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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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