

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;

STEPHEN M. HAHN,
in his official capacity as Commissioner of the
United States Food and Drug Administration;
and

ALEX M. AZAR II,
in his official capacity as Secretary of the United
States Department of Health and Human
Services;

Defendants.

CIVIL ACTION NO. 6:20-cv-00176

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

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

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 at ¶¶ 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.* at ¶¶ 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.* at ¶ 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). In addition, Defendants filed a motion to dismiss for improper venue. Defs.’ Mot. to Dismiss, ECF No. 36 (July 2, 2020). Those motions remain pending before the Court. At a status conference on November 19, 2020, the Court indicated that it will rule on the motion to dismiss imminently and that it anticipates scheduling an oral argument on the merits motions.

4. 199 days have elapsed since the Court postponed the Rule's effective date, and the Manufacturer Plaintiffs now find themselves facing the same imminent compliance costs that the original postponement was designed to address. These costs include the need to spend millions of dollars and thousands of employee hours to prepare to comply with the Rule. *See* Pls.' Mot. for Summ. J. and a Prelim. Inj. at 59–64; Pls.' Combined Reply and Resp., ECF No. 59 at 39–40 (Aug. 14, 2020); Decl. of Lamar W. Huckabee, ECF No. 34-5 (May 15, 2020) (“Huckabee Decl.”) (reattached here as Exhibit A); Decl. of Kim Reed, ECF No. 34-6 (May 15, 2020) (“Reed Decl.”) (reattached here as Exhibit B); Decl. of Francis G. Wall, ECF No. 34-7 (May 15, 2020) (“Wall Decl.”) (reattached here as Exhibit C). If the current effective date remains in place, the Manufacturer Plaintiffs will incur, *inter alia*, the following imminent compliance costs:

- a. The Manufacturer Plaintiffs will need to re-design hundreds of packaging labels (not including the variations required to accommodate the eleven different graphic warnings) to comply with the Rule. *See* Huckabee Decl. ¶ 8 (390 labels total for R.J. Reynolds Tobacco Co. and Santa Fe Natural Tobacco Co., Inc.); Reed Decl. ¶ 7 (121 labels for ITG Brands, LLC); Wall Decl. ¶ 13 (200 labels for Liggett Group LLC). This in turn requires the Manufacturer Plaintiffs to spend significant funds and thousands of hours of employee and supplier time related to modifying the current printing process, redesigning the packages, and gaining approval for the new designs and operational changes. *See* Huckabee Decl. ¶¶ 10, 12–13; Reed Decl. ¶¶ 9, 11–12; Wall Decl. ¶¶ 17–18. Some of this logistics, design, and approval work has already had to be done, *see* Huckabee Decl. ¶ 10 (“process has been underway”); Reed Decl. ¶ 18 (“must continue with these steps”); Wall Decl. ¶ 7 (“continuing economic costs”), and all of it necessarily must be completed before the next substantial compliance step: the engraving of the printing cylinders. It must therefore be finished before December 2020 for Liggett and before January 2021 for R.J. Reynolds, Santa Fe, and ITG Brands. *See* Huckabee Decl. ¶ 11; Reed Decl. ¶ 10; Wall Decl. ¶ 19.

- b. The Manufacturer Plaintiffs must also purchase additional blank cylinder bases and tools. *See* Huckabee Decl. ¶ 11; Reed Decl. ¶ 10; Wall Decl. ¶ 19. They must then hire companies to begin engraving cylinders that will be used to apply ink to new packages—at a cost of over \$17.8 million—by December 2020 for Liggett and by January 2020 for R.J. Reynolds, Santa Fe, and ITG Brands. *See* Huckabee Decl. ¶ 11 (“the work to engrave the cylinders will take several months and must begin within ten months after the Rule is published (taking into account the 120-day postponement of the effective date)”; Reed Decl. ¶ 10 (“the work to engrave the cylinders will take at least five months and must begin within ten months after the Rule is published”); Wall Decl. ¶¶ 19, 23 (“Under ideal circumstances, the engraving process would take approximately five or six months, meaning engraving would need to begin by December 2020. This estimate likely materially underestimates the time required to complete the engraving process, especially given the COVID-19 crisis.”); *see also id.* ¶ 23 (noting that there are a “limited number of companies that engrave cylinders and print packaging” and that “many different cigarette manufacturers would be competing for finite engraving and printing capacity”).
- c. After that, the Manufacturer Plaintiffs must incur additional costs of more than ten million dollars and thousands of employee and supplier hours to redesign webpages, and to redesign, print, and replace point-of-sale advertisements at hundreds of thousands of retailers. *See* Huckabee Decl. ¶ 15; Reed Decl. ¶ 15; Wall Decl. ¶ 25.
- d. The Manufacturer Plaintiffs must then manufacture cigarettes in compliant packaging starting no later than July 2021, which would result in hundreds of millions of dollars of misbranded inventory if the Rule were subsequently invalidated. *See* Huckabee Decl. ¶ 16; Reed Decl. ¶ 16; Wall Decl. ¶¶ 11, 28.
5. These expenditures of resources for the purpose of meeting the Rule’s requirements constitute irreparable harm because Plaintiffs cannot recover money damages should the Rule and/or the graphic-warning requirement in the Tobacco Control Act be invalidated. *See* Pls.’ Mot. for Summ. J. and a Prelim. Inj. at 62–63; Postponement Order at 2. Moreover, compliance efforts would be even

more burdensome and complex given the COVID-19 pandemic and the accompanying disruptions to business operations. *See* Huckabee Decl. ¶ 17; Reed Decl. ¶ 14; Wall Decl. ¶ 15.

6. Given the imminent irreparable injury that Plaintiffs face if the postponement of the Rule is not extended, Plaintiffs request that the Court issue an order, pursuant to 5 U.S.C. § 705, that the postponement of the Rule's effective date be extended by 90 days, until January 14, 2022, and that any obligation to comply with other deadlines tied to the issuance of the Rule is also postponed for an additional 90 days.¹ Plaintiffs have presented “a substantial case on the merits” of their claims, which involve serious legal questions. *See Weingarten Realty Investors v. Miller*, 661 F.3d 904, 910 (5th Cir. 2011) (explaining “the movant only needs to present a substantial case on the merits” when “there is a serious legal question involved and the balance of equities heavily favors a stay”); *see also Texas v. EPA*, 829 F.3d 405, 424, 435 (5th Cir. 2016) (applying stay factors from *Nken v. Holder*, 556 U.S. 418 (2009), in deciding to grant a stay under § 705); *Nevada v. United States Dep't of Labor*, 227 F. Supp. 3d 696, 698 (E.D. Tex. 2017) (concluding that “whether the Department of Labor's proposed overtime regulations are legal” is a serious legal question); Tr. of Mot. to Dismiss Hearing (Sept. 9, 2020), at 17:6–10 (interpreting the case law as requiring “the Court to consider all of the equitable factors” and noting the Court “reviewed and made some preliminary assessment of the likelihood of success on the merits”). In addition, the “balance of equities heavily favors a stay,” *Miller*, 661 F.3d at 910, particularly in light of the serious injuries that Plaintiffs face if an extension is not granted and the fact

¹ The Tobacco Control Act imposes several additional labeling requirements, *see* 15 U.S.C. § 1333(a)(1), 21 U.S.C. §§ 387c(a)(2), 387t(a), tied to the effective date of the graphic-warnings Rule, *see* Pub. L. No. 111-31, § 201(b); *id.* § 103(q)(5); *id.* § 301. If this Court extends the postponement of the effective date of the Rule by 90 additional days, Plaintiffs request that any obligation to comply with these additional requirements be postponed by an additional 90 days. *See* Postponement Order at 2 (“Any obligation to comply with a deadline tied to the effective date of the rule is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.”). The Rule also recommended (but did not require) that manufacturers submit compliance plans “as soon as possible . . . , and in any event within five months after publication of th[e] final rule.” 85 Fed. Reg. at 15,695. If the Court grants the relief sought in this motion, Plaintiffs would understand that language to recommend submission of the plans as soon as possible, and in any event within 5 months plus 210 days after the Rule's publication.

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