UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: TASIGNA (NILOTINIB)
PRODUCTS LIABILITY LITIGATION

Case No. 6:21-md-3006-RBD-DAB
(MDL No. 3006)

This document relates to all actions.

PRETRIAL ORDER NO. 3

The second status conference for this matter was held on Tuesday, October 26, 2021. (Doc. 46.) This Order memorializes the Court's oral pronouncements at that hearing.

I. PFS and DFS

The Court reviewed the parties' competing Plaintiff Fact Sheets ("PFS") (Docs. 29-1, 30-1) and their joint implementing order for the PFS (Doc. 30-2). The Court has fashioned its own PFS using input from both parties' submissions. The final PFS will be attached to a forthcoming separate implementing order, which will be based on the parties' joint proposed language.

The Court also reviewed the parties' joint Defendant Fact Sheet ("DFS") (Doc. 28-1) and the parties' competing implementing orders for the DFS (Docs. 28-2, 28-3). As there is no reason for Defendant to wait until case-specific discovery begins to serve the DFS, nor will the Court pause Defendant's production of the DFS so Defendant can challenge the PFS, the Court rejects

Defendant's proposed order. (*See* Doc. 28-3.) The Court adopts Plaintiffs' proposed order. (Doc. 28-2.) The final DFS will be attached to a forthcoming separate implementing order, which will be based on Plaintiffs' proposed language.

II. Search Terms and Custodians

The Court **REFERS** the issues of appropriate search terms and custodians to U.S. Magistrate Judge David A. Baker for final disposition. His ruling will be set forth by separate order.

III. Motion for Judgment on the Pleadings

At the hearing, the Court orally **DENIED** Defendant's motion for judgment on the pleadings for the reasons set forth therein and explained further below. (Doc. 27; Case No. 6:21-cv-1327, Doc. 87.)[1]

Defendant argued that Plaintiff Colella's claims are preempted primarily because no newly acquired information was discovered after the FDA approved the Tasigna label that would have allowed Defendant to change the label without approval in accordance with the "changes being effected" ("CBE") regulation. (Doc. 27, p. 1.) Plaintiff countered that: (1) preemption is an affirmative defense, so Plaintiff is not required to plead around it in her Complaint, and Defendant's

[1] Although Defendant filed this motion in the lead case, it relates only to the *Colella* member case, No. 6:21-cv-1327, as reflected in Defendant's caption. (Doc. 27, p. 1.) The Clerk then copied the filing into that member case. (Case No. 6:21-cv-1327, Doc. 87.) The *Colella* Plaintiff then appropriately responded in the member case only. (*Id.*, Doc. 89.) The Clerk is **DIRECTED** to file a copy of this Order in that member case in addition to the lead case. Moving forward, Defendant should file case-specific motions only in the relevant member case.

argument improperly attempts to shift its heavy burden of proving preemption to Plaintiff; and (2) the Complaint sufficiently alleges that Defendant did receive newly acquired information that required it to invoke the CBE regulation and change the label. (Case No. 6:21-cv-1327, Doc. 89, pp. 7–18.)

"The standard of review for a motion for judgment on the pleadings is identical to that used to decide motions to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *White v. State Nat'l Ins. Co.*, No. 8:12-cv-2828, 2013 WL 12156318, at *1 (M.D. Fla. Apr. 12, 2013). So the Court must accept the factual allegations in the Complaint as true and construe them "in the light most favorable" to Plaintiff. *See United Techs. Corp. v. Mazer*, 556 F.3d 1260, 1269 (11th Cir. 2009).

A claim is preempted when it is "impossible for a private party to comply with both state and federal requirements." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). To succeed in an impossibility preemption defense—which is "demanding"—the manufacturer must show that "federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law." *Id.* at 1678. "[A]bsent clear evidence that the FDA would not have approved a change to [the] label," courts should not conclude that it was impossible for the manufacturer to comply with both federal and state requirements. *Id.* (cleaned up). "[C]lear evidence" is

"evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *See id.* at 1672.

Here, the Complaint specifically alleges—and the Court accepts as true—that Defendant had newly acquired information not only permitting it, but in fact requiring it, to change the label via the CBE regulation without prior FDA approval. (Case No. 6:21-cv-1327, Doc. 1, ¶¶ 37–48.) And it specifically alleges that Defendant did not fully inform the FDA of the justification for a stronger warning, so the FDA could not possibly have rejected a label change that Defendant never submitted. (*Id.*) As such, the Complaint is sufficiently pled.[2] *See Merck Sharp*, 139 S. Ct. at 1672, 1678. So the Court denied Defendant's motion.

IV. Mediation

The mediation deadline in this matter is **Friday, December 9, 2022**. The Court **APPROVES** the parties' joint selection of mediator Dominic Caparello, Esq.

V. Status Conferences

The next status conference will take place on **Monday, December 6, 2021, at 1:30 p.m.** in person in Courtroom 4A of the Orlando Federal Courthouse. Non-

[2] Defendant acknowledges that its Motion does not even attempt to establish clear evidence. (Doc. 27, p. 15 n.14.)

speaking parties and counsel may appear via telephone. A call-in number will be provided by separate order.

Lead and liaison counsel are **DIRECTED** to meet and confer on a joint proposed agenda for the next status conference. The agenda is due on **Monday, November 22, 2021**. Thereafter, agendas will be due at least ten days prior to status conferences, unless otherwise ordered.

Moving forward, the parties' joint proposed agendas should include: (1) a bullet-point list of agenda items; (2) an indication of whether each item is primarily discovery-related, dispositive, or otherwise; and (3) a brief, non-argumentative statement of each party's position on each item, supported by authority. The agenda must not exceed five pages.

IT IS SO ORDERED.

DONE AND ORDERED in Chambers in Orlando, Florida, on October 28, 2021.

ROY B. DALTON JR.
United States District Judge