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,

CIVIL ACTION NO._____

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DECLARATION OF WILLIAM MELTON

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

Introduction & Issues to be Addressed

1. I am the Vice President – Compliance and Regulations for Commonwealth Brands, Inc. ("Commonwealth"). Commonwealth is an indirect wholly owned subsidiary of Imperial Tobacco Group, PLC. Commonwealth is a Kentucky corporation with its principal place of business in Bowling Green, Kentucky. Its manufacturing operation is in Reidsville, North Carolina.

2. Commonwealth was founded in 1991. Commonwealth manufactures cigarettes and other tobacco products and is the fourth largest manufacturer in the United States. Commonwealth is heavily concentrated in the "discount" tobacco category and has one of the nation's best selling brands, USA Gold. Other of its cigarette brands include Davidoff, Sonoma, Fortuna, Rave, West, and Montclair.

3. I began working for Commonwealth Brands in March 1992. I took my current position with Commonwealth in July 2001.

4. In my current position, I have responsibility for state and federal regulatory compliance.

5. I hold a Bachelor of Science Degree and MBA from the Indiana University School of Business.

6. I have held marketing and management positions in a career spanning more than 30 years with the following companies: RJ Reynolds Tobacco Company, Sara Lee, General Metropolitan USA, AJM Communications Corp. and Commonwealth Brands.

7. This declaration will address the steps Commonwealth must take to comply with the new labeling requirements imposed by the Food and Drug Administration ("FDA") in its Final Rule implementing the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) (the "Act"). *See Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36628 (June 22, 2011) ("the Rule"). The declaration outlines the steps that Commonwealth must take, the cost of those steps, and the timeline Commonwealth will follow, in order to meet the Rule's September 22, 2012 effective date.

Costs of Commonwealth's Implementation of Packaging Changes

8. The Rule requires that Commonwealth make major revisions to every style of packaging for every one of its cigarette products. Commonwealth has over 150 separate selling units. These products are packaged in individual packs, cartons, and cases. As a result, Commonwealth will need to completely redesign over 450 distinct package designs. As the FDA has recognized, implementing a packaging change of this magnitude in an orderly fashion requires approximately 15 months. *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."); *id.* at 36716 (explaining that the agency included "10 percent rush charges" in calculating the cost of the Rule because "[r]esources are scarce and a large number of labeling changes [would have to be] simultaneously rushed" to meet the 15-month deadline).

9. The Rule's labeling requirements will apply to any cigarette manufactured on or after September 22, 2012, and any cigarette introduced into commerce on or after October 22, 2012. In order to develop the inventory necessary to comply with these deadlines, Commonwealth will need to begin manufacturing cigarettes in compliant packaging beginning in May of 2012. If the Rule were invalidated after September 1, 2012, Commonwealth could suffer from unrecoverable manufacturing costs that would exceed $18.4 million.

10. In order to meet the September 22, 2012 and October 22, 2012 effective dates, Commonwealth will need to purchase 620 blank metal printing cylinder bases, which will be engraved and used to apply the ink on the new cigarette packaging. This will cost Commonwealth approximately $420,000.

11. Commonwealth has hired a graphics design firm to design the new labeling. The designers will need to revise current package designs in light of the Rule's requirement that Commonwealth's own branding and marketing be limited to the bottom half of both the front and the back of the package. Commonwealth estimates that the cost of this graphic design to Commonwealth will be approximately $1.4 million.

12. Commonwealth will also have to contract with its third-party design firm to engrave printing cylinders with the new packaging designs. It will cost Commonwealth $1.24 million for the printing cylinders for its cigarette packs and cartons. It will cost Commonwealth $67,000 to modify the case printing plates. Commonwealth also uses offset printing for certain lower volume brands and it will cost Commonwealth $100,000 to replace the offset printing plates. It will cost Commonwealth $700,000 to purchase 14 embossing units.

Timing Concerns For Commonwealth's Implementation of Packaging Changes

13. Commonwealth will need to provide the engraved cylinders to its third-party printer and contract for the production of new packaging by March, 2012. The printer must begin production in March because it will need to produce the new packaging while still producing Commonwealth's current packaging. The manufacturer will therefore not have its full capacity available for the new packaging.

14. In addition, there are a limited number of third-parties who perform the type of specialized work involved in redesigning and printing cigarette packaging. Therefore, it is difficult to estimate the additional time and expense that may be involved for smaller companies such as Commonwealth as a result of the large number of labeling changes that will have to be simultaneously rushed most of which will come from larger companies whose orders may take priority.

15. Commonwealth is required to submit its graphics and warning plans for pre-approval by FDA under 15 U.S.C. § 1333(c)(1). However, FDA explicitly "opted not to address these issues" in its recent rule. *See* 76 Fed. Reg. at 36693. Instead, FDA indicated that it would separately issue guidance on the approval requirements. *Id.* Because FDA has not yet issued this guidance and the approval is a pre-requisite, Commonwealth can only take the above-described steps after FDA issues the necessary guidance.

16. Moreover, the overwhelming majority of states will require Commonwealth to submit the new packaging in order to be properly certified to sell cigarettes into that state. This state approval process cannot even begin until after Commonwealth has FDA's approval letter in regard to its packaging and advertising rotational plans, as such is a prerequisite to the process. These other agencies include state fire marshals for fire safe certification and state AGs for MSA certification. For instance, Commonwealth will have to submit the packaging to the state Attorney Generals in 42 states, plus the District of Columbia. Based on Commonwealth's past experience this approval process alone can take up to 6 months.

17. Finalizing the appropriate packaging will also include internal review and approval of approximately 450 individual designs by numerous different departments, including Marketing, Legal, Sales, and Manufacturing.

18. In addition to the monetary costs described above, the foregoing tasks will occupy over 3,500-4,000 hours of Commonwealth employee time.

19. Based on its best estimates, Commonwealth will need to incur the foregoing costs according to the above timeline unless the effective dates of the Regulation, along with the related labeling changes tied to the effective date of the Regulation, are postponed so that

Commonwealth may begin this implementation process after the conclusion of direct and appellate judicial review.

20. Absent a postponement, Commonwealth will have no choice other than to continue with its implementation even if the District Court were to invalidate the Regulation, as it could not risk the possibility of noncompliance should the District Court reject its challenge, or should the District Court invalidate the regulation but be reversed on appeal.

William Melton