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. ______________

DECLARATION OF GREGORY A. SULIN

I, Gregory A. Sulin, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

Introduction and Issues

1. I am Senior Vice President and Chief Operating Officer of Liggett Group LLC ("Liggett"). Liggett and its predecessors have been in business for over 135 years. Liggett today has approximately 3.7 percent of the United States cigarette market in terms of unit sales.[1] Liggett's national cigarette brands are *Pyramid*, *Grand Prix*, *Liggett Select*, and *Eve*. Liggett

[1] In this declaration, company data such as market share, numbers of cigarette and packaging styles, costs, and similar information reflect the combined data of both Liggett and its affiliate, Vector Tobacco Inc. Liggett contract manufactures most of the Vector Tobacco Inc. cigarette styles.

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also manufactures several brands that are dedicated to particular retail customers. Liggett manufactures and sells cigarettes only in the United States. The pricing for all of Liggett's cigarette brands places them in what is commonly referred to as the "discount segment" of the domestic cigarette market.

2. I have held my current position since October 2000. I report to the President and Chief Executive Officer. I have responsibility for all aspects of Liggett's manufacturing operations, including the following departments: Manufacturing, Engineering and Maintenance, Operations Finance, Logistics, Research, Product Development, Purchasing, and Tobacco Purchasing. I am also responsible for managing relations with the three unions that represent our manufacturing employees.

3. I have worked in the tobacco industry in various capacities for 41 years. Except for three years, I have been employed by Liggett since 1983. I attended The Pennsylvania State University; studied industrial management at The University of North Carolina at Chapel Hill; and participated in the Manufacturing Executive Program in 1992 sponsored by the Kenan-Flagler Business School at The University of North Carolina at Chapel Hill.

4. This declaration addresses the steps Liggett must take to comply with the new package labeling requirements imposed by the Food and Drug Administration ("FDA") in its regulation implementing the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) (the "Act"). *See* 76 Fed. Reg. 36628 (June 22, 2011) ("the Regulation"). In particular, this declaration describes each step Liggett must take, the cost of each step, and the timeline Liggett will follow, in order to meet the Regulation's September 22, 2012 effective date.

5. The Regulation will require Liggett to redesign completely every pack and carton of every style of all of its cigarette brands. Liggett manufactures approximately 110 separate cigarette styles, each of which is packaged in individual packs, cartons, and cases. Accordingly, the Regulation will require Liggett to overhaul more than 220 distinct packaging designs.

6. In the Act, Congress recognized that it would take cigarette manufacturers at least 15 months to comply with the new labeling requirements, 123 Stat. at 1845, and in the Regulation FDA agreed that this 15-month implementation period was necessary to give cigarette manufacturers time to comply, *see* 76 Fed. Reg. at 36703 ("The Tobacco Control Act specifies a 15-month implementation period for cigarette manufacturers to include required warnings on their packages and for all cigarette advertisements to comply with this rule. We agree this is an appropriate amount of time for implementation of the rule.").

7. Fifteen months is actually a conservative estimate of how long it will take to prepare new labels. *See id.* at 36716 (explaining that the agency included "10 percent rush charges" in calculating the cost of the Regulation because "[r]esources are scarce and a large number of labeling changes [would have to be] simultaneously rushed" to meet the 15-month deadline). To meet the current effective date, under which the Regulation's labeling requirements will apply to any cigarettes manufactured on or after September 22, 2012, and any cigarettes introduced into commerce on or after October 22, 2012, Liggett began taking steps to prepare new labels in 2009. As set forth in greater detail below, to meet these deadlines, Liggett determined that it must begin manufacturing cigarettes in compliant packaging by March 2012 at the latest, and there are a substantial number of steps that must be undertaken before Liggett begins manufacturing cigarettes in the new packaging. Thus, Liggett has already incurred substantial costs—and will continue to incur substantial costs—to undertake the planning and

preparation that necessarily must precede actual manufacturing, including packaging artwork design, printing cylinder acquisition and engraving, and producing sufficient inventories of new packaging for Liggett's entire product line.

8. In the absence of a postponed effective date, Liggett will also incur additional costs because of the legal uncertainty surrounding the Regulation. The Act requires packaging changes that are separate from those required by the Regulation, such as requirements that the packaging include the legend "Sale only allowed in the United States," a statement of the percentages of domestic and foreign tobacco in the product, and the "established name" of the product (cigarettes) in a position and font size yet to be prescribed by FDA. Because these packaging changes will be required by the Act even if those required by the Regulation are held unconstitutional, Liggett will need to have its design agency prepare two complete sets of packaging designs: (1) packaging designs, which implement the packaging changes required by the Act, but not those required by the Regulation and (2) packaging designs, which implement the packaging changes required by both the Act and the Regulation.

9. Accordingly, if the effective date of the Regulation is not postponed, Liggett will be required to incur substantial costs—costs it will not be able to recoup—even if the Regulation is ultimately held unconstitutional.

Tasks and Costs to Implement Packaging Changes

10. Since 2010, Liggett has had its outside design agency working to develop the 220 completely new pack and carton designs that will be needed to comply with the Act and the Regulation. This design work is ongoing and is expected to continue for most of the rest of this year. Liggett has spent approximately $400,000 on the outside agency design work completed thus far, and Liggett estimates that the remaining work will cost approximately $285,000.

11. Given the nature of the packaging changes and the number of individual designs, Liggett has put in place an extensive internal review and approval process. Numerous departments—including Marketing, Sales, Manufacturing, Legal, Purchasing, as well as senior executive management—have been and will continue to be involved in the review and approval process. Liggett estimates that this review process will require an average of approximately 12 hours per design. This internal review process has already begun and, like the design process itself, will continue for at least the rest of this year and most of 2012.

12. In addition to the extensive and expensive packaging artwork preparations already underway, the complete packaging overhaul required by the Act and the Regulation has already required Liggett to purchase an additional 682 printing cylinder bases—an increase of nearly 100 percent over the number of bases Liggett already owns. Liggett has already purchased these bases from two sources—American Cylinder and Cylicron Engineered Cylinders—at a total cost of over $800,000.

13. The printing cylinder bases will need to be clad with copper, which will then be engraved. Each printing cylinder applies a different color of ink to the paper used to print the cigarette packs and cartons, so multiple cylinders are needed for each of the 220 different packaging configurations. Liggett will have its cylinder engraving done by WRE/ColorTech. WRE has informed Liggett that under the best of circumstances, assuming no work stoppages or other interruptions, WRE has the capacity to engrave approximately 40 cylinders per week. Accordingly, in a best case scenario, it will take over four months to complete the engraving of all of the additional cylinders Liggett needs to comply with the mandated packaging changes. More realistically, the engraving process will probably take closer to five or six months. The

cost to Liggett for cylinder engraving will be approximately $1,000 per cylinder, for a total of over $680,000.

14. After the packaging artwork is finished and the printing cylinders have been engraved, Liggett will begin the process of printing the 220 different variations of new packaging. Based on planning and projections regarding the amount of time needed to make the transition from old to new packaging, Liggett estimates that the printing and transition process will take seven to eight months. If less than this amount of time is available, Liggett will incur additional costs relating to the destruction and write-off of old packaging that cannot be used in the time available.

15. Part of the complexity of the overall packaging transition required by the Act and the Regulation lies in the fact that not all product styles sell at the same rate—there are faster and slower selling brands and styles within brands. Packaging, however, must be ordered in certain minimum quantities to avoid the excessive costs of special-quantity orders. Obviously, a pallet of packaging lasts longer for a slower-selling style than it does for a faster-selling style, so it is not possible to apply a "one-size-fits-all" transition schedule to all product styles. The effort to schedule a cost-efficient packaging transition is made more complicated because the available inventory of packs and cartons for a particular product style will almost never be exhausted at the same time. The more time that is available for the transition, the better the transition can be managed to minimize extraordinary costs and disruptions to efficient operations.

16. The limited number of companies that engrave cylinders and print packaging also complicates scheduling the transition from old to new packaging because many different cigarette manufacturers will be competing for a finite amount of engraving and printing capacity, at a time when the entire industry has to overhaul all of its packaging by the same deadline.

Liggett, for example, uses two printers—AmCor and Dominion. AmCor also prints for R.J. Reynolds, Lorillard, and Commonwealth Brands. Dominion also prints packaging for Philip Morris, R.J. Reynolds, and Lorillard. In addition, Dominion has other customers (such as McDonald's) that require and demand press time for their packaging needs. This not only complicates scheduling, but also means that some cigarette manufacturers will need to begin incurring costs earlier than others if all are to have their labeling ready by the same date.

17. The three largest U.S. cigarette manufacturers—Philip Morris, R.J. Reynolds, and Lorillard—are all substantially larger and have greater financial resources than Liggett and all other U.S.-based companies. The three together have over 85% of the domestic cigarette market and virtually 100% of the higher revenue generating "premium brand" segment of the market. Accordingly, they typically have greater "clout" with printers and other suppliers enabling them to receive priority over smaller companies in procuring the goods and services essential for compliance with the new labeling requirements. Moreover, the costs of transition to the new labeling requirements will represent a much higher percentage of Liggett's revenues than they will for the three largest companies. To the extent that Liggett incurs transition costs that are ultimately determined to be unnecessary, those costs will have a disproportionate adverse impact on Liggett compared to the larger companies.

18. Thus, many considerations and variables—some of which are beyond Liggett's control—must be taken into account and coordinated to achieve a smooth and cost-effective transition of all packaging across a company's entire product line. As Congress recognized, it certainly is not simply a matter of "flipping a switch" and quickly or easily changing from old packaging to new. The process is complex, and requires extensive planning and long lead times

if it is to be accomplished on any reasonable basis without unnecessary and burdensome extra costs, and without debilitating disruptions in the manufacturing and distribution processes.

19. The last step in the process is the distribution of finished goods. This step will also take careful planning and significant lead time if Liggett is to comply with the deadlines in the Act and the Regulation. Once the cigarettes are manufactured at Liggett's factory in North Carolina, they are shipped to 18 different public warehouses around the country. Liggett does not own these warehouses; they are owned by third parties. Liggett (and, in most cases, many other tobacco companies) rent space in the warehouses. Liggett's products are shipped from the warehouses to Liggett's direct-buying customers. FDA has indicated that it considers the cigarettes introduced into commerce when they are shipped to a customer from the public warehouse.

20. Because the Regulation provides that all cigarettes introduced into commerce on or after October 22, 2012 must bear the new warnings, Liggett must have all 18 of its public warehouses fully stocked with product in new packaging by that date, and must have removed from the 18 warehouses all inventories of product in old packaging. To exhaust the inventories of old packaging without having to bear the excessive cost of discarding huge quantities of it, and to have enough time to manufacture sufficient quantities of the new packaging product in time to fully stock all the warehouses by the October 2012 deadline, Liggett will necessarily need to be manufacturing product in the new packaging by March 2012 at the latest. And to ensure a smooth transition and avoid having to place expensive special orders for small quantities of packaging or incur large write-off costs from discarding old packaging materials or finished goods in old packaging, Liggett would have to begin introducing new packaging product as early as January 2012.

21. The foregoing does not address the time, effort, and expense that Liggett has incurred and will continue to incur from its personnel performing the multitude of tasks necessary to transition the company's entire product line to the new packaging required by the Regulation. As noted above, almost every department will be involved in the process—including Marketing, Sales, Manufacturing, Legal, Purchasing, and senior executive management. Liggett estimates that it has so far spent nearly 4,000 person-hours on tasks relating to the transition to new warnings, and that it will spend many thousands of additional person-hours on such tasks between now and the end of 2012. These hours translate to a cost to Liggett of over $1,200,000 using a conservative estimate for average salary and benefit costs.

22. Based on its best estimates, Liggett will incur a total cost of approximately $4,000,000 to comply with the Act and Regulation (including the costs to prepare two complete sets of packaging designs, as explained above), and it will need to incur the foregoing costs according to the above timeline unless the effective date of the Regulation is postponed so that Liggett has the full statutorily-provided 15-month implementation period after the Court's ruling on Plaintiffs' summary judgment motion.

Respectfully submitted, this 15th day of August, 2011.

Gregory A. Sulin

Gregory A. Sulin
Senior Vice President & Chief Operating Officer
Liggett Group LLC