IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
(Miami Division)

ENRIQUE FERNANDO SANCHEZ ICAZA and GLOBAL PREMIUM CIGARS, LLC.,

Plaintiffs,

vs.

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Springs, MD 20993,

ROBERT CALIFF, M.D.,
Commissioner of Food and Drugs,
10903 New Hampshire Avenue
Silver Springs, MD 20993,

and

SYLVIA MATHEWS BURWELL,
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Defendants.

Civil Action No. _____

COMPLAINT FOR VIOLATION OF A.P.A. AND RELATED CAUSES

Plaintiff Enrique Fernando Sanchez Icaza and Global Premium Cigars, LLC., (hereinafter collectively "Plaintiffs") brings this Complaint to set aside Defendants' unlawful final rule, "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," No.

FDA-2014-N-0189, 81 Fed. Reg. 28, 973 (May 10, 2016) ("Deeming Rule" or "the Rule").

INTRODUCTION

1. This suit concerns FDA's regulation of cigars.

2. Premium cigar manufacturing has existed in the United States, Cuba, Dominican Republic, Nicaragua, Honduras, Costa Rica and other countries for hundreds of years.

3. During this time, premium cigars have been manufactured and marketed in much the same way without any public outcry.

4. Premium cigars are marketed as luxury products and often contain highly detailed illustrative art on the packaging often referencing the cigar makers' cultural background, history, and other communicative messages.

5. Premium cigar packaging contains some of the most expressive and highly detailed illustrative artwork printing of any commercial product. The makers of premium cigar products are often small businesses who take great pride in their brands and accompanying artwork and are willing to spend on high end printing in order to celebrate the rich history of the noble art of cigar making.

6. The size of a cigar box is normally much larger than the packaging of most other tobacco products.

7. Historically, cigar manufacturers have utilized these larger boxes in order to display their trademarked and copyrighted artworks in an effort to express their cultural and political speech and to create a competitive advantage through label recognition.

8. Many small manufacturers use symbols, flags, cultural, and other historical references in their artwork printed on the cigar box top and inside "vista."

9. Plaintiffs are a small business that started offering their cigars after February 15, 2007. Plaintiffs' compliance with the Deeming Rules will cost-prohibitive.

10. Plaintiffs' ability to market their products and new products will be severely limited due to the overreaching obligations set forth in in the Deeming Rules.

11. Plaintiffs' trademark rights and accompanying copyrights, developed over the past several years, in their illustrative artwork will be diminished by the Deeming Rules. Specifically, the Deeming Rules will constitute an unlawful taking or otherwise constitute a violation of Plaintiffs substantive due process rights under the United States Constitution.

PARTIES

12. Enrique Fernando Sanchez Icaza is an individual residing in Miami-Dade County, Florida and, along with his wife, owner and principal of Plaintiff Global Premium Cigars, LLC.

13. Global Premium Cigars, LLC., is a family owned small company located in Miami-Dade County, Florida that manufactures and distributes premium cigars in United States commerce. Global Premium Cigars, LLC., imports their cigars from Esteli, Nicaragua.

14. Defendant FDA is an agency of the United States Government within the Department of Health and Human Services, with an office at 10903 New Hampshire Ave., Silver Springs, MD 20993. The Secretary of Health and Human Services has delegated to FDA the authority to administer the relevant provisions of the Act, 21 U.S.C. §§387a, 387a-1.

15. Defendant Robert Califf, M.D., is Commissioner of Food and Drugs and is the senior official of the FDA. He is sued in his official capacity. Dr. Califf maintains an office at 10903 New Hampshire Ave., Silver Springs, MD 20993.

16. Defendant Sylvia Mathews Burwell is Secretary of Health and Human Services and the official charged by law with administering the Act. She is sued in her official capacity. Secretary Burwell maintains an office at 200 Independence Avenue SW, Washington, DC 20201.

17. All defendants are collectively referred to hereinafter as "FDA" or "Defendants."

REGULATORY AND STATUTORY BACKGROUND

18. The Deeming Rule was adopted and publically released by FDA on May 5, 2016, and was published in the Federal Register on May 10, 2016.

19. The Deeming Rule dramatically expands the FDA's exercise of its regulatory authority under the Tobacco Control Act ("Act"), a statute enacted in 2009 that is designed to address the "cancer, heart disease, and other serious adverse health effects" associated with use of "tobacco products." Pub. L. No. 111-31, 123 Stat. 177, §2(1) (2009); *see also id.* § 3 (reciting ten statutory purposes, each focused on "tobacco" or "tobacco products").

20. The Act appears in chapter IX of the Food, Drug, and Cosmetic Act ("FDCA") and grants FDA authority to regulate the manufacture, sale, and marketing of "tobacco products."

21. The Act defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw material other than tobacco used in manufacturing a component, part, or accessory of a tobacco product.)" 21 U.S.C. §321(rr).

22. Among other things, the Act: (i) imposes a rigorous premarket approval procedure, similar to the procedure for new drug applications under the FDCA, for many new tobacco products; (ii.) makes it unlawful to market misbranded or adulterated tobacco products; (iii) requires manufacturers of tobacco products to submit detailed product and advertising information to FDA; (iv) requires manufacturers to register manufacturing facilities with FDA and open such facilities for biannual FDA inspections; (v) authorizes FDA to impose restrictions on the sale and distribution of tobacco products, and to require warning labels for tobacco products; (vi) authorizes FDA to regulate the methods used in manufacturing tobacco products; (vii) grants FDA authority to mandate new product safety standards regarding the composition and characteristics of tobacco products; (viii) directs tobacco product manufacturers to keep certain records; (ix) requires manufacturers to obtain advance FDA approval before making a variety of advertising and labeling claims; and (x) grants FDA authority to promulgate testing requirements for tobacco products. 21 U.S. C. §§387a-387k, 387o, 387t.

23. The mandates "apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary [of HHS] by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b).

24. In the Deeming Rule, FDA purports to exercise the deeming authority provided in 21 U.S.C §387a by subjecting "all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products,' to regulation under the Act.

JURISDICTION AND VENUE

25. This action arises under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §601 et seq.; Administrative Procedure Act ("APA"), 5 U.S.C.§ 500 et seq.; the FDCA, 21 U.S.C. § 301 et seq.' and the Tobacco Control Act, 21 U.S.C. § 387 et. Seq. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 2201-02.

26. Jurisdiction review is authorized by the APA, 5 U.S.C. § 701 et seq., which provides for judicial review of final agency actions.

27. FDA's promulgation of the Deeming Rule constitutes final agency action with the meaning of 5 U.S.C. § 704.

28. Venue is proper under 28 U.S.C. §1391(e).

THE DEEMING RULE'S EFFECTS ON THE PLAINTIFFS

29. When the Deeming Rules become effective on August 8, 2016, Plaintiffs will suffer immediate financial and other harm to their business since all of their cigar products were launched after February 15, 2007.

30. As such, in order to keep these products in the market, Plaintiffs will be required to file for an Exemption to Substantial Equivalence (before August 8,

2017), a Substantial Equivalence application (before February 8, 2018), or a PMTA.

31. The predicate date of February 15, 2007 is a violation of Plaintiffs' Fifth Amendment substantive due process rights.

32. The predicate date of February 15, 2007 is nine years in the past. There is no reasonable way that Plaintiffs could have known or been aware of this date and the subsequent obligations.

33. The pre-market pathways are costly, time-consuming, and create an extremely high-hurdle for cigar manufacturers to meet before they can launch a product on the market.

34. The 30 percent rule for the warning labels on the cigar packaging appears to be arbitrary as there is no scientific evidence provided to demonstrate that the specific size of the enlarged warning labels achieve the Rules desired outcome of the consumer reading the warning.

35. The 30 percent rule for the warning labels on the cigar packaging infringes upon Plaintiffs' First and Fifth Amendment right as it is an unconstitutional restraint upon Plaintiffs' speech and an unconstitutional taking without just compensation.

36. The Predicate date of February 15, 2007 is a violation of Plaintiffs' Fifth Amendment substantive due process.

37. The 20 percent rule for the warning labels on the advertisements for the premium cigars appears to be arbitrary as there is no scientific evidence provided to demonstrate that the specific size of the warnings achieve the Rules desired purpose of the consumer reading the warning.

FIRST CLAIM FOR RELIEF
Violation of the Regulatory Flexibility Act- §601 et seq.

38. The above paragraphs are incorporated herein by reference.

39. The Regulatory Flexibility Act (RFA), 5 U.S.C. §601 et seq., requires federal agencies to consider the impact of their regulatory proposals on small entities, and *inter alia*, to analyze effective alternatives that minimize small entity impacts.

40. The FDA failed to properly fulfill this obligation. Because of this, Plaintiffs are and will continue to be adversely affected and aggrieved by the Deeming Rules, which constitute final agency action. Therefore, Plaintiffs are entitled to a judicial review of the FDA compliance with the requirements of sections 601, 604, 605(b), and 610 in accordance with [5 U.S.C §701, et seq.]. 5 U.S.C § 611(a).

> Because the Deeming Rules "have a significant economic impact on a substantial number of small entities," the RFA requires that FDA perform a full regulatory flexibility analysis that includes a discussion of each element identified in 603 (b) of the RFA. Section 603(b) of the RFA provides that: "Each initial regulatory flexibility analysis required under this section shall contain—
> **(1)** a description of the reasons why action by the agency is being

> considered;
> **(2)** a succinct statement of the objectives of, and legal basis for, the proposed rule;
> **(3)** a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
> **(4)** a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
> **(5)** an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule." 5 U.S.C. §603(b).

41. Significant Alternatives to the proposed rule that accomplish the stated objectives and minimize the rule's economic impact on small entities are imperative to an Initial Regulatory Flexibility Analysis.

42. It is the development and adoption of these alternatives that provide regulatory relief to small entities.

43. By analyzing significant alternatives, a process is established so that the agency can achieve the regulatory goals in an effective and efficient manner without placing undue burden on small entities.

44. The RFA requires the agency to conduct an analysis that determines how the rule impacts the small entities. Then the agency must consider alternatives in an effort to reduce or minimize the impacts.

45. Possible alternatives vary based on the regulatory objective and the characteristics of the regulated industry. However, section 603(c) of the RFA gives agencies some alternatives that they MUST consider at a minimum:

> "Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as—
>
> **(1)** the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
>
> **(2)** the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
>
> **(3)** the use of performance rather than design standards; and
>
> **(4)** an exemption from coverage of the rule, or any part thereof, for such small entities." 5 U.S.C. §603 (c).

46. The FDA's IRFA lacked the essential information required under the Regulatory Flexibility Act (RFA), 5 U.S.C. §601 et seq.

47. The FDA's IRFA failed to discuss any objective or subjective costs of the proposed rule with regard to the potentially affected small entities, like Plaintiffs.

48. Likewise, the analysis did not adequately consider or explain significant alternatives that could accomplish the objectives while at the same time, minimizing the impact on small entities, like Plaintiffs.

49. In its comments to the IRFA, the Office of Advocacy of the U.S. Small Business Administration ("SBA") wrote:

> "Based on input from small business stakeholders, Advocacy is concerned that the Initial Regulatory Flexibility Analysis (IRFA) contained in the proposed rule lacks essential information required under the Regulatory Flexibility Act (RFA). Specifically, the IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. Moreover, given the extent of the anticipated costs of this proposal, the IRFA does not adequately consider or explain significant alternatives which accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking." www.sba.gov/advocacy/61114-deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act-amended-family.

50. Rather than make appropriate corrections to the IRFA, the FDA simply wrote "We disagree that the proposed rule's IRFA is deficient or that a Supplemental IRFA should be published." See, Docket No. FDA-2014-N-0189, Deeming tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the sale and distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements, Final Regulatory Impact Analysis, May 2016, p.54.

51. Because the FDA failed to sufficiently examine significant alternatives that would have reduced the harmful impacts to small entities, like Plaintiffs, the Deeming Rule violates the provisions of 5 U.S.C § 601 et seq.

52. Had the FDA cured the deficiencies presented prior to proceeding with rulemaking, the public would have been competently informed of how the Deeming Rule would impact small entities, like Plaintiffs.

53. Additionally, less burdensome significant alternatives would have been available for public knowledge.

54. Although the FDA received many comments to the Deeming Rule that specifically spoke to appropriate alternatives, the FDA did not take these alternatives under consideration.

55. The FDA is obligated under the RFA to tailor its regulations in an effort to mitigate the economic impact on small and medium sized businesses, like Plaintiffs and other cigar companies.

56. While the FDA's Initial Regulatory Flexibility Act analysis did acknowledge that a substantial number of small entities would be impacted by the Deeming Rule, the Small Business Administration believes that these costs were likely underestimated.

57. Further, the Small Business Administration stated that the rule "may be disproportionately burdensome to small entities that do not have the legal resources of larger businesses." www.sba.gov/advocacy/61114-deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act-amended-family.

58. Plaintiffs have been and will be harmed by the Deeming Rule.

SECOND CLAIM FOR RELIEF
Violation of APA- Arbitrary and Capricious Agency Action

59. The above paragraphs are incorporated herein by reference.

60. The APA, 5 U.S.C. § 706 (2)(A), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Under this provision, agency action is unlawful if the agency failed to articulate a rational connection between the facts found and the choice made, failed to consider an important aspect of the problem, or offered an explanation for its decision that runs counter to the evidence. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.,* 463 U.S. 29, 43 (1983).

61. The Deeming Rule is unlawful when judged against that standard.

62. Under the Act, "tobacco products" may not be sold without prior approval from the FDA. 21 U.S.C. § 387(a)(2). The Act provides three options for obtaining FDA approval:

a. The substantial equivalence ("SE") pathway, which requires the manufacturer to show that its product "is substantially equivalent to a tobacco product commercially marketed … in the United States as of February 15, 2007," 21 U.S.C. §387j(b)(2);
b. The SE exemption pathway, under which the manufacturer must show that its product is only a "minor modification" of a tobacco product that was on the market as of February 15, 2007, and that the modification only involves a change in additive levels, *Id*. §§ 387(j)(3), 387j(a)(2)(A)(ii); and

c. The premarket tobacco application ("PMTA") pathway, under which the manufacturer must obtain FDA approval based on a detailed application documenting the product's health risks, ingredients, manufacturing methods, and other characteristics, *Id*. § 387j(b)(1).

63. The PMTA process is comparable to the new drug application (NDA) process of the FDCA. Courts described this process as "expensive and time-consuming." *Am. Bioscience, Inc. v. Thompson*, 269 F. 3d 1077, 1079 (D.C. Cir 2001). The PMTA language does in fact, literally repeat many portions of the provision that governs the NDA process. Compare 21 U.S.C. §355(b)(1) with §21 U.S.C. 387j(b)(1).

64. The PMTA pathway will be the only avenue available to a majority of the cigar manufacturers, like Plaintiffs as their products were not on the market "as of February 15, 2007."

65. The Deeming Rule has arbitrarily set forth the premarket pathways without taking into account the extreme burden and hardship that is now presented to many cigar manufacturers, like Plaintiffs.

66. Additionally, the Deeming Rule requires, "tobacco products" must display "WARNING: This product contains nicotine. Nicotine is an addictive chemical." As well as one of five additional warnings that must be rotated evenly during the period in which the cigar is sold.

67. Under the Deeming Rule, the above warning must "be located in a conspicuous and prominent place on the two principal display panels of the

package and the warning area must comprise at least 30 percent of each of the principal display panels."

68. The Deeming Rule mirrors the Act's warning size requirements established for smokeless tobacco. 15 U.S.C. §§4402(a)(2)(A), (b)(2)(B)

69. The Deeming Rule arbitrarily assigned the 30 percent requirement to cigar boxes and provided no evidence or reasoning as to why 30 percent applies to a cigar box.

70. The Deeming Rules intended purpose for the enlarged warning size is to ensure that the health warning is seen by the consumer.

71. The evidence presented and referenced in the Deeming Rule relates primarily to cigarette packaging and warning labels.

72. There has been no scientific evidence provided to support that an enlarged intrusive warning label on a cigar box (which is significantly larger than a cigarette pack) will ensure that the consumer sees the warning label.

73. As there is no explanation to support the implementation of enlarged intrusive warning labels on cigar packaging, it is reasonable to conclude that this rule was arrived at in an arbitrary and capricious manner.

74. Plaintiffs have been and will be harmed by the Deeming Rule.

THIRD CLAIM FOR RELIEF
Violation of APA- Unlawful Cost-Benefit Analysis

75. The above paragraphs are incorporated herein by reference.

76. The APA, 5 U.S.C. §§706(2)(A), (C)-(D), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law."

77. The Deeming Rule's cost-benefit analysis violates the APA.

78. The cost-benefit analysis arrives at the conclusion that the benefits of the Rule outweigh the costs. However, this conclusion is based on faulty reasoning and overestimating the benefits of the Rule.

79. A substantial number of newly deemed tobacco products will not be appropriate predicate products that were on the market as of February 15, 2007. As a result, a majority of cigar manufacturers, like Plaintiffs, will have no other pathway to the market other than to file PMTAs.

80. The Deeming Rule underestimates the number of PMTAs that manufacturers, like Plaintiffs, will be required to file which will have to be reviewed by the FDA. The Deeming Rule approximates that 750 PMTA annual responses will be filed and the total predicted hours spent for "Applications for premarket review of New Tobacco products" will be 1,285,550. However, because a majority of cigars will not meet the predicate date of February 15, 2007 or fall under an exception, it is likely that this actual number of PMTAs filed will far

exceed this estimate. Additionally, the Deeming Rule has not taken into account the costs associated with this reviewing endeavor.

81. The Deeming Rule imposes harsh filing costs and burdens on cigar manufacturers, which will be particularly felt by smaller manufacturers like Plaintiffs. The cost of filing a PMTA is predicted to be quite costly.

82. The Deeming Rule imposes harsh requirements on the PMTA applicant which include but are not limited to a full statement of components, ingredients, a full description of methods used in, and the facilities and controls used for the manufacture and processing.

83. Additionally, the applicant must furnish full reports of all information, published or known to, or which should be reasonably known regarding investigations which were made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products.

84. The Deeming Rule allows 180 days for review of the PMTA.

85. The PMTA process is time-consuming and expensive not just for cigar manufacturers but also for the FDA as they will be required to review each and every filed PMTA.

86. Additionally, the Deeming rule will effectively eliminate all limited releases or seasonal cigars due to the high expense and lengthy time requirements associated with the review.

87. The high costs of these lengthy and time-consuming requirements that burden the applicant greatly outweighs any benefits created by the Deeming Rule.

88. Further, the Deeming Rule forces the manufacturer to create six versions of the label used on the cigar box in order to comply with the warning label requirements.

89. The Deeming Rule requires that the warning label be rotated so that each one is used and equal number of times during the 12-month period a cigar product is sold.

90. Hence, six separate labels will need to be created which also must be submitted to the FDA, meaning another time-consuming restraint that the manufacturer must comply with before they can put the product on the market.

91. Again, the lengthy, time-consuming compliance requirements associated with creating at the minimum, six separate labels greatly outweigh any benefits the Deeming Rule has created in mandating these warning labels.

92. A more accurate cost-benefit analysis, as required by law, would demonstrate that the Deeming Rule imposes harsh regulatory burdens on manufacturers, especially, small cigar manufacturers like Plaintiffs, by requiring compliance with extensive premarket approval, reporting, recordkeeping, labeling, manufacturing, testing, and other requirements.

93. Plaintiffs have been and will be harmed by the Deeming Rule.

FOUTH CLAIM FOR RELIEF
Violation of First Amendment

94. The above paragraphs are incorporated herein by reference.

95. The Deeming Rule should be vacated and set aside as it violates Plaintiffs' First Amendment Rights

96. The APA, 5 U.S.C. §706(2)(B), provides that a reviewing court shall hold unlawful and set aside agency action that is "contrary to constitutional right, power, privilege, or immunity."

97. Commercial speech may be restricted only to further a substantial government interest and only if the restriction actually furthers that interest. *Central Hudson Gas & Electric Co. v. Public Service Commission*, 447 U.S. 557, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980).

98. Additionally, it is well established that Congress may not impose limitations unless the restriction is "narrowly tailored to promote a compelling Government interest. If a less restrictive alternative would serve the Government's purpose, the legislature must use that alternative. To do otherwise would be to restrict speech without an adequate justification." *United State v. Playboy Entm't Group*, 529 U.S. 803, 813 (2000).

99. The Tobacco Control Act imposes numerous limitations without exceptions on commercial and non-commercial speech.

100. The Government's primary justification for the Act is to reduce youth smoking. 21 U.S.C. §387, et seq.

101. However, the majority of the Act does not remotely touch upon that goal.

102. Rather, the Act broadly and indiscriminately restricts speech regardless of whether it is directed at adults or at youth or advances the asserted goal of reducing youth smoking. In essence, the broad generalized application of the Act creates a chilling effect upon the entire cigar industry.

Warning Labels

103. The required warnings are a form of compelled disclosure, and are thus subject to First Amendment scrutiny. *Milavetz, Gallop & Milavetz, P.A.* v. *United States,* 559 U.S. 229, 249 (2010); *Riley* v. *Nat'l Fed'n of the Blind of N.C., Inc.,* 487 U.S. 781, 797-98 (1988).

104. The warning requirement mirrors the Act's warning size requirements established for smokeless tobacco. 15 U.S.C. §§ 4402(a)(2)(A), (b)(2)(B).

105. The Deeming Rule requires cigar boxes to display warnings occupying 30 percent of two of the principal display panels. The specific size of the warning label requirement violates Plaintiffs' First Amendment rights.

106. In addition to the "warning" occupying no less than 30 percent of two primary display panels in at least 12-point font, Plaintiffs must prominently and

conspicuously place on its packaging, inter alia: (1) a mandatory statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; (2) the product's "established name" (a term not yet explained by the FDA), "name and place of the business of the tobacco product manufacturer, packer, or distributor."; (3) "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and if the FDA should require (4) "directions for use". 21 U.S.C. §§387c(a)(2)(A)-(C), 387c(a)(3)-(5).

107. The specific size and intrusiveness of the required warnings far outweighs any interest in conveying factual information to consumers.

108. The desired purpose of the Deeming Rule's required warning in this enlarged size purported to ensure that it was more visible.

109. No evidence has been presented specifically speaking to cigars in regard to the enlarged warnings.

110. In fact, the referenced study (Health warning messages on tobacco products: a review David Hammond) in the Deeming Rule regarding warning label size focused primarily on cigarettes and stated that cigars fall under the heading of "alternative tobacco." The study states that at this time there is no real evidence with regard to "alternative" tobacco products.

111. The warning requirements are unduly burdensome as they effectively cover the majority of the cigar box top and inside the "vista," in turn, overtaking Plaintiffs' speech, trademarks, and copyrights. Likewise, no evidence has been presented as to cigar boxes that the intrusive warnings actually ensure that the health risk is seen by the viewer.

112. By requiring that excessive space be devoted to Government messages, the Act, violates Plaintiffs' First Amendment by effectively hindering Plaintiffs' ability to communicate with the public through packaging, advertising, and intellectual property.

113. The FDA has not provided any evidence to support this ban as related to cigars that will in fact, curb their desired intention of curbing youth initiation.

Prior Restraint

114. Prior restraints are unconstitutional, except in extremely limited circumstances such as national security issue. *Near v. Minnesota*, 283 U.S. 697 (1931).

115. Any prior restraint on expression comes with a "heavy presumption" against its constitutional validity. *Carroll v. Princess Anne*, 393 U.S. 175, 181 (1968); *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 70 (1963). Respondent thus carries a heavy burden of showing justification for the imposition of such a restraint.

116. Under the Deeming Rule, any cigars that do not meet the requisite predicate date of February 15, 2007, must obtain comply with and ultimately obtain approval from the FDA.

117. Under the Act, "tobacco products" may not be sold without prior approval from the FDA. 21 U.S.C. § 387(a)(2). The Act provides three options for obtaining FDA approval:

a. The substantial equivalence ("SE") pathway, which requires the manufacturer to show that its product "is substantially equivalent to a tobacco product commercially marketed … in the United States as of February 15, 2007," 21 U.S.C. § 387j(b)(2);
b. The SE exemption pathway, under which the manufacturer must show that its product is only a "minor modification" of a tobacco product that was on the market as of February 15, 2007, and that the modification only involves a change in additive levels, *Id*. §§ 387(j)(3), 387j(a)(2)(A)(ii); and
c. The premarket tobacco application ("PMTA") pathway, under which the manufacturer must obtain FDA approval based on a detailed application documenting the product's health risks, ingredients, manufacturing methods, and other characteristics, *Id*. § 387j(b)(1).

118. The PMTA approval precludes Plaintiffs from marketing or advertising a cigar until the FDA goes through a lengthy review process that can last as long as 180 days.

119. The premarket approval requires applicants to submit "proposed labeling," "sample products," and "proposed sample products" which is speech that the FDA holds captive until the review is complete.

120. In holding the speech captive and requiring premarket approval, the FDA is undoubtedly imposing a prior restraint and in violation of Plaintiffs' First Amendment rights.

121. Plaintiffs have been and will be harmed by the Deeming Rule.

FIFTH CLAIM FOR RELIEF
Violation of the Fifth Amendment Takings Clause

122. The above paragraphs are incorporated herein by reference.

123. The Fifth Amendment of United States Constitution includes a provisions known as the Takings Clause, which states that "private property [shall not] be taken for public use, without just compensation." The Fifth Amendment extends to all tangible and intangible property, including, but not limited to intellectual property, i.e., trademarks and copyrights.

124. The purpose behind the takings doctrine is to prevent government from forcing an individual to bear burdens that should be carried by the public as a whole. *Armstrong v. United States,* 364 U.S. 40, 49, 80 S.Ct. 1563, 4 L.Ed.2d 1554 (1960).

125. "Regulation will constitute a taking when either: (1) it does not substantially advance a legitimate state interest; or (2) it denies the owner economically viable use of her land." *Agins v. City of Tiburon*, 447 U.S. 225 (1980).

126. The Tobacco Control Act violates the Plaintiff's Fifth Amendment rights by effectively seizing Plaintiffs' packaging, advertising, and intellectual property for the sole purpose of furthering the Government's message.

127. Plaintiffs have Registered Trademarks with the United States Patent and Trademark Office in "1502 Handmade Nicaragua Ruby" (Registration Number 4554226), "1502 Handmade Nicaragua Emerald" (Registration Number 4554224), and "1502 Handmade Nicaragua Black Gold" (Registration Number 4554223).

128. Additionally, the artwork associated with Plaintiffs' product packaging is protected under Copyright law.

129. The law recognizes that trademarked logos and copyrighted artwork are commercially valuable property rights.

130. The Deeming Rule's mandated warning requirement covering 30 percent of two principal display panels of the cigar box, deprives Plaintiffs of the use of their trademarks, trade dress, copyright, packaging, and advertising without just compensation.

131. The artwork on each cigar box manufactured by Plaintiffs includes the above referenced trademarks and copyrights on the Principal Display Panel.

132. Requiring Plaintiffs to cover the trademarks and copyrighted illustrations on the cigar box with an arbitrarily sized intrusive warning label amounts to a taking without just compensation.

133. Further, requiring the Plaintiffs to cover the trademarked and copyrighted illustrations on the cigar box put the Plaintiffs at a disadvantage with regard to label recognition by customers.

134. The FDA has not taken steps to remedy this issue by exploring less restrictive alternate labeling solutions.

135. Although the Deeming Rule provides an exception for products sold in "small packages" in the form of placing warnings on "the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag otherwise firmly and permanently affixed to the tobacco product package," this "exception" is inconsequential to Plaintiffs and other cigar sellers as no alternative surface exists.

136. Plaintiffs have been and will be harmed by the Deeming Rule.

SIXTH CLAIM FOR RELIEF
Violation of the Fifth Amendment Substantive Due Process

137. The above paragraphs are incorporated herein by reference.

138. The Fifth Amendment of United States Constitution provides that no one shall be "deprived of life, liberty or property without due process of law."

139. Substantive Due Process doctrine requires that legislation be fair and reasonable in content and to further a legitimate governmental objective.

140. The Deeming Rule's predicate date of February 15, 2007 is a violation of Plaintiffs' Substantive Due Process as this date was arbitrarily selected and is nine years old.

141. As February 15, 2007 is nine years in the past it is unreasonable and unfair to cigar manufacturers as there is no way most cigar manufactures, like Plaintiffs could have been on notice of this date. The retroactive nature of this is excessive and unreasonable.

142. No legitimate governmental objective is being satisfied by the use of the arbitrary date of February 15, 2007.

143. Plaintiffs have been and will be harmed by the Deeming Rule

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Vacate and set aside the Deeming Rule;

B. Declare that:

i. the Deeming Rule is opposing to and exceeds the FDA's authority under the Regulatory Flexibility Act;

ii. the Deeming Rule is opposing to and exceeds FDA's statutory authority under the Act and the FDCA;

iii. the Deeming Rule's cost-benefit analysis is unlawful; and

iv. the Deeming Rule is opposing to the First and Fifth Amendments.

v. The Predicate Date of February 15, 2007 should be deemed unlawful and the actual Predicate Date should be August 8, 2016 (the effective date).

C. Issue a preliminary injunction enjoining enforcement of the Deeming Rule and prohibiting the FDA from taking any action under the Deeming Rule pending resolution of this action on the merits;

D. Grant Plaintiffs reasonable attorney's fees and expenses; and

E. Award any such further relief that this Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiffs reserve their right to trial by jury.

June 1, 2016

Respectfully submitted,

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