IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO COMPANY, LORILLARD TOBACCO COMPANY, COMMONWEALTH BRANDS, INC., LIGGETT GROUP LLC, and SANTA FE NATURAL TOBACCO COMPANY, INC.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration, and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,

Defendants.

Civil Action No. 11-01482 (RCL)

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO ESTABLISH BRIEFING SCHEDULE

On August 19, 2011, Plaintiffs filed a Motion for Summary Judgment on their claim that FDA's recent regulation requiring shocking and disturbing graphic warnings on all cigarette packaging and advertising violates the First Amendment and was promulgated in violation of the Administrative Procedure Act ("APA"). Dkt. No. 10 ("SJ Motion") (challenging FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) ("the Rule")). At the same time, Plaintiffs also filed a Motion for Preliminary Injunction pursuant to 5 U.S.C. § 705 and Federal Rule of Civil Procedure 65, in which they seek a short postponement of the effective date of the Rule and the related labeling requirements tied to the effective date of the Rule. Dkt. No. 11 ("PI Motion")). On August 22, 2011, Defendants filed a motion proposing a briefing schedule for Plaintiffs' PI Motion and the parties' dispositive motions. *See*

Dkt. No. 14 ("Extension Motion"). As explained below, the schedule proposed by Defendants is facially unreasonable and would cause irreparable injury to Plaintiffs, and should therefore be rejected by this Court. Instead, the Court should adopt Plaintiffs' proposed briefing schedule, which itself significantly extends the time Defendants have to respond while avoiding the unjustified imposition of irreparable harm on Plaintiffs.

1. Plaintiffs face irreparable injury absent a preliminary injunction: As explained in Plaintiffs' PI Motion (pp. 14-17), it will take Plaintiffs more than a year of vigorous efforts, at a cost of millions of dollars, to redesign, order, install and test equipment capable of printing the new warnings in the colors and styles required by the Rule. Indeed, Congress provided for a 15-month implementation period of the Rule, and FDA "agree[d] this is an appropriate amount of time for implementation." 76 Fed. Reg. at 36,703. It is likewise clear that Plaintiffs cannot risk disregarding the Rule until there is greater legal certainty about its validity. As a practical matter, this means that Plaintiffs cannot wait for this Court to rule on their summary judgment motion before beginning to prepare their new packaging. Therefore, unless the effective date of the new warnings is enjoined until 15 months after this Court rules on the merits of Plaintiffs' claims, Plaintiffs will be forced to spend millions of dollars and thousands of employee-hours, which would be irretrievably lost if, as is likely, Plaintiffs prevail on their ultimate claims. *See Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D. D.C. 2010) (holding that economic injury caused by FDA's APA violation is irreparable "because plaintiffs cannot recover money damages against FDA") (Leon, J.). Conversely, given the unhurried pace at which Congress and FDA acted to implement the new warnings, as well as FDA's findings that the Rule will produce minimal or no benefits, it is clear that a brief delay in implementation of the Rule will cause no harm to the interests of the Government or the public.

2. Motions for preliminary injunctions must be resolved on an expedited basis: This case presents precisely the situation in which 5 U.S.C. § 705, the Federal Rules of Civil Procedure, the Local Rules, and basic principles of equity call for the issuance of prompt preliminary relief to avoid irreparable injury. Under 5 U.S.C. § 705, a court reviewing agency action is explicitly authorized to "postpone the effective date of an agency action or to preserve status or rights *pending conclusion of the review proceedings*." (Emphasis added.) Likewise, Federal Rule of Civil Procedure 65 as well as Local Civil Rule 65.1 both recognize the courts' power to issue preliminary injunctions in a case *prior to a determination of the ultimate merits.* This authority is derived from an "equity practice with a background of several hundred years of history," *Fed. Trade Comm'n v. Weyerhaeuser Co.*, 665 F.2d 1072, 1084 (D.C. Cir. 1981), under which courts have traditionally had the power to issue injunctive relief on an expedited basis where necessary to avoid irreparable injury prior to adjudicating the ultimate merits. Indeed, Local Rule 65.1(c) reflects the expedited nature of the preliminary injunction process by providing that "[t]he opposition [to a motion for preliminary injunction] shall be served and filed within seven days after service." LCvR 65.1(c). Likewise, Local Rule 65.1(d) sets out a presumptive rule that "a hearing on an application for preliminary injunction shall be set by the court no later than 21 days after its filing" and allows the Court to refuse to hear live witness "where the need for live testimony is outweighed by considerations of undue delay." LCvR 65.1(d).

3. The extension sought by Defendants is facially excessive and unjustified: In their Motion To Establish Briefing Schedule, however, Defendants seeks to extend the 7-day period called for under the Local Rules to *60 days*. Extension Motion at 3. Defendants thus seek to file their opposition to Plaintiffs' request for *preliminary* relief at the same time they seek to file their

opposition to Plaintiffs' request for *final* relief. Under this schedule, the Court could not reasonably be expected to rule on Plaintiffs' motion for *preliminary* relief before January 2012, four and a half months after it was filed.

Adopting Defendants' proposed schedule would effectively deny Plaintiffs' motion for a preliminary injunction, because it would require that Plaintiffs suffer millions of dollars of irreparable harm before this Court issues a ruling. Indeed, Plaintiff R.J. Reynolds alone plans to spend over $4 million between November, 2011 and January, 2012 in order to meet the current effective date of September 22, 2012. *See* PI Motion, Exhibit 5, Declaration of J. Brice O'Brien ¶¶ 9-12. Plaintiffs Lorillard Tobacco Company, Commonwealth Brands, Inc., Liggett Group LLC, and Santa Fe Natural Tobacco Company similarly plan to expend significant amounts of money in unrecoverable compliance costs. *See generally* Declaration of Stephen Klepper; Declaration of Victor D. Lindsley, III; Declaration of William Melton; Declaration of Gregory A. Sulin; Declaration of David D. Depalma.

Defendants do not dispute these costs, but instead argue that the extraordinary extension they seek is justified by "Plaintiffs' delay" and because simultaneous briefing is "more efficient." Extension Motion at 4. Neither argument is well founded: Plaintiffs have left more than adequate time for briefing on their PI motion and delaying the adjudication of preliminary relief until final judgment will result in the unnecessary expenditure of millions of dollars.

First, Defendants note that some of the Plaintiffs in this action briefed "arguments similar to those made here" in their 2009 challenge to various provisions of the Tobacco Control Act. *Id.* at 2 (citing *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010)). Defendants then argue that, in light of their familiarity with the general legal issues at stake in this case, Plaintiffs unduly delayed by not filing their complaint more quickly after publication of

the Rule. *Id.* at 1-2. As an initial matter, it is of little relevance that some of the Plaintiffs here were also parties in the *Commonwealth Brands* case. The plaintiffs in *Commonwealth Brands* argued that the Act's general warnings requirement was facially unconstitutional, but they did not raise the claim brought by Plaintiffs here—that the particular warnings selected by the Rule are unconstitutional as applied. Nor could they have raised such a claim, as the Rule had not yet been promulgated when that case was filed. As demonstrated by Plaintiffs' Summary Judgment Motion, which turns almost exclusively on the findings and and requriements of FDA's Rule, Plaintiffs' claims in this action arise from factual predicates and a legal context that simply did not exist in the *Commonwealth Brands* case.

Plaintiffs' timing, moreover, was eminently reasonable and provides the court and Defendants with more than adequate time to resolve their PI motion. The Rule at issue in this case occupies 149 pages of the Federal Register and extensively cites complex social science research and economic analysis. *See* 76 Fed. Reg. 36,628-67,777. Although Defendants may be intimately familiar with the Rule, Plaintiffs could of course not fully analyze it until it was published. As FDA itself noted, although "manufacturers have known this rule was coming, in some form, since the passage of the [Act], it is only with the publication of the final rule that they . . . [knew] its exact form." 76 Fed. Reg. at 36,716. Plaintiffs acted promptly to file this case after publication of the Rule and have left adequate time for the Court to decide their preliminary injunction motion. Indeed, Plaintiffs have always been willing to agree to a briefing schedule that would provide the Government three times the normal period to file its opposition to their PI motion. Consequently, Defendants have more than ample time to address the issues raised therein.

Second, Defendants argue that their briefing schedule will be "more efficient" because Plaintiffs' PI Motion will turn in part on the ultimate merits of Plaintiffs' claims. Extension Motion at 4. This is plainly wrong, since it would require Plaintiffs to unnecessarily expend millions of dollars that can never be recouped. And it would do this where the record is clear that a short delay in the Rule will have *zero* impact on public health. This is a definition of "efficiency" that only the Government could adopt. Moreover, it is contrary to the recognized need to act expeditiously on motions for preliminary injunctions in order to avoid irreparable harm. After all, *every* motion for a preliminary injunction turns in part on the merits of the movant's ultimate claim. Thus, *every* motion for a preliminary injunction involves the type of "inefficiency" cited by the Government. That is obviously no basis to delay adjudication of preliminary injunctions until final adjudication of the merits, because the paramount "inefficiency" that the law recognizes is the irreparable harm caused by failure to adjudicate such issues quickly. *Cf. Weyerhaeuser*, 665 F.2d at 1083 ("The determination of a likelihood of success must be made under time pressure and on incomplete evidence."). Indeed, the very premise of the preliminary injunction process is that preliminary relief will be decided *before* the ultimate merits.

The briefing schedule sought by the Government would deprive Plaintiffs of the very relief they seek in their PI Motion by forcing them to incur millions of dollars in costs that would be irretrievably wasted if, as is likely, the Court were to invalidate the Rule. If Defendants disagree with the substance of Plaintiffs' PI motion, they may voice that disagreement in their Opposition and allow the Court to grant or deny preliminary relief while there is still time to avoid irreparable injury to Plaintiffs. But Defendants should not be allowed to deny Plaintiffs preliminary equitable relief simply by running out the clock through a briefing schedule.

4. Plaintiffs' proposed schedule: In light of the foregoing, Plaintiffs respectfully request the following PI briefing schedule:

- September 9, 2011 (21 days after Plaintiffs' Motion): Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction.

- September 23, 2011 (14 days after Defendants' Opposition): Plaintiffs' Reply in Support of Plaintiffs' Motion for Preliminary Injunction.

If the Court agrees, then Plaintiffs do not object to Defendants' proposed schedule for SJ. However, if the Court disagrees and wishes to set a combined schedule, then Plaintiffs submit that, absent preliminary relief, the Government's proposal unnecessarily delays resolution of the case, inflicting unnecessary and irreparable injury on Plaintiffs. Therefore, if the Court rejects Plaintiffs' request for preliminary briefing on their PI Motion, Plaintiffs alternatively propose the following deadlines, which already reflect substantial extensions beyond the default briefing periods set forth in Local Rule 7 for summary judgment motions and Local Rule 65.1 for preliminary injunction motions:

- September 19, 2011 (30 days after Plaintiffs' Motions): Defendants' consolidated response to Plaintiffs Motion for Preliminary Injunction and Motion for Summary Judgment; Defendants' Cross-Motion for Summary Judgment; Administrative Record.

- October 10, 2011 (21 days after prior briefing): Plaintiffs' consolidated reply in support of their motions and opposition to Defendants' Cross-Motion for Summary Judgment.

- October 24, 2011 (14 days after prior briefing): Government's Reply in Support of Defendant's Cross-Motion for Summary Judgment.

Conclusion

For the foregoing reasons, Plaintiffs respectfully request that the Court deny in part and grant in part Defendants' Motion To Establish Briefing Schedule and enter the Proposed Order provided herewith.

Respectfully Submitted,

Dated: August 22, 2011

/s/ Noel J. Francisco

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