

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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

CIVIL ACTION NO. _____

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.

DECLARATION OF STEPHEN BRICE KLEPPER

I, Stephen Brice Klepper, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the Manager, Package Development, of Lorillard Tobacco Company (“Lorillard”), a manufacturer of tobacco products, including Newport cigarettes. I have been employed by Lorillard, and have held that position, for five years. My prior positions have included eight years holding various positions at International Playing Card & Label Company, a rotogravure converting company (now Mundet Tennessee), and provider of soft pack labels, innerframe, and promotional material to the tobacco industry. My responsibilities included development of artwork and engineering specifications, press trials, product development, and technical sales and support to Philip Morris USA, Brown & Williamson and R.J. Reynolds. I

received a Bachelor of Science, Technology, Engineering Design, Graphics/Digital Media from East Tennessee State University in 2003.

2. My responsibilities in my current position at Lorillard as Manager, Product Development, include responsibility for packaging material development and procurement. I ensure that Lorillard's packaging meets all marketing, legal and manufacturing requirements.

3. As a result of my employment by Lorillard, I am fully familiar with Lorillard's manufacturing process, including the steps that will need to be taken, and the time frame that will be required to take steps to comply with new labeling regulations promulgated by the Food and Drug Administration ("FDA") on June 22, 2011, 21 C.F.R. 1141 ("the Regulations") pursuant to Section 201 of the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) ("the Act").

4. I submit this Declaration in support of Plaintiffs' Motion to Postpone the Effective Date of the Regulations to allow Plaintiffs fifteen months, following the entry of Final Judgment by the Court on Plaintiffs' claims in this case, to implement the cigarette labeling requirements of the Regulations, as may be modified or changed as a result of such judicial review. The facts stated herein are based on my personal knowledge regarding the time frames required to change, and the costs of changing existing product labels to comply with the Regulations as they address graphic warnings on cigarette packaging, and the impact on Lorillard with regard to such changes.

The Regulations

5. I have reviewed the portions of the Act and Regulations related to requirements for the inclusion of graphic warnings on cigarette packages. The Act and Regulations require that "the top 50 percent of the front and rear panels of" a package of cigarettes must contain one

of nine specified “WARNINGS” and describe the graphic images that will be required with each Warning, including formatting requirements for each image. The term “package” is defined to include all forms of packaging (*i.e.*, pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers). The Act and Regulations also require rotation of images and warnings.

6. To comply with the Regulations, Lorillard will have to make significant changes to its packaging and labeling for each of its cigarette products so that they include the required warnings and graphic images on every style of packaging, and comply with the mandatory requirements for rotations. Lorillard packages cigarettes in two basic packaging forms, the “crush proof box” and the “soft pack.” These different packs are offered in King Size and 100mm versions. These packs of twenty cigarettes are then packaged into cartons of ten packs. The cartons are then packaged into corrugated cases for shipping. The color, text, and graphic warnings as specified by the FDA Regulations must appear on the pack and carton packages. Regulatory requirements also specify that packaging, including corrugated case containers, bear the statement “Sale Only Allowed in the United States.” Lorillard does not manufacture any packaging materials, and must rely on external vendors to manufacture our packaging needs. It is understood that these same vendors are also used by a large majority of other tobacco manufacturers. As such, there is a possibility of an industry capacity shortage during the implementation of the FDA health warning requirements.

7. The FDA recognized in its Proposed Regulations that implementing a packaging change of this magnitude in an orderly fashion cannot be done quickly, and will require a minimum of one year, and very likely more, from the date when the final configuration of the warnings and graphic images required have been finally determined. *See, e.g., Required*

Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69524, 69554 (Nov. 12, 2010) (“The model further assumes that 12 months is the shortest compliance period that can be met without resorting to covering up the old labels with stickers as a temporary solution.”).

8. The Final Regulations require that all cigarette packaging materials manufactured on or after September 22, 2012, and cigarette packaging introduced into commerce on or after October 22, 2012, must comply with the final labeling requirements as provided for in the Regulations, and cigarettes in noncomplying packaging will be deemed to be misbranded. In order to develop the inventory necessary to comply with these deadlines, Lorillard would need to begin manufacturing cigarettes in compliant packaging beginning in April and May of 2012.

9. To ensure compliance, Lorillard will have to incur significant costs to redesign, manufacture and distribute all the packaging. The steps Lorillard will need to take are described in greater detail below. If, as a result of the judicial challenge by the Plaintiffs in this litigation to the Regulations, changes were required to the Regulations, Lorillard would not only be unable to use, but may have to destroy the inventory of newly-labeled packaging materials and any packed cigarettes in the revised packages that would be nonconforming with the Regulations following judicial review.

Redesigning and Distribution of Packaging

10. There are 16 Lorillard brand families, which include 64 brand packings, that are affected by the Regulations. For each Lorillard brand or brand extension, there are numerous different aspects of packaging (including, *e.g.*, packs, cartons, shipping cases). In total, approximately 207 different Lorillard product packagings would need to be modified in order to comply with any new labeling requirements. The necessary steps and the estimated time required to complete those steps to implement changes to current packaging are detailed below.

11. Lorillard's cigarette packs and packaging materials are created in a multi-step process. In the first step, Lorillard provides Southern Graphic Systems ("Southern Graphics"), with art direction for the design layout for each packaging component. Southern Graphics is an independent company, which holds a requirements contract with Lorillard. Southern Graphics manufactures the plates and cylinders that are used in printing presses to "ink" the packaging according to the design layout.

12. Approximately 823 plates and cylinders must be manufactured in order to create the 207 different product-packaging materials that must be modified. We anticipate that Lorillard can complete and provide art direction to Southern Graphics by mid-September 2011 according to Lorillard's 2012 Packaging Conversion Timeline.

13. After receiving the approval from Lorillard for the design layout, Southern Graphics, in conjunction with Lorillard, produces a "mechanical," which is a paper proof of each of the packaging materials. Printed proofs and digital files of the "mechanical" are created and sent to Lorillard for approval and to the independent businesses that do the printing of Lorillard packaging materials for internal proofing. These proofs must be sent to Lorillard's outside printers because each printing press uses plates and cylinders that are, for the most part, unique to it, and plates and cylinders must therefore be manufactured for the specific printing presses that will be used.

14. The outside printers must supply the necessary specifications for the printing presses that will be used in the printing presses in order for the plates and cylinders manufactured by Southern Graphics to function properly. There are only two printing companies that are equipped to handle the particular challenges inherent in printing the soft packaging used in high-speed cigarette manufacturing machines, and there are only three suppliers of "crush proof"

boxes. We estimate that the mechanical preparation, review, and finalization will take approximately 10 weeks according to the Lorillard 2012 Packaging Conversion Timeline.

15. After Southern Graphics has received the specifications from the outside printers, and the final proofs have been approved, Southern Graphics engraves the required plates and cylinders. A printing cylinder must be prepared by plating the steel core with copper, engraving the copper, and plating the copper with a layer of polished chrome for protection. The quickest and most efficient process is to recycle the existing steel bases currently being used on the engraved printing cylinders. This process requires that the cylinders be returned from the printers to Southern Graphics so that Southern Graphics can strip and remove the existing engraving and etching. Southern Graphics estimates that it would take approximately 18 to 22 weeks (according to the Packaging Conversion Timeline) to produce the 823 plates and cylinders, assuming there are no problems in securing the return of the cylinder to be recycled, no delays occasioned in securing substitute steel bases, and no delays occasioned by the fact that all major cigarette manufacturers may be simultaneously placing very large orders for the engraving of plates and cylinders.

16. In the next step, the finalized plates and cylinders are shipped by Southern Graphics to the various outside printers, and Lorillard must schedule press time from the outside printers for the specific printing presses for which the cylinders and plates were manufactured. Printing presses of the type required to print cigarette packaging materials are almost never immediately available, and therefore require advance scheduling of press time. Moreover, the change in printing jobs requires down time for process changes and printing press adjustments.

17. Lorillard cannot presently estimate the length of the delay between the time that the plates and cylinders become available, and the printing of the first set of product packaging

using the revised labels can begin, although a minimum of approximately six weeks is required. Given that all major cigarette manufacturers would be making similar requests for revised product packagings for hundreds of products, that assumption is likely to greatly understate the time required for this aspect of the process. Even if the six week assumption related to normal conditions could be considered reasonable (which is not likely under the circumstances), the completion of the printing and manufacturing of the packagings would require a minimum of 24 weeks.

18. A stay of the date for compliance that applied only to the requirement for adding the graphic images (and not to the nine new textual warnings) does not solve this dilemma. As a practical matter, all the same steps described above would need to be undertaken if Lorillard is required to begin using the new textual warnings on its packaging in September of 2012. The same steps would need to be undertaken and almost the same number of plates and cylinders would be affected even if the location of the textual warnings were left on the side as opposed to the front and back of the packs.

19. We estimate the costs to Lorillard of acquiring the new printing plates and cylinder to produce compliant packaging will be no less than \$2,250,000.

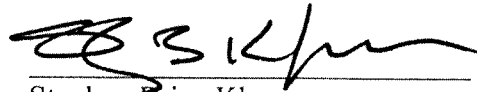
20. So long as any uncertainty exists with regard to the final labeling requirements promulgated by the FDA, Lorillard would need to incur at least the foregoing packaging costs, which I estimate to be approximately \$2,250,000, based on the best estimates Lorillard is able to make at this time. These costs would be incurred between now and September, 2010, even though review by the courts may result in revisions to, or modification of the Regulation, unless the effective date of the Regulations with regard to required labeling changes are postponed, and the company is given fifteen months from the District Court's Final Order to come into

compliance with any revised Regulation. This would enable Lorillard to commence the process of implementing the required changes only after the courts have determined the configuration of the warning statements and graphic images that will actually be required.

21. Absent a postponement, Lorillard would have no choice other than to proceed with implementing the extensive changes necessary to implement the Regulations even before judicial review can take place, as it could not otherwise risk the possibility of noncompliance, regardless of the outcome of judicial review.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on the __1st__ of August, 2011 in Greensboro, North Carolina.



Stephen Brice Klepper
Manager, Package Development
Lorillard Tobacco Company