UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

FEDERAL TRADE COMMISSION STATE OF CALIFORNIA STATE OF ILLINOIS STATE OF MINNESOTA STATE OF NEW YORK STATE OF WASHINGTON and STATE OF WISCONSIN Plaintiffs, v. AMGEN INC. And HORIZON THERAPEUTICS PLC. Defendants.	Case No. 1:23-cv-03053 Judge John F. Kness

PLAINTIFFS' STATEMENT IN ADVANCE OF PRELIMINARY PRETRIAL CONFERENCE

On August 25, 2023, the Plaintiffs and Defendants jointly requested a preliminary pretrial conference to address certain issues concerning scheduling and presentation of evidence. *See* ECF No. 142. Plaintiffs provide below their positions on the relevant issues.

1. The schedule for and anticipated length of the evidentiary hearing.

The parties agree that the evidentiary hearing should begin no earlier than September 13. Subject to the Court's preference for the length of trial days, in Plaintiffs' view it is practicable to begin the evidentiary hearing on September 14 or 15 and still conclude the hearing no later than September 22. Plaintiffs estimate they will require less than 18 hours to present testimony from live witnesses, inclusive of cross-examination of Defendants' witnesses as well as any necessary rebuttal testimony. Plaintiffs anticipate that if necessary at all, fewer than two additional hours will be required for Plaintiffs to present deposition testimony by designation, inclusive of counter-designations. Assuming that Defendants are granted an equal amount of time, and that the Court desires to hear opening statements and closing arguments that consume a total of three hours or less, the evidentiary hearing can be concluded in fewer than eight days.

Plaintiffs believe that the parties can achieve a streamlined presentation due to the relatively narrow issues presented by this case. First, the relevant antitrust markets in which the Court should assess the transaction do not appear to be seriously disputed. While Defendants have declined to jointly stipulate that the relevant antitrust markets are the sale within the United States of FDA-approved drugs to treat Thyroid Eye Disease ("TED") and Chronic Refractory Gout ("CRG"), s*ee* Compl., ECF No. 20, at ¶¶ 37, 46, 47, Defendants did not attempt to undermine Plaintiffs' proposed relevant markets in their Opposition to Plaintiffs' Motion for a Preliminary Injunction. *See* ECF No. 130. Further, Defendants' expert reports neither dispute Plaintiffs' proposed relevant markets nor argue that alternative antitrust markets might be

appropriate. Thus, Plaintiffs expect that limited time during the evidentiary hearing will be required to carry Plaintiffs' burden of proof regarding the relevant markets alleged in the Complaint, despite Defendants' refusal to stipulate on the issue.

Second, Plaintiffs believe that minimal time will be required to establish Horizon's monopoly power within the relevant markets. There is no dispute that Horizon is the only provider within the United States of drugs currently approved by the FDA for the treatment of TED and CRG (i.e., Tepezza and Krystexxa, respectively). *See* Defendants' Answer, ECF No. 77, at ¶¶ 40, 48.

Third, based on the preliminary witness lists exchanged between the parties, no more than 11 fact witnesses will testify at the evidentiary hearing. Plaintiffs intend to call live at the hearing at most seven fact witnesses, and Defendants have identified four additional fact witnesses. In addition to fact witnesses, Plaintiffs intend to call during their case-in-chief four expert witnesses: Plaintiffs anticipate that three of these four will require little time because, as noted above, the appropriate relevant market is not seriously disputed. Defendants have identified six expert witnesses that they may call at the hearing: based on a review of these experts' reports, Plaintiffs anticipate that Defendants' experts largely will offer testimony that is overlapping or entirely duplicative, and Plaintiffs anticipate that any cross-examination will not require significant trial time. Finally, depending on how the Court resolves the issue of rebuttal witnesses (discussed below) and any evidentiary disputes, if necessary Plaintiffs may call one additional expert witness in rebuttal and may also call in rebuttal one of their affirmative experts.

2. The date/time for the final pretrial conference, and date for submission of proposals regarding a final pretrial order.

Plaintiffs request that the final pretrial conference take place close in time to the start of the evidentiary hearing. Accordingly, in the event that the Court determines that the evidentiary

hearing should begin on September 14 or 15, Plaintiffs request that the final pretrial conference take place on September 13 or 14.

Plaintiffs understand that one of the attorneys representing Amgen cannot accommodate a final pretrial conference on September 11 or 12. To accommodate Amgen's counsel, in the event that the Court determines that the evidentiary hearing should begin on September 13, Plaintiffs will join Defendants in a request for a final pretrial conference on September 8.

Plaintiffs' position is that the parties' proposals for a final pretrial order should be submitted two business days prior to the final pretrial conference.

3. Whether the parties can cite in post-trial findings to testimony that was taken during investigational hearings or depositions and was not designated in advance of, or presented to the Court during, the evidentiary hearing.

a. The Court should consider testimony taken during investigational hearings

The Court should consider Plaintiffs' request for a preliminary injunction in light of all of the evidence that will be available in the administrative proceeding to the ultimate finder of fact, as this Court's role is to assess whether Plaintiffs have "raise[d] substantial doubts" about the proposed transaction – that is, "questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance and ultimately by the Court of Appeals." *FTC v. Advoc. Health Care*, No. 15 C 11473, 2017 WL 1022015, at *2 (N.D. Ill. Mar. 16, 2017) (quotations omitted). The evidence that will be available to the Commission, which will act as the ultimate finder of fact during the administrative proceeding, will include all of the sworn testimony taken in pre-Complaint investigational hearings and all of the testimony taken in depositions following the filing of the Complaint. *See* 16 C.F.R. § 3.43(b).[1] This Court should

[1] "If otherwise meeting the standards for admissibility described in this paragraph,

not overlook testimony taken during investigational hearings, as this would risk forcing the Court to consider an incomplete record when assessing Plaintiffs' likelihood of "success on the merits in the underlying administrative proceeding." *FTC v. Meta Platforms Inc.*, No. 5:22-cv-04325, 2022 WL 16637996, at *6 (N.D. Cal. Nov. 2, 2022) ("Section 13(b)'s 'likelihood of ultimate success' inquiry [means] the likelihood of the FTC's success on the merits in the underlying administrative proceedings"). For this reason, federal courts in similar cases in which the FTC has sought a preliminary injunction have routinely considered testimony offered during depositions and investigational hearings. *See, e.g.*, *FTC, et al. v. Thomas Jefferson Univ., et al.*, 20-cv-01113 (E.D. Pa. Sept. 10, 2020), Dkt. No. 224 (permitting FTC to present investigational hearing testimony because "part of the Court's role in the preliminary injunction proceeding will be to determine Plaintiffs' likelihood of success on the merits in the administrative adjudication"); *FTC v. Peabody Energy Corp.*, 492 F. Supp. 3d 865, 897 (E.D. Mo. 2020) (court's opinion citing to an "IH" (i.e., Investigational Hearing) transcript). This Court should do the same.

To the extent that Defendants have objections to any testimony offered during an investigational hearing or deposition, Defendants should file an appropriate motion in limine, to which Plaintiffs should have an opportunity to respond.

b. The Court should not require the parties to either present at the evidentiary hearing or designate in advance of trial all testimony that might be cited in post-trial findings of fact

Defendants appear to propose that the Court should not allow the parties to cite in post-trial proposed findings *any* testimony from depositions or investigational hearings that is not

depositions, investigational hearings, prior testimony in Commission or other proceedings, expert reports, and any other form of hearsay, shall be admissible and shall not be excluded solely on the ground that they are or contain hearsay." 16 C.F.R. § 3.43(b).

presented live at the evidentiary hearing. This would impose an unwarranted burden on the Court. Plaintiffs' goal is to ensure that testimony presented during the evidentiary hearing focus on the crux of the issues in dispute, as it would waste the Court's time to present deposition testimony during the evidentiary hearing that relates to peripheral points. Presumably, Defendants share this goal. Moreover, each party will undoubtedly attempt to present during the evidentiary hearing the testimony that the party deems most salient and persuasive.

As a practical matter, a large amount of testimony has been developed during investigational hearings and depositions that is repetitive of testimony that will likely be provided by live witnesses during the evidentiary hearing, or relates to minor points that do not illuminate the core issues facing the Court. It would waste the parties' resources to designate and counter-designate, in advance of the hearing, a large quantity of testimony to guard against a remote chance that similar testimony is not developed during the evidentiary hearing, or to designate and counter-designate testimony that relates to minor points. For this reason, the Court should not require designations, in advance of the evidentiary hearing, of the testimony that the parties may cite in post-trial findings of fact.

To be clear: Plaintiffs agree with Defendants that any deposition or investigational hearing testimony that will be presented to the Court during the evidentiary hearing should be subject to pre-hearing designations and counter-designations. The parties have discussed a schedule for exchanging such designations and counter-designations, to ensure that the Court is not presented with snippets of testimony that might, due to incompleteness, create a risk of misleading the Court. However, testimony cited in post-trial findings of fact does not create a similar risk, because the entire deposition transcript will be available for the Court's review.

4. Whether Plaintiffs are entitled to present rebuttal witnesses following the close of Defendants' case.

It would create inefficiency for the Court to determine, in advance of the evidentiary hearing, that Plaintiffs should not have any opportunity to present rebuttal witnesses following the close of Defendants' case. Key issues on which Plaintiffs may wish to present rebuttal witnesses relate to Defendants' thirteen affirmative defenses, on which Defendants bear the burden of proof. It would be inefficient to require Plaintiffs to "pre-but" during their case-in-chief every conceivable argument Defendants might make—it will likely benefit the Court to allow Plaintiffs to focus their case-in-chief on the issues on which Plaintiffs bear the burden of proof, and then to allow Plaintiffs to assess after the close of Defendants' case which, if any, of Defendants' affirmative defenses merit rebuttal.

In this instance, it will be particularly inefficient to force Plaintiffs to "pre-but" Defendants' affirmative defense claiming that the proposed transaction might be justified based on efficiencies, Answer at 33, notwithstanding the fact that an efficiencies "defense has never been sanctioned by the Supreme Court," *Advoc. Health Care*, 2017 WL 1022015 at *12. Plaintiffs cannot effectively "pre-but" all of the various supposed efficiencies Defendants have claimed, as a number of Defendants' claimed efficiencies are ill-defined and legally or factually insupportable. Defendants' presentation at the evidentiary hearing will presumably narrow and focus their assertions on the supposed efficiencies that Defendants view as most likely to persuade the Court. Further, a number of Defendants' assertions may fall apart during Defendants' case based on Plaintiffs' cross examination of Defendants' witnesses, such that Plaintiffs will determine that it is unnecessary to proffer any expert testimony to address the supposed efficiency. Permitting Plaintiffs to address Defendants' claims in rebuttal may thus spare the Court and the parties from needing to address some of Defendants' more implausible

claimed efficiencies that are clearly not "merger specific" or "verifiable." *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 349 (3d Cir. 2016).

Moreover, Plaintiffs' proposal does not *require* the Court to hear from rebuttal witnesses; it merely preserves the possibility of a rebuttal case in the event that one is necessary. After the close of Defendants' case, the Court can determine and control the scope of any rebuttal case that Plaintiffs might be allowed to offer. At that point both the Court and the Plaintiffs will be in a better position than they are at present—when Defendants' proof regarding efficiencies has not yet been proffered— to decide whether testimony from one of Plaintiffs' experts might prove illuminating regarding any particular supposed efficiency. Plaintiffs' proposal thus provides the Court with the opportunity to increase the efficiency of the hearing based on more-complete information, while Defendants have not suggested to Plaintiffs any reason that a prohibition on rebuttal witnesses would increase the efficiency of the hearing or conserve judicial resources.

5. Page limits on post-trial proposed findings of fact and conclusions of law.

The parties have agreed that the Court need not address this issue during the preliminary pretrial conference. The parties will continue to meet and confer after Plaintiffs serve their rebuttal expert reports and submit their Reply brief supporting a preliminary injunction, and present either an agreed-upon proposal or competing proposals at the final pretrial conference.

6. Numerical limits on the number of exhibits.

The parties have agreed that this issue need not be addressed during the preliminary pretrial conference. The parties will exchange preliminary exhibit lists limited to 200 exhibits, and both parties anticipate that their final exhibit lists will contain fewer than 200 exhibits.

Dated: August 28, 2023

Respectfully submitted,

/s/ Nathan Brenner

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