acknowledged a need for a modification and urged the parties to discuss and jointly propose a modification to PTO 30. In the weeks thereafter, despite repeated attempts, the parties were unable to reach agreement.

DEFENDANTS' DISCOVERY DELAYS

Defendants' discovery delays are too extensive to fully discuss in the context of this motion. The following three examples are merely illustrative:

- Since March 24, 2021 alone, there have been *almost 2 million documents produced totaling over 10 million pages*. Prior to that, there had been *less than 450,000 documents produced combined from all Defendants* between June 2020 and March 10, 2021.[7]
- GSK produced *more than 65%* of its total document production between March 24, 2021 and May 6, 2021.
- Generic Wockhardt has produced ***more documents in the month of April 2021*** than GSK, BI, Sanofi or Pfizer have produced in the ***entire litigation***.[8] Generics Strides and Perrigo each produced between 225,000 and 266,000 documents, respectively, despite the

[6] Many of the deadlines established in PTO 63 have already been missed or been moved. For example, based on the revelations made and issues raised during the Discovery Conferences on April 22, 2021 and April 30, 2021, Magistrate Judge Reinhart ordered GSK to provide answers to Plaintiffs and the Court concerning the identification, location and production of hundreds of studies and spreadsheet entries and documentation [DE 3321], up to and through May 5, 2021. The May 5 deadline passed without full answers. Another Discovery Conference is set for May 14, 2021, to continue to address the "batch records" analytical testing discovery issues outstanding with GSK and BI (that should serve as a template for the remaining manufacturing Defendants).

[7] *See* March 10, 2021 Hearing Transcript, p. 20.

[8] Generic Wockhardt produced over 500,000 documents between April 1, 2021 and May 1, 2021. To date, GSK has *only* produced approximately 375,000 total documents; BI has only produced approximately 296,000 total documents; Sanofi has only produced 92,802 total documents; and Pfizer has produced 134,027 total documents.

fact that, as Generics, they *did not even have* a clinical development program.[9] This is proof positive that the Brands' productions are *still* significantly incomplete.

Three of the four Brands have repeatedly violated Court-ordered deadlines relating to discovery.[10] The following are examples of these three Brands' discovery violations.

GlaxoSmithKline (GSK)

- Over eighty percent (80%) of GSK's initial document production in the summer of 2020 was redacted. After countless hours meeting and conferring, Plaintiffs filed a PTO 32 dispute resolution memorandum on September 11, 2020. Only then did GSK agree to reproduce the documents unredacted; but it took over three more months for GSK to complete that production.[11]
- GSK failed to begin Tranche 1 custodial file production by November 24, 2020, and failed to substantially complete it by December 31, 2020, as required by PTO 47. As

[9] *Id.*; *See* Exhibit B.

[10] The production issues are not unique to the Brands. The majority of scheduled depositions of the Generics, and the underlying document productions that were supposed to have taken place well in advance of those depositions, have been pushed back. Pursuant to PTO 60, most of the scheduled Generics' storage and transportation depositions had to be postponed. Five more storage and transportation depositions are scheduled between May 6 and May 15, but there are others that will not be completed in the first half of May. Seven of these depositions have already been rescheduled three or four times. As Plaintiffs' leadership predicted, most of these depositions are crammed into the final days of May, although Plaintiffs are beginning to receive correspondence from certain Generics indicating uncertainty about their ability to complete productions 14 days in advance. There are 17 more depositions scheduled in June, which was reserved for overflow. Plaintiffs take the Generics at their word that they are producing documents as quickly as possible, but Plaintiffs *only* option when high volumes of documents are produced in close proximity to a deposition is to either reschedule the deposition or take it based on incomplete information. Both "choices" prejudice Plaintiffs. The prejudice is compounded by Section (E)(5) of PTO 54, which precludes Plaintiffs from taking the deposition based on the incomplete documents and leaving the deposition open. As currently written, so long as Plaintiffs are notified more than five days in advance that additional documents are coming, Plaintiffs are precluded from taking the deposition and reserving their right to take it again. This issue has been raised repeatedly with the Court during the Case Management Conferences because it conflicts with the advice previously given (to move forward with the depositions and take a second deposition when the document production is complete).

[11] *See* DE 3062, 3062-4.

of December 31, 2020, GSK had only produced 10% of its Tranche 1 custodial file documents.[12]

- Between the entry of PTO 47 on October 3, 2020, and the GSK document production deadline on March 15, 2021, GSK failed to make substantial rolling productions of documents in contravention of PTO 47.[13]
- In February 2021, GSK notified Plaintiffs that it had "mistakenly" failed to run key search terms the parties had agreed on, including basic terms such as "Zantac" and "NDMA," across the custodial files and, therefore, the custodial files were incomplete, with over 250,000 documents that needed to be reviewed and produced.
- In February 2021, Plaintiffs learned that GSK unilaterally decided to stop collecting, reviewing, or producing documents from custodial files that post-dated September 13, 2019 (the date of the Valisure Citizen's Petition filed with the FDA), contrary to GSK's prior representations that custodial files were being produced "until present."[14]
- GSK's continued late productions caused delay in conducting the remainder of the Rule 30(b)(6) depositions, including Pharmacovigilance, Clinical/Preclinical, Manufacturing and Supply Chain, Sales and Marketing, and Regulatory (which was postponed three times due to substantial last-minute productions),[15] as well as depositions of fact witnesses. As of May 6, 2021, *only two depositions of GSK witnesses* have been taken.
- Until the Discovery Conference on April 22, 2021, GSK refused to identify which clinical and preclinical studies had and had not been produced. GSK also failed to identify all electronic databases where relevant information could be – and actually was – stored, and misrepresented the existence of master lists/indices of clinical trials related to ranitidine.[16]

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[12] *See* Hearing Transcript January 6, 2021; DE 3062.

[13] *See* DE 3062, 3062-7.

[14] *See* DE 3062, 3062-6, 3062-7, p. 19.

[15] *See* DE 3062, 3062-6, 3062-7, pp. 2, 10.

[16] *See* April 22, 2021 Hearing Transcript.

- Plaintiffs also learned for the first time on April 22, 2021, that GSK has only produced 216 of the 760+ human clinical trials that it conducted in relation to Zantac/ranitidine, and was refusing to produce any additional animal studies, safety documents and evaluations, nonclinical testing and studies located on its PIER database indices.[17] GSK was ordered to produce information relating to the withheld documents to provide clarity, and Plaintiffs were directed to file a motion to compel.[18] At the Discovery Conference on April 30, 2021, GSK agreed to search and produce the human clinical trial documents if they have them.[19]
- GSK was ordered to provide Plaintiffs with a status update by May 5, 2021, regarding which Medtrack studies had been produced versus which studies GSK was raising a legal objection to producing.[20] GSK did not provide an update on May 5, 2021. The last update that Plaintiffs received was during the Discovery Conference on April 30, 2021.[21]

Sanofi

- Sanofi failed to begin Tranche 1 custodial productions until December 4, 2020, and only after Plaintiff convened a PTO 32 final meet and confer.
- Sanofi first notified Plaintiffs on December 22, 2020, of its widespread destruction of employees' emails in violation of three Preservation Orders dating back to November 2019.
- Sanofi's counsel provided a "report" to Plaintiffs on February 19, 2021 (updated on February 23, 2021), concerning its root cause investigation, recovery and remedial positions. On March 1, 2021, Plaintiffs requested documents, information, and discovery concerning the conditions, circumstances, and events that led to the destruction of many custodians' emails during a critical timeframe in this litigation,

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[17] *Id.*

[18] *Id*. at p. 57, lines 3-20.

[19] *See* April 30, 2021 Hearing Transcript, pp. 21-22.

[20] *See* DE 3321, para 3.

[21] *See* April 30, 2021 Hearing Transcript.

but it was not until this week that Sanofi agreed to allow that discovery process to proceed.

- Sanofi's ongoing remediation efforts will not be completed until July 30, 2021, with a final remediation report provided 30 days thereafter.
- Sanofi's destruction of responsive ESI has resulted in the delay and/or postponement of many key Sanofi depositions (some more than once) until it has substantially completed its remediation efforts.
- For those Sanofi witnesses Plaintiffs have attempted to depose, Sanofi made large, late productions of custodial documents that caused further delays. For example, on the ***night before*** the April 9, 2021, ***already rescheduled*** Regulatory 30(b)(6) deposition, Sanofi produced almost 1000 new documents from the remedial custodial file of the Rule 30(b)(6) witness (Mike Bailey) in violation of PTO 54, forcing Plaintiffs to reschedule this deposition yet again.
- Sanofi failed to make substantial rolling productions of documents in violation of PTO 47. In fact, Sanofi produced ***less than 50%*** of its non-custodial documents by the December 20, 2020 date required under PTO 47. [22]

Boehringer Ingelheim (BI)

- BI failed to begin Tranche 1 custodial production until December 4, 2020.
- BI only produced 23,661 custodial documents by the December 31, 2020 deadline, and has produced 19,339 more since January 1, 2021.
- BI was still producing Tranche 1 custodial file documents in April 2021, almost four months late, in contravention of APTO 47 and PTO 54, potentially necessitating second depositions of BI witnesses who have *already been deposed,* (*e.g.* Andrew Gee, David Dobbins, Ellen Gold, and Pamela Geelan).[23]
- BI unilaterally decided to cut off its custodial file collection as of February 2020, several months prior to the FDA recall of Zantac and before the BI investigation into NDMA in Zantac conducted in the summer of 2020.

[22] *See* Exhibit B.

[23] BOE_ZAN_MDL_0001262662.

- BI failed to produce critical non-custodial documents related to 1) BI's NDMA investigation,[24] and 2) regulatory files, including Form 483 FDA investigation and audit reports from December 2019 relating to Zantac and its manufacturing practices, deficient stability testing.[25] Incredibly, BI did not notify Plaintiffs of the existence or withholding of the documents related to the NDMA investigation. They were discovered *by chance* during Plaintiffs' review of *Sanofi's* documents in February 2021.[26] BI only notified Plaintiffs in late-February 2021 that they withheld the FDA audit documents from December 2019 onward, on the eve of the deposition of a BI employee who was involved in the regulatory communication with the FDA on these issues. In addition, Plaintiffs recently learned that BI still has not completed this production and continues to withhold critical documents the FDA reviewed and inspected during its audit of the Promeco facilities, and manufacturing and testing of Zantac.
- BI failed to produce other non-custodial documents due by the December 20, 2020 deadline specifically from its IDEA4CON and Trackwise databases, producing them more than three months late (it is still unclear if BI has completed this production).
- BI failed to disclose certain electronic data sources where certain batch records for Zantac are electronically maintained. BI has continuously represented to Plaintiffs and the Court that the batch testing of Zantac was only available in hard copy at the Promeco facility and inaccessible due to Covid restrictions. Plaintiffs first learned of the existence of *electronic data sources* of batch testing around April 22, 2021, the date the parties were ordered to reach an agreement on production of batch record documents.[27]

[24] *See* DE 3062-6.

[25] BOE_ZAN_MDL_0001262662; BOE_ZAN_MDL_0001394234; SANOFI_ZAN_MDL_0000168507.

[26] SANOFI_ZAN_MDL_0000065237; SANOFI_ZAN_MDL_0000065219

[27] *See* email dated April 22, 2021 attached as Exhibit C; April 22, 2021 Hearing Transcript, p. 92, lines 22-25; May 1, 2021 Hearing Transcript, pp. 18-19.

- BI failed to disclose the LIMS, BICHROM, and EMPOWER databases used to conduct chromatography testing and to store data and results, including chromatograms and stability testing, despite Plaintiffs' specific discovery requests and continued requests during subsequent meet and confers.[28] Instead, BI repeatedly represented to the Court and to Plaintiffs that the batch records were in hard copy at the Promeco facility, and would require many months to access them. [29]

PLAINTIFFS' PROPOSED SCHEDULE MODIFICATIONS

Plaintiffs' proposed schedule modifications are grounded in need. To fulfill their basic obligations as advocates, Plaintiffs need to: prepare for and take depositions of the Brands' fact witnesses and Rule 30(b)(6) witnesses; prepare for and take depositions of the Generics' Rule 30(b)(6) witnesses; identify, prepare for, and take additional fact witness depositions of the Brands, Generics, Retailers and Distributors; commence and conduct discovery of the non-U.S. Generics that have challenged personal jurisdiction (assuming their personal jurisdiction motion is denied); review over 10 million pages of ***newly produced*** documents; receive, review and analyze hundreds of ***belatedly and not yet produced*** clinical and preclinical trials, adverse event data, and chemistry and analytical testing from GSK and other Defendants; and review and analyze many millions of pages of *yet to be produced* documents and custodial files across all Defendants.

General causation experts, both epidemiological and non-epidemiological, have no role in the document review process. They rely upon counsel to provide them with documents relating to the history, design, development, studies [human, animal, in vivo, and in vitro], testing and analysis of ranitidine over a 40-plus year timeframe. Ranitidine breaks down into NDMA in

[28] *See* April 6, 2021 correspondence attached as Exhibit D; April 23, 2021 correspondence attached as Exhibit E.

[29] *See* March 28, 2021 Hearing Transcript, pp. 57-58, 68-70, lines 17-8.

various ways so experts cannot confine their analysis to one phase of the manufacturing process or one link in the distribution chain. They instead must review manufacturing, chemistry, stability, and storage and handling documents. In addition, there are corresponding issues raised and addressed (or omitted) in the regulatory and pharmacovigilance processes.

Extensive production delays substantially prejudice Plaintiffs' ability to prepare expert reports. Defendants have had nearly 40 years to review their internal documents and test their products. Even if the clock started in September 2019, when the FDA notified Defendants of NDMA in their products, Defendants have already had almost two years to review all their internal documents from the past 40 years and to test their products before their expert reports are due. In fact, when regulatory agencies around the world began notifying Defendants that testing found NDMA in Zantac/ranitidine, Defendants immediately convened large groups of scientists (epidemiologists, chemists, pathologists, toxicologists, regulatory experts, etc.) to begin reviewing historical documents and testing, conduct additional testing and analysis of the root cause of how and why NDMA was in their products. This holds true for GSK, Sanofi, BI and the Generics.[30]

Defendants' documents contain *indispensable* information from clinical trials, adverse events, laboratory testing, root cause analyses, and other key science that experts need to form their opinions. Defendants have already stated their intent to rely on the 40-plus year clinical history relating to Zantac/ranitidine that includes the clinical trials and other pre and post marketing studies conducted. It is obvious, therefore, that Plaintiffs need the ability to review

[30]SANOFI_ZAN_MDL_0000391821; SANOFI_ZAN_MDL-0000391803; Aurobindo_prod2_0000000208; DRLMDL0000069991; SANOFI_ZAN_MDL_0000119928; SANOFI_ZAN_MDL_0000141793; GSKZAN0000071155; GSKZAN0000178581; GSKZAN0000052019; DRLMDL0000069778; GSKZAN0000120419; GLENMARK-0000031031; ApotexCorp_0000030812; Amneal_prod1_0000002938.

those same documents to properly counter the defenses in this litigation. Remarkably, those documents have still not all been collected, reviewed, and produced, and the ones that have been produced came extremely late.[31]

Plaintiffs' proposed schedule include five overarching characteristics. First, it extends the deadline for disclosure of Plaintiffs' general causation experts and reports from August 2, 2021 until January 24, 2022 (five and a half months), contingent on Defendants' completion of production of clinical, preclinical, non-clinical, and study-related documents and data no later than June 15, 2021, and completion of all noncustodial document production by September 1, 2021.[32] Second, it maintains the December 20, 2021 deadline for the completion of all fact discovery set forth in PTO 30, also contingent on Defendants' completion of production of clinical, preclinical, non-clinical, and study-related documents and data no later than June 15, 2021, and completion of all noncustodial document production by September 1, 2021. Third, it extends the deadline for the filing of general causation *Daubert* motions from December 20,

[31] Some examples of GSK's actions include: 1) refusal to provide additional ranitidine animal studies referenced in its PIER index without a showing of relevance; 2) refusal to identify which clinical or other studies they have or have not produced and where it is in the production; 3) production of study summaries instead of full reports; 4) failure to disclose they had a spreadsheet tracking all of the human clinical trials conducted on ranitidine until March 2021 despite multiple requests since last May wherein Plaintiffs were told it did not exist; 5) not identifying over 50% of the clinical trial data that existed; and 6) producing over 60% of its total document production between March 24, 2021 and April 22, 2021. BI's actions include: 1) producing more than 50% of its total document production since February 2, 2021; 2) refusal to commit to produce or object to produce the ANDA's for the generic products it manufactured and marketed for over 12 years; and 3) failure to identify that its Promeco batch testing was available electronically. Sanofi's issues include its late-December 2020 revelation of the widespread destruction of employees' emails and the ensuing delays occasioned as a result of its ongoing remediation efforts.

[32] This date differs from Plaintiffs' earlier proposal of December 20, 2020 for two reasons. First, unlike the lawyers, it is extremely difficult and unfair to expect experts to sacrifice their holidays to work the long hours that are the norm when finalizing expert reports. Second, expert depositions will not be conducted over the holidays. Thus, the January 24, 2022 deadline recognizes the practical reality that there will be no activity involving general causation experts between mid-December 2021 and early January 2022.

2021 until June 9, 2022, and modifies the ensuing briefing schedules on those motions by shortening the period for Plaintiffs' oppositions and Defendants' replies. Fourth, it postpones the filing of motions for class certification and class certification expert reports, and the corresponding briefing on class certification, until after this Court issues its decisions on general causation *Daubert*.[33] Fifth, it provides a new series of events requiring the parties to develop and submit Bellwether selection plans in advance of the ruling on general causation *Daubert* motions.

Currently, PTO 30 does not contain deadlines for Bellwether selection, case-specific discovery, expert submissions, and Bellwether trials, because the Brands refused to include anything beyond general discovery, *Daubert*, and class certification motions at the time PTO 30 was negotiated. During those negotiations, Plaintiffs originally proposed a full schedule through Bellwether discovery and trials, including disclosure of specific causation expert reports, timing of specific causation *Daubert* motions, and dispositive motions.[34] Defendants opposed the inclusion of any Bellwether discovery or Bellwether trial dates because they wanted to wait until after the *Daubert* rulings contemplated by PTO 30. The time has come to schedule these events. There are approximately 1,300 filed cases and 70,000 registered (non-deficient) claims involving the 10 designated cancers. The process for selecting Bellwether trial pools, conducting initial core discovery to reduce the pool and select cases for trial, and

[33] The parties originally proposed, and the Court adopted in PTO 30, reluctantly, to schedule *Daubert* and class certification motions on a substantially similar path. In the proposed modified schedule, Plaintiffs have de-coupled the class certification motions and class certification expert reports and expert depositions so they now follow the Court's ruling on general causation *Daubert*. Doing so will allow the parties and the Court to focus more time and resources on general causation *Daubert* and Bellwether selection, and reduce the time to completion of the *Daubert* motions.

[34] The Court recently asked about dispositive motions and Plaintiffs advised that under the typical MDL process and procedure, dispositive motions are dealt with in the context of individual Bellwether cases, where the individual facts and law can properly be considered. Defendants did not offer a response.

completing the discovery, specific causation expert disclosures, and *Daubert* and dispositive motions practice associated therewith, is a monumental project, requiring enormous time and resources. If a path forward is not considered and planned now, the first trials in this MDL will not happen for a long time after *Daubert* rulings.

The relief sought by Plaintiffs is ***justified and essential*** based on the facts and circumstances presented to the Court. Plaintiffs do not seek this relief lightly, as we are eager to obtain redress for Plaintiffs' injuries as quickly as the judicial system can accommodate them. That cannot happen, however, until Plaintiffs receive the evidence and testimony this Court ordered the Defendants to produce months ago. Plaintiffs' proposal is also fair and equitable given the broad and ongoing failures and delays on the part of the Brands to meet APTO 47 deadlines, the complexities of the issues in this litigation, and the unfair prejudice that will result if Plaintiffs are unable to obtain critical discovery necessary to appropriately develop their cases.

CONCLUSION

Based on the foregoing, Plaintiffs respectfully request that the Court adopt the proposed modified schedule attached as Exhibit A, and such other relief as this Court deems appropriate.

LOCAL RULE 7.1 CERTIFICATE

Pursuant to Local Rule 7.1, prior to filing this motion, undersigned counsel certify that they conferred with Defendants in a good faith effort to resolve by agreement the relief sought in this motion. Specifically, on Monday, May 3, 2021, Plaintiffs provided Defendants Co-Lead Counsel and the Special Master with Plaintiffs' proposed schedule (Exhibit A). The Brands notified Plaintiffs that they oppose Plaintiffs' proposed schedule (Exhibit A). The Generics have never notified Plaintiffs of their position. The Distributor, Retailer and Pharmacy Defendants

notified Plaintiffs that they defer to the position of the Brands, and do not take an independent position regarding the competing scheduling proposals.

Dated: May 7, 2021

Respectfully submitted,

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Plaintiffs' Leadership Development Committee

CERTIFICATE OF SERVICE

I hereby certify that on May 7, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

/s/ *Robert C. Gilbert*
Robert C. Gilbert

EXHIBIT A

PLAINTIFFS' MODIFIED PTO 30 SCHEDULE

The modified schedule below is contingent on and subject to Defendants' certification of completion of production of clinical, preclinical, nonclinical and study related documents and data no later than June 15, 2021, and certification of completion of all noncustodial document production by September 1, 2021. Failure of Defendants to certify completion of production by these dates will necessitate further modification of subsequent deadlines set forth hereunder.

PTO 30	**New Deadline**	**Event**
May 14, 2021	May 14, 2021	Parties begin discussions regarding process for selection of potential bellwether personal injury cases. (Bellwether Selection)
May 14, 2021	July 15, 2021	Parties meet and confer concerning any outstanding general causation discovery.
August 16, 2021	August 16, 2021	Completion of joint process and plan for selecting potential bellwether personal injury cases (Bellwether Selection). The Parties, in conjunction with the Special Master, shall hereafter begin implementation of the Bellwether Selection process and plan, utilizing the Registry and any other resources, including formal discovery, as agreed to by the Parties, or as ordered by the Court. The Parties and Special Master shall submit regular reports to the Court on the status of the implementation and narrowing of the Bellwether Selection pool, to be refined and amended for good cause as appropriate until final Bellwether Selection following the Court's general causation *Daubert* ruling.
June 2, 2021	October 22, 2021	Plaintiffs' disclosures of disciplines and specializations of general causation experts, and areas of expertise relevant to each expert's general causation expert report. The parties shall meet and confer about the format of these disclosures.
____	November 16, 2021	The Parties and Special Master shall submit a report, preferably jointly, to the Court on the status of the implementation and narrowing of the Bellwether Selection pool.

PTO 30	**New Deadline**	**Event**
July 2, 2021	November 19, 2021	Defendants' disclosures of disciplines and specializations of general causation experts, and areas of expertise relevant to each expert's general causation expert report. The parties shall meet and confer about the format of these disclosures.
July 16, 2021	December 3, 2021	Plaintiffs' supplemental disclosures, if any, of disciplines and specializations of general causation experts, and areas of expertise relevant to each expert's general causation expert report, based on Defendants' disclosures. The parties shall meet and confer about the format of these disclosures.
December 20, 2021	December 20, 2021[1]	Completion of all fact discovery of Defendants, including on issues related to general causation and class certification.
August 2, 2021	January 24, 2022[2]	Plaintiffs' expert reports on general causation and provision of three (3) dates on which each expert is available for deposition.
September 21, 2021	March 14, 2022	Defendants' expert reports on general causation and provision of three (3) dates on which each expert is available for deposition.
——	March 16, 2022	The Parties and Special Master shall submit a report, preferably jointly, to the Court on the status of the implementation and narrowing of the Bellwether Selection pool.
October 12, 2021	April 7, 2022	Plaintiffs' rebuttal reports, if any, on general causation.
December 13, 2021	May 20, 2022	Completion of expert depositions on general causation.
December 20, 2021	June 9, 2022	*Daubert* motions on general causation.

[1] This date is contingent on the certification of completion of Defendants' production of clinical, preclinical, nonclinical and study related documents and data no later than June 15, 2021, and certification of completion of all noncustodial document production by September 1, 2021.

[2] *See* footnote 1.

PTO 30	**New Deadline**	**Event**
——	June 16, 2022	The Parties and Special Master shall submit a report, preferably jointly, to the Court on the status of the implementation and narrowing of the Bellwether Selection pool.
March 21, 2022	July 24, 2022	Oppositions to *Daubert* motions on general causation.
April 21, 2022	August 8, 2022	Replies in support of *Daubert* motions on general causation.
——	September 16, 2022	The Parties and Special Master shall submit a report, preferably jointly, to the Court on the status of the implementation and narrowing of the Bellwether Selection pool.
14 days after General Causation Daubert ruling	14 days after General Causation Daubert ruling	The Parties will submit a final report to the Court on status of Bellwether Selection.
December 20, 2021	45 days after General Causation Daubert ruling	Plaintiffs' class certification motions and expert reports.
February 4, 2022	45 days after Plaintiffs' class certification motions	Completion of depositions of Plaintiffs' class certification experts.
March 21, 2022	30 days after completion of depositions of Plaintiffs' class certification experts	Defendants' oppositions to Plaintiffs' class certification motions and expert reports. Defendants' *Daubert* motions directed to Plaintiffs' class certification experts.
April 21, 2022	45 days after Defendants' Oppositions and Daubert motions due	Completion of depositions of Defendants' class certification experts.

PTO 30	**New Deadline**	**Event**
June 4, 2022	30 days after completion of depositions of Defendants' class certification experts	Plaintiffs' replies in support of class certification motions and rebuttal expert reports, if any, on class certification. Plaintiffs' oppositions to Defendants' *Daubert* motions directed to Plaintiffs' class certification experts. Plaintiffs' *Daubert* motions directed to Defendants' class certification experts.
July 5, 2022	20 days after Plaintiffs' replies, oppositions and Daubert motions	Defendants' oppositions to Plaintiffs' *Daubert* motions directed to Defendants' class certification experts. Defendants' replies in support of *Daubert* motions directed to Plaintiffs' class certification experts.
August 3, 2022	20 days after Defendants' oppositions and replies	Plaintiffs' replies in support of *Daubert* motions directed to Defendants' class certification experts.

Exhibit B

STATUS OF TRANCHE 1 CUSTODIAL DOCUMENT PRODUCTION – BRANDS ONLY DUE BY 12/31

green boxes = timely red boxes = late	GSK	BI	Sanofi	Pfizer
# Tranche 1 custodial documents produced between 10/2-11/24	0	0	0	33,410
# of Tranche 1 custodial documents produced between 11/25-12/31	2557	23,661	30,848	30,768
January 2021	7791	389	3633	4,363
PRODUCED LATE FEBRUARY 2021	25,830	6766	6771	1,681
PRODUCED LATE MARCH 2021	17,515	257	3848	2
PRODUCED LATE APRIL 2021	36,523	11,927	4,137	3,140
PRODUCED LATE MAY 1-6, 2021	441	0	6,688	0
TOTAL PRODUCED	90,657 (80,309 LATE)	43,000 (18,950 LATE)	55,925 (21,444 LATE)	72,561 (4823 LATE)

STATUS OF TRANCHE 2 CUSTODIAL DOCUMENT PRODUCTION – BRANDS ONLY

# of **Tranche 2** custodial documents produced in April and May 2021	GSK	BI	SANOFI	PFIZER
	47,182	50,479	258	50,344

STATUS OF NONCUSTODIAL DOCUMENT PRODUCTION – BRANDS ONLY (*varying due dates)				
green boxes = timely red boxes = late	GSK PTO 47 Substantial completion by 3/15	BI PTO 47 Substantial completion by 12/31	Sanofi PTO 47 Substantial completion by 12/20	Pfizer PTO 47 Substantial completion by 10/30
6/1-10/2	78,087	10,742	7185	3504
10/3-11/24	5,778	3844	121	5413
11/25-12/31	1,876	66162	5288	0
January 2021	3,888	579	10,658	2
February 2021	2,947	389	28	1537
March 2021	17,660	67,487	2,827	2
April 2021	117,635	32,138	10,511	669
May 1-May 6 2021	8,898	24,656	0	0
TOTAL:	236,769 (126,533 LATE)	205,997 (125,249 LATE)	36,618 (24,024 LATE)	11,127 (2210 LATE)

EXHIBIT C

Finken, Tracy

From: Finken, Tracy
Sent: Thursday, April 22, 2021 4:51 PM
To: Shortnacy, Michael; Friedman, Robert; Bayman, Andy
Cc: Mike McGlamry; Roopal Luhana; Frank Woodson; DODGE, JAIME LYNNE
Subject: RE: Form 483 and FDA inspection audit

Michael,

Once again your response now raises more questions than answers. The first being why are we just now hearing there are electronic sources that store chromatography and stability testing results? These are specific items we have been requesting from the batch records and could have streamlined the entire discussion and potentially negating the delay of document production from Promeco and once again demonstrates BI withholding highly relevant information until Plaintiffs happened to stumble across your information in document production or decipher between the lines of what you are alluding to in random emails. This is extremely disappointing considering the disingenuous position you all are taking in terms of the PTO 30 modification of deadlines.

Second, I just ran a quick search of BICHROM across our document repository and the documents reference another datasource "Empower 3" which houses chromatrograms. In addition, the documents reference multiple BICHROM and Empower SOP's and such that do not appear to have been produced at this point. We will send a letter on this shortly.

And, third, you are not answering my question in relation to FDA Form 483 audit and inspection. What specifically has BI withheld as too burdensome? How can we identify "specific follow up information" if we have no idea of what is being withheld other than some vague references to other products, etc. Please let us know asap what specific documents have been withheld from the production relating to the FDA Form 483 audit, inspection and CAPAs, etc.

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From: Shortnacy, Michael <MShortnacy@KSLAW.com>
Sent: Thursday, April 22, 2021 2:19 AM
To: Finken, Tracy <tfinken@anapolweiss.com>; Friedman, Robert <RFriedman@KSLAW.com>; Bayman, Andy <ABayman@KSLAW.com>
Cc: Mike McGlamry <mmcglamry@pmkm.com>; Roopal Luhana <luhana@chaffinluhana.com>; Frank Woodson <Frank.Woodson@BeasleyAllen.com>; DODGE, JAIME LYNNE <jdodge@emory.edu>
Subject: RE: Form 483 and FDA inspection audit

Tracy,

1. Regarding your first question on the 483 documents, BI has produced to date around 775 documents relating to the 483. These documents are sourced from custodial files and noncustodial files (including the formal

correspondence with FDA). We pulled documents from the custodial files of key custodians involved in the 483 (as well as others, in total, 26 custodians), and also from a sharefile where relevant 483 documents are stored.

We have an additional 150 sharefile documents to produce on **4/30**, including Excel files that require native redactions because they relate to other products than Zantac. We are not withholding other relevant documents on grounds of burdensome redactions.

We have tried to be very transparent with you about the fact that there *are* other documents relating to the 483 generally (including the inspection, the 483, and remediation) that BI is not producing because that scope is overly broad in that it seeks irrelevant information. In addition, pulling all of those documents that do not relate Zantac in any way would be burdensome. We have said this from the start in our written discovery responses in September 2020, and in our discussions this February and March. And, we have asked that if on review of the 483 materials BI has produced (and we tried to identify them when we produce them), you ask for specific follow up information we will meet and confer on it. But we have not received such an ask from you. We are not hiding the ball, but have been telling you we do not appear to agree on the scope of your ask. We believe Plaintiffs have the relevant information.

Regarding your third bullet point, we are obtaining the latest quarterly submission to FDA, as I said in my email before, and we will produce it to you if it contains Zantac related information. We are trying our best to do this promptly as we appreciate the May 12 depo date is three weeks away.

2. With respect to the Promeco batch records, BI is on track to voluntarily produce 553 additional batch records this Friday, **4/23** (about 21,451 documents, bringing the total then produced to about 25,000 documents). We have shown you a chart with the time distribution over the period 2015-2019, and believe you will have the complete year of 2019. For the earlier period of 2009 to 2015, our proposal last week was to provide a statistically significant sample. We believe there should not be disagreement here, and also have not heard from you a response on BI's proposal made last week.

   If it is helpful to reach agreement, BI can provide some form of declaration attesting to its collection process. In short, batch records are being pulled by time period by the archivist and once the records are delivered to the vendor for on-site scanning, those records enter a pipeline to production to you. There is no intermediary step where records are hand-selected or cherry picked. That is simply not the process, and if that is any concern to Plaintiffs BI will attest to its collection process.

   With respect to your second bullet, our understanding is that *all* batch-level testing is reflected in the hard copy batch records that BI has been electronically scanning and producing in the litigation since April 2nd. The electronic sources I was referring to below are two BI data systems called "LIMS" and "BICHROM". These systems store raw test data, including relating to chromatography and stability testing. These are the sources I mentioned in our last meet and confer as the underlying data – where the results and chromatograms are entered on the printed pages (including Certificates of Analysis) being provided to you. We have not previously met and conferred on these specific sources with you, but are prepared to meet and confer to discuss the burdens and understand from you why underlying data (when you have results) is necessary or proportional.

   Also, please remember that stability test data are also found, in some cases, on various BI network share file locations, which are sometimes nominated in the file path as produced in this litigation with the Spanish words: "Estabilidad" or "estabilidades."

We hope this adds further clarity to these topics, and that the parties can report to the Court agreement on the question of batch records by Friday 4/23.

Michael

Michael B. Shortnacy
Partner

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From: Finken, Tracy <tfinken@anapolweiss.com>
Sent: Tuesday, April 20, 2021 10:38 AM
To: Michael Shortnacy <MShortnacy@KSLAW.com>; Robert Friedman <RFriedman@KSLAW.com>; Andy Bayman <ABayman@KSLAW.com>
Cc: Mike McGlamry <mmcglamry@pmkm.com>; Roopal Luhana <luhana@chaffinluhana.com>; Frank Woodson <Frank.Woodson@BeasleyAllen.com>; DODGE, JAIME LYNNE <jdodge@emory.edu>
Subject: RE: Form 483 and FDA inspection audit

External Sender

1) Let me ask this question more simply. What specific documents relating to the Form 483 audit have been withheld as being too cumbersome to redact? We need to know the specifics of what has been withheld.

2) I didn't raise any new questions. I clarified my prior question because it appeared that you misunderstood and then I asked a follow up question related to the "electronic sources" that you referred to in your email. What are those electronic sources relating to batch testing/records and have those sources been disclosed in prior correspondence and/or your discovery responses?

3) Rob had previously represented to me that Geelan could not testify in mid-march because of a meeting or hearing that was going to occur with the FDA regarding the Form 483 audit. Have all documents and communications relating to that meeting or hearing or whatever it was that occurred in mid-March, been produced?

Thanks,

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From: Shortnacy, Michael <MShortnacy@KSLAW.com>
Sent: Tuesday, April 20, 2021 1:30 PM
To: Finken, Tracy <tfinken@anapolweiss.com>; Friedman, Robert <RFriedman@KSLAW.com>; Bayman, Andy <ABayman@KSLAW.com>
Cc: Mike McGlamry <mmcglamry@pmkm.com>; Roopal Luhana <luhana@chaffinluhana.com>; Frank Woodson <Frank.Woodson@BeasleyAllen.com>; DODGE, JAIME LYNNE <jdodge@emory.edu>
Subject: RE: Form 483 and FDA inspection audit

Tracy,

In response to your email of Sunday (4/18) and further to Rob's response below (regarding the 483), we wanted to provide some additional information. You have now raised other follow up questions on batch records in your email of a few minutes ago that are off-thread, and ones are not (because you just posed them) addressed below. We will read your email and respond to you as we can on your new / follow up batch record questions.

First, to clarify, in our meet and confer discussions about the FDA inspection, BI never agreed to produce what you describe below in your email as "all of the documents related to the Form 483 inspection." BI has maintained that "all documents related" is not proportionate because there are non-Zantac / other products included in this 483 (requiring substantial redaction for non-relevance) and that the observations that do not mention or relate to Zantac in any away pertain to products BI markets as a part of its ongoing business (and are thus highly confidential).

For example, in our email to you and Mike on 3/19, in addition to describing what BI had already produced on this issue, we also requested that you review the records BI was producing and, if you had additional questions or wanted to know specific pieces of additional information, you would bring those specific issues to our attention.

In our 3/19 email to you, we wrote:

> BI has produced more than just the communications with and presentations to the FDA; in addition, the produced records also include:
>
> - Internal BI communications regarding preparation for the FDA inspection, including a preparatory audit in September 2019;
> - Internal BI communications regarding the 483 observations;
> - Communications with Sanofi before and after the 483;
> - Communications with FDA, including about the 483 observations, FDA EIR, BI responses, further requests from FDA, supplements from BI, and quarterly reports regarding remediation efforts;
> - Internal BI correspondence regarding responding to FDA inquiries and communications from FDA;
> - Internal BI correspondence regarding responding to inquiries and communications from Sanofi;
> - Post inspection draft meeting minutes; and
> - QxP investigation related documents shared with FDA.

In its production transmittal letter on 2/19/2021, BI identified the 483-related documents it was producing:

Documents from non-custodial data sources including those related to the FDA 483 inspection and supply agreements	BOE_ZAN_MDL_000087 3221	BOE_ZAN_MDL_000087 8161
Official correspondence, report and associated documentation relating to the 483 Inspection	BOE_ZAN_MDL_000087 8162	BOE_ZAN_MDL_000087 8743

Since that time, BI has produced an additional 100 or so documents relating to the 483, including in volumes 47 and 49:

Share file documents including monthly sales and pricing reports, chromatography test results, risk assessments, and various other documents.	BOE_ZAN_MDL_000146 1529	BOE_ZAN_MDL_000147 0062

If you have reviewed BI's productions, then you know that BI has produced the Zantac-related information in the categories you identify in your email below.

On a related document production note, we understand that BI is making a quarterly submission to FDA relating to the 483 this month. We do not know whether the submission will have any relation to Zantac, but if it does we will produce it to you as soon as we can after it is submitted.

Second, you also ask below about whether "other FDA investigations/audits of the Promeco facility" during the time period BI was marketing Zantac have been produced. We can confirm there were no prior FDA inspections of Promeco that generated a 483, let alone one that related to Zantac, since the time that Promeco began manufacturing Zantac. And, for further clarity, we also want to stress that BI did not agree to produce "all documents related to FDA inspections of Promeco generally", and it does not believe such information is relevant or proportional to the needs of this case. BI stated this position in its 9/15/2020 responses to Plaintiffs RFP's.

We hope this provides you the information you are seeking and provides some clarity on the 483. We are happy to meet and confer with you about this if, after completing your review of BI's document productions on this topic, you have specific questions.

Michael

Michael B. Shortnacy
Partner

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From: Finken, Tracy <tfinken@anapolweiss.com>
Sent: Tuesday, April 20, 2021 10:23 AM
To: Robert Friedman <RFriedman@KSLAW.com>; Michael Shortnacy <MShortnacy@KSLAW.com>; Andy Bayman <ABayman@KSLAW.com>
Cc: Mike McGlamry <mmcglamry@pmkm.com>; Roopal Luhana <luhana@chaffinluhana.com>; Frank Woodson <Frank.Woodson@BeasleyAllen.com>; DODGE, JAIME LYNNE <jdodge@emory.edu>
Subject: RE: Form 483 and FDA inspection audit
Importance: High

External Sender

Following up on the email string below. And also following up on the subsequent email that I sent which I attach here as well. I understand Michael stated

> "Finally, Tracy raised a question yesterday (Sunday, 4/18) about batch records and testing data. We are addressing Tracy's question here. We did not say that all testing reflected in the batch records has been produced electronically. Rather, we discussed in our meet and confer last week that, typically, in the loose files at the end of the bag of records, printouts of test results, and also chromatograms can be located. But as we told you, those results and values are entered manually on the batch records (and thus you have all the actual results, and not high level summaries, like "pass" "no pass"). The underlying raw data points are in electronic sources that are burdensome to collect, and are challenging to tie to the specifics of each record, making the test results printed in the batch records the easiest and most direct source for the results you seek."

However this is not responsive to the question I asked which was **"You had previously indicated to us and during the last status conference that all of the *electronic records* relating to batch testing of ranitidine/zantac have been produced. Can you give us a bates range where those documents can be found in your production?"**

I didn't ask if all of the testing reflected in the batch records has been produced electronically. I asked for the bates range of where the Electronic records relating to batch testing of ranitidine/Zantac can be found in the production. This question is stemming from the last hearing where you had informed the magistrate that the electronic records related to batch records have been produced. I am trying to determine where the electronic records are in your production related to batch testing.

In addition, you now refer to electronic sources that keep the underlying raw data points. I am assuming that these "electronic sources" have been identified in your discovery responses and prior systems disclosures. Can you please identify which "electronic sources" you are referring to specifically?

Last, I would appreciate a response to the questions I raise regarding Form 483, etc, stated below and in the attached email. Thanks.

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From: Finken, Tracy
Sent: Sunday, April 18, 2021 10:51 AM
To: Friedman, Robert <RFriedman@KSLAW.com>; Shortnacy, Michael <MShortnacy@KSLAW.com>; Bayman, Andy <ABayman@KSLAW.com>
Cc: Mike McGlamry <mmcglamry@pmkm.com>; Roopal Luhana <luhana@chaffinluhana.com>; Frank Woodson <Frank.Woodson@BeasleyAllen.com>; DODGE, JAIME LYNNE <jdodge@emory.edu>
Subject: Form 483 and FDA inspection audit

Rob/Michael/Andy,

When we were scheduling and rescheduling the deposition of Pam Geelan, you had told us that she was going to be in front of the FDA in mid March related to the Form 483 inspection audit that occurred in December 2019. Have you produced all of the documents related to the Form 483 inspection audit through present including:

1) the investigation into it,
2) the CAPAs,
3) the internal files related to this investigation,
4) the FDA communications
5) and any other applicable internal or external documents or data regarding the December 2019 audit and regulatory/remedial measures including but not limited to chromatograms reviewed and/or other testing reviewed, reports, notes, memos, analyses, etc.
6) any transcripts of any FDA hearing or minutes of meetings, or any OTHER documents related to FDA interaction regarding this issue.
7) Any other documents related to this audit/investigation

Please let us know asap.

Thanks,
Tracy

EXHIBIT D

CHAFFIN LUHANA LLP
Doing Good by Doing Right™

Sent from: New York Office

April 6, 2021

Sent Via E-Mail
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Robert B. Friedman
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1180 Peachtree Street NE, Suite 1600
Atlanta, GA 30309
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Re: BIPI Batch Records

Dear Michael and Rob,

I write to follow-up on Plaintiffs' Request for production of batch records. Our goal is to cooperatively work together to come up with a reasonable proposal. Instead of requesting batch records for the 11+ years Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) manufactured, marketed and sold Zantac/ranitidine, we propose limiting batch records to the first two (2) years after each new manufacturing process was implemented for each NDA BIPI held. We expect the batch records (including API and Finished Dose Batch Records) will include the synthesis process, residual solvent testing, assay/impurity testing, API source/manufacturer, temperature controls, humidity controls, packaging details for the API/pills, date of manufacturer of API and finished dose, process and ingredients used to make tablets and coating, temperature used during the tablet formation and when coating is applied and other batch details. To the extent that BIPI was required to collect other information or performed other testing in addition to that which is specifically noted above and which would be included in the "batch records," please let us know.

We also request that BIPI produce all mass spectrometry results with the underlying chromatograms performed on Zantac/ranitidine.

Additionally, we request that BIPI produce all GC-Headspace testing performed on Zantac/ranitidine including results and chromatograms.

If this is acceptable, please let us know when you will be able to start a rolling production of these documents. If you would like to discuss this further, please let us know a good time this week and we will make ourselves available.

Sincerely,

Roopal P. Luhana

cc: Andy Bayman, Esq.
Tracy Finken, Esq.
Michael McGlamry, Esq.
Special Master Jaime Dodge

EXHIBIT E

CHAFFIN LUHANA LLP
Doing Good by Doing Right™

Sent from: New York Office

April 23, 2021

Via E-Mail
Michael Shortnacy, Esq.
King & Spalding LLP
633 West Fifth Street, Suite 1600
Los Angeles, CA 90071
mshortnacy@kslaw.com

Re: Batch Records and Stability Testing

Dear Michael,

We write to follow-up on the batch records and stability testing. We are very concerned with what we have learned and what Tracy has addressed in her emails to you and need to schedule a meet and confer immediately. Please provide a time on Monday that you are able to do so.

As you are aware, my April 6th letter specifically asked for: BIPI to produce all GC-Headspace testing performed on Zantac/ranitidine including results and chromatograms. We met and conferred to address my letter and this very request on April 13th. At this meet and confer, we discussed the sample batch records that were recently produced including everything that was contained in the Batch Record "bag." Then I specifically asked if any of this data is housed anywhere electronically. Your response was no.

In your ESI disclosures, the April 13th Meet and Confer, prior e-mails regarding batch records and discussions regarding the same, you have never disclosed that there are two BI data systems "LIMS" and "BICHROM" that electronically house chromatograms and this data. We find it very concerning you never disclosed this these systems existed and any reference to them was buried in documents described as the FDA 483 inspection and supply agreement documents that were produced in late February. All this time, you have represented the overwhelming burden of producing hard copy records from your Mexico manufacturing plant and yet we just learn that some of this information is electronic.

Moreover, as we discussed on our last call, we'd like to come up with a proposal that works instead of you unilaterally producing documents that we don't believe move the ball forward. Please stop producing any more batch records until we have a chance to properly review what's been produced (where the majority has been in spanish) and then subsequently discuss with you. Additionally, please provide answers to below.

I. Outsourced API

a. What testing did BIPI conduct on API Bulk Batches or samples during the Relevant Time Period for the US Market?
b. Did BIPI initially test (and also periodically test) the outsourced API Bulk Batches or samples during the Relevant Time Period?
c. If so, please identify the Testing, Testing Methods and Testing SOPs and produce them or if already produced, please identify the bates numbers.
d. Did BIPI do Residual Solvent Testing via GC, GC/MS or GC Head-space? If so, we would ask you to produce these chromatograms and testing reports or data, including mass spectrometry results.
e. Produce Stability Records and all stability testing and results including chromatograms and other recorded data for any API samples that did not meet specifications that BIPI tested.

II. Finished Dose Manufacturer

1. Produce Master Batch Template Record include all data fields collected (and explanation of each field).
2. Identify the testing that BIPI did on a finished batch when it exceeded impurity specifications or was deemed OOS or OOT.
3. Identify the SOPs for testing done on the finished batch when it exceeded impurity specifications or was deemed OOS or OOT during the Relevant Time Period; please produce or if already produced, please identify the bates numbers.
4. Produce Stability Records and all stability testing and results including chromatograms and other recorded data, including mass spectrometry results, for any samples that did not meet specifications.
5. Produce Batch Records and all testing and results including chromatograms and other recorded data for failed batches including mass spectrometry results.
6. Please produce the following documents that are identified in SOP 039-PT-21-01747 (BOE_ZAN_MDL_0000874817): 039-PT-21-00869-V "Chemical analysis of semi-finished, finished and in-process product" and 039-PT-21-00020-V "Raw Material Analysis."

In addition, the SOPs you have identified in your April 19th e-mail relating to Stability Testing, Out of Specification Quality Control, Batch Audits and general Product Review are largely from 2020; please produce the applicable SOPs for the entire Relevant Time Period, including each SOP's respective previous versions. Also, these SOPs have general language regarding investigations and re-tests but do not identify the types of testing conducted and therefore do not answer the questions we have raised above.

Lastly, please produce all SOPs and their respective previous versions and other corporate documents such as training guides, data retention policies, etc., related to the BIPI Empower, BICHROM, and LIMS data sources including legacy systems thereto. We are also requesting that BIPI produce all chromatograms and testing reports or data, including mass spectrometry results, relating thereto for ranitidine/Zantac that are electronically available on any of these systems.

Sincerely,

Roopal P. Luhana

cc: Special Master Jaime Dodge
Tracy Finken
Mike McGlamry
Robert Friedman
Andy Bayman
Courtney Griffin