

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY;
SANTA FE NATURAL TOBACCO
COMPANY, INC.; ITG BRANDS, LLC;
LIGGETT GROUP LLC; NEOCOM, INC.;
RANGILA ENTERPRISES INC.; RANGILA
LLC; SAHIL ISMAIL, INC.; and IS LIKE
YOU INC.;

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION;

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;

JANET WOODCOCK,
in her official capacity as Acting Commissioner
of the United States Food and Drug
Administration; and

NORRIS COCHRAN,
in his official capacity as Acting Secretary of the
United States Department of Health and
Human Services;

Defendants.

CIVIL ACTION NO. 6:20-cv-00176

**PLAINTIFFS' SECOND MOTION TO EXTEND POSTPONEMENT
OF RULE'S EFFECTIVE DATE**

Plaintiffs respectfully request that the Court grant a second 90-day extension of the initial 120-day postponement of the Rule's effective date, without prejudice to Plaintiffs' ability to seek additional relief if it becomes necessary.¹ In support of this request, Plaintiffs state as follows:

¹ Two former Defendants—Stephen M. Hahn and Alex M. Azar II—have left their official positions. Accordingly, this Motion is directed to their successors, Janet Woodcock and Norris

1. On May 6, 2020, Plaintiffs and Defendants filed a joint motion requesting that the Court postpone for 120 days the effective date of a Final Rule issued by the Food and Drug Administration (“FDA”), which would require the use of eleven new graphic warnings on cigarette packages and advertisements, *see Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141) (“the Rule”). *See* Joint Mot., ECF No. 30, ¶¶ 1, 4, 7 (May 6, 2020). Defendants stipulated that, “[i]n light of the disruptive effects of the global outbreak of COVID-19 on both the regulated community affected by the Rule and on FDA, . . . justice require[d] a 120-day postponement of the Rule’s effective date, from June 18, 2021, to October 16, 2021.” *See id.* ¶ 4. Plaintiffs explained that the Rule would cause irreparable harm, including substantial compliance costs for the Manufacturer Plaintiffs. *See id.* ¶¶ 5–6. Plaintiffs further noted that they would need to seek expedited relief from the Court if the joint motion were not granted. *See id.* ¶ 5.

2. On May 8, 2020, the Court granted the parties’ joint motion. *See* Order, ECF No. 33 (May 8, 2020) (“Postponement Order”). The Court agreed that Plaintiffs would suffer “irreparable injury absent postponement of the rule’s effective date” because they “would face imminent compliance costs” and “those costs would not be reimbursed by the government if plaintiffs prevail[ed] on the merits.” *See id.* at 1–2. The Court thus postponed the Rule’s effective date for 120 days—from June 18, 2021, to October 16, 2021—and set forth a briefing schedule to facilitate an orderly and efficient resolution of this case. *See id.* at 1–4.

3. The parties then proceeded to file merits briefs in accordance with the schedule in the Court’s May 8, 2020 order. *See, e.g.,* Pls.’ Mot. for Summ. J. and a Prelim. Inj., ECF No. 34 (May 15, 2020); Defs.’ Combined Cross-Mot. for Summ. J. and Opp. to Pls.’ Mot., ECF No. 37 (July 2, 2020).

Cochran, as well as the two agency defendants. Although Defendants have not filed a substitution notice relating to the two new officer defendants, such substitution occurs automatically under the Federal Rules of Civil Procedure. Fed. R. Civ. P. 25(d) (“An action does not abate when a public officer who is a party in an official capacity . . . ceases to hold office while the action is pending. The officer’s successor is automatically substituted as a party. Later proceedings should be in the substituted party’s name The court may order substitution at any time, but the absence of such an order does not affect the substitution.”).

In addition, Defendants filed a motion to dismiss for improper venue. Defs.’ Mot. to Dismiss, ECF No. 36 (July 2, 2020). These motions remain pending before the Court.

4. On November 23, 2020, Plaintiffs filed a motion seeking a 90-day extension of the 120-day postponement of the Rule’s effective date. *See* Pls.’ Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 76 (Nov. 23, 2020). Plaintiffs explained that “199 days ha[d] elapsed since the Court postponed the Rule’s effective date, and the Manufacturer Plaintiffs [were again] . . . facing the same imminent compliance costs that the original postponement was designed to address.” *See id.* ¶ 4. Specifically, Plaintiffs noted that the Manufacturer Plaintiffs would have to redesign packaging, modify the printing process, purchase and engrave printing cylinders, print compliant packages, and redesign, modify, and replace point-of-sale advertisements at hundreds of thousands of retailers. *See id.* ¶ 4(a)–(d). Plaintiffs further explained that these steps would cost millions of dollars and thousands of employee hours, which would be unrecoverable if Plaintiffs prevailed, and that the balance of equities strongly favored granting a stay. *See id.* ¶¶ 4–6. Defendants opposed the motion. *See* Defs.’ Opp. to Mot. to Extend Postponement of Rule’s Effective Date, ECF No. 79 (Nov. 25, 2020).

5. Based on the “equitable reasons given in plaintiffs’ motion” and “the reasons stated in the court’s [previous] order . . . postponing the effective date of the challenged rule,” the Court granted Plaintiffs’ motion for an extension of the original postponement. *See* Order, ECF No. 80 (Dec. 2, 2020) (“Extension Order”). Accordingly, the Court postponed the Rule’s effective date and related requirements for “an additional 90 days, until January 14, 2022.” *Id.* at 1 (“The court **orders** that the effective date of the rule is postponed for an additional 90 days, until January 14, 2022. Any obligation to comply with the Tobacco Control Act’s warning requirements, [1]5 U.S.C. § 1333(a)(1) and (b)(1), and the additional requirements in 21 U.S.C. §§ 387c(a)(2) and 387t(a), is also postponed for an additional 90 days, as is any other obligation to comply with a deadline tied to the effective date of the rule.”). The Court further ordered that oral argument on the merits motions would occur on December 11, 2020. *See id.*

6. At that December 11 hearing, the Court asked Plaintiffs when they would “again face imminent compliance cost[s] that will prompt them, if there is no merits ruling at that point and no

injunction, . . . to seek another stay of the rule’s effectiveness.” Tr. of Merits Hr’g (Dec. 11, 2020), at 8:18–22. Plaintiffs’ counsel informed the Court that, if there was no merits ruling and no injunction, Plaintiffs would again face imminent compliance costs requiring them to seek a further extension of the postponement in March 2021—90 days after the December 2020 date on which they would have started to incur engraving costs if not for the extension of the original postponement. *See id.* at 8:23–9:3; Tr. of Status Hr’g (Nov. 19, 2020), at 10:7–18.

7. Eighty-six days have now elapsed since this Court’s order granting a 90-day extension. The Manufacturer Plaintiffs are once again on the threshold of incurring the same irreparable and imminent compliance costs that were identified in the previous joint motion for a stay, the first motion to extend postponement of Rule’s effective date, and the merits briefs and supporting declarations, and that the previous postponement orders were designed to address. *See* Joint Mot. ¶¶ 5–6; Pls.’ Mot. to Extend Postponement ¶¶ 4–5; Pls.’ Mot. for Summ. J. and Prelim. Inj. at 59–64; Decl. of Lamar W. Huckabee, ECF No. 34-5 (May 15, 2020) (attached as Exhibit A); Decl. of Kim Reed, ECF No. 34-6 (May 15, 2020) (attached as Exhibit B); Decl. of Francis G. Wall, ECF No. 34-7 (May 15, 2020) (attached as Exhibit C); Pls.’ Combined Reply and Resp., ECF No. 59, at 39–40. The legal analysis and balance of the equities are indistinguishable from the previous extension motion, which this Court granted in December 2020. *See* Extension Order at 1; Pls.’ Mot. to Extend Postponement ¶¶ 5–6. Another extension is therefore warranted under 5 U.S.C. § 705.

8. Accordingly, Plaintiffs request an additional 90-day extension of the postponement of the Rule’s effective date and related requirements, from January 14, 2022 to April 14, 2022. *See* Extension Order at 1. Plaintiffs further request that the additional 90-day extension be granted without prejudice to Plaintiffs’ right to move for additional relief at a later date, including another motion requesting a further postponement of the Rule’s effective date, and without prejudice to Plaintiffs’ pending motions.

9. As detailed in the certificate of conference, counsel for Plaintiffs and Defendants have discussed Plaintiffs’ intention to file this motion, and Defendants’ counsel has informed Plaintiffs’

counsel that Defendants oppose this motion for substantially the same reasons set forth in Defendants' opposition to Plaintiffs' previous motion for a 90-day extension.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.