UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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U.S. SMOKELESS TOBACCO MANUFACTURING COMPANY, LLC and
U.S. SMOKELESS TOBACCO BRANDS, INC.,

Plaintiffs,

- against -

09 Civ. 10511 (CM)

CITY OF NEW YORK,

Defendant.

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MEMORANDUM DECISION AND ORDER DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT, GRANTING DEFENDANT'S CROSS-MOTION, AND DISMISSING THE COMPLAINT

INTRODUCTION

Plaintiffs U.S. Smokeless Tobacco Manufacturing Company LLC and U.S. Smokeless Tobacco Brands Inc. move for summary judgment declaring that Defendant City of New York's local ordinance banning the sale of flavored smokeless tobacco, 17 New York City Administrative Code 17-715 (the "Ordinance"), is preempted by the federal Family Smoking Prevention and Tobacco Control Act ("FSPTCA"). Pub. L. No, 111-31, 123 Stat. 1776 (2009), codified at 21 U.S.C. § 387 et seq.

In March 2010, this Court issued a decision and order denying Plaintiffs' motion for a preliminary injunction on the same ground. In it, I found that Plaintiffs were "highly unlikely" to "ultimately prevail on the merits" of their preemption claim. U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York, 703 F. Supp. 2d 329, 343 (S.D.N.Y. 2010) (the "PI Order"). Discovery taken since last March has uncovered no new facts. The relevant portions of the

FSPTCA read the same now as they did then; so does the City Ordinance. The Food and Drug Administration ("FDA") has not exercised its regulatory power under the FSPTCA in any way that affects the analysis in this case.

The City, agreeing with Plaintiffs that no material facts are in dispute, has cross-moved for summary judgment dismissing the complaint, seeking a final determination that the Ordinance is not preempted as a matter of law.

For the reasons discussed in the PI Order and below, Plaintiffs' motion for summary judgment is DENIED, the City's cross-motion is GRANTED, and the complaint in this action is dismissed.

BACKGROUND

The PI Order sets forth in detail the facts, the provisions of the FSPTCA and the Ordinance, and the controlling principles of law; that exercise will not be repeated in full here. See U.S. Smokeless Tobacco, 703 F. Supp. 2d at 332-42. Rather, the PI Order should be deemed incorporated herein, and I will restate only so much of the analysis as is required to dispose of Plaintiffs' arguments on this motion, many of which are not new.

A. The PI Order

In the PI Order, I interpreted three provisions of the FSPTCA pertinent to the preemption issue raised on the cross motions. First, the Preservation Clause provides that State and local governments retain their historical power to regulate, among other things, the sale or distribution of tobacco products within their jurisdictions:

> Except as provided in [the Preemption Clause], nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of . . . a State or political subdivision of a State . . . to enact, adopt, promulgate,

> and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, *including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age*, information reporting to the State, or measures relating to fire safety standards for tobacco products . . . .

21 U.S.C. § 387p(a)(1) (emphasis added); Austin v. Tennessee, 179 U.S. 343 (State prohibition of cigarette sales); cf. Brown & Williamson Tobacco Corp. v. Pataki, 320 F.3d 200, 216-17 (2d Cir. 2003). In other words, with respect to regulations relating to, or even prohibiting sales of tobacco products, local governments are free to go above any federal floor set either by the FSPTCA or by the FDA acting pursuant to it.

Next, notwithstanding the preservation of local authority to create restrictions or prohibitions on the sale or distribution of tobacco, the Preemption Clause makes clear that the federal government will have exclusive control over, among other things, "tobacco product standards":

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter *relating to tobacco product standards*, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

Id. § 387p(a)(2)(A) (emphasis added). Thus, whenever the FSPTCA, or the FDA acting pursuant thereto, promulgates a "tobacco product standard," any State law requirement that differs from or conflicts with that standard is preempted.

Finally, the Saving Clause makes clear that the Preemption Clause does not reach local sales or distribution regulations of the kind referred to the in the Preservation Clause.

> [The Preemption Clause] *does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age*, or relating to fire safety standards for tobacco products . . . .

21 U.S.C. § 387p(a) (emphasis added).

Reading these clauses together, and in light of provisions of the statute governing "tobacco product standards" (id. §§ 387g, 387f(d)), I concluded that the statute gives the federal government the exclusive power to regulate the manufacture and/or fabrication of tobacco products, while reserving to the States their historical power to regulate the sale and distribution of such products above any federal floor:

> Carving out an exception to federal preemption for local ordinances relating to the sale or distribution of tobacco products makes perfect sense. While the FDA is authorized to restrict the sale or distribution of tobacco products if it finds that such a restriction is in the public interest – and while any such restriction could fall under the rubric "tobacco product standards" – it seems clear that the primary purpose of the "tobacco product standards" is to regulate the manufacture of tobacco products. Nearly all of the "tobacco product standards" mentioned in the FSPTCA relate to the content of tobacco products. (Citations omitted.) Each of these standards relates clearly and directly to the fabrication of tobacco products – an area in which uniform regulation is not only advisable but necessary. . . .
>
> [T]he FSPTCA grants states and localities the power to regulate sales – without qualification. By explicitly "preserving" and "saving" the right of state and local governments to regulate the sale and distribution more (but not less) restrictively than the FDA might, Congress expressed a clear and unmistakable preference for limiting the federal government's role to setting a floor below which no local sales regulations could go, while remaining sensitive to differing sensibilities about the use of tobacco products in different parts of the country.

U.S. Smokeless Tobacco, 703 F. Supp. 2d at 344-45.

In other words, local sales restrictions, including prohibitions of subclasses of tobacco products, are not within the scope of the Preemption Clause at all – notwithstanding the reality that the FDA may eventually promulgate a "tobacco product standard" that sets a floor for all sales or distributions of a class of tobacco products. Rather, what are preempted are locally-imposed manufacturing or fabrication requirements that are inconsistent with federal standards of the same sort. The power to impose sales restrictions, on the other hand, are specifically

preserved to the States and saved from any reading of the Preemption Clause that might seem to reach them.

I then found it highly unlikely that Plaintiffs could establish that the City's Ordinance was preempted. As noted above, and as discussed at length in the PI Order, the Ordinance prohibits the sale of flavored smokeless tobacco anywhere in the City other than at a "tobacco bar." See id. at 341 (citing N.Y. City Admin. Code § 17-715); see also N.Y. City Admin. Code § 17-502(jj) (defining "tobacco bar"). I ruled that the Ordinance therefore did no more than the express language of the FSPTCA allowed the City to do: prohibit the sale or distribution of a subclass of tobacco product, except at certain locations.

I also found that the Ordinance did not conflict with the purposes or objectives of the FSPTCA. That the FDA may someday choose to regulate smokeless tobacco products in a manner inconsistent with the Ordinance does not mean that the City is deprived of its power to regulate in the absence of such action. To the contrary, all of the evidence indicated that Congress specifically intended a continued role for State and local regulation, as long as that regulation did not intrude into tobacco product standards aimed at manufacturing. U.S. Smokeless Tobacco, 703 F. Supp. 2d at 346-48.

B. The reasoning of the PI Order, to which I adhere, mandates summary judgment for the City

Nothing has changed since I issued the PI Order. None of the relevant provisions of law has been amended, and the FDA has not issued any sales-related tobacco product standard that actually conflicts with the Ordinance. No new facts that might affect the analysis of 18 months ago have been adduced.

Unable to rely on any intervening developments, Plaintiffs argue for preemption from two premises that were necessarily rejected by my earlier analysis.

First, Plaintiffs argue that a local sales restriction that altogether prohibits a tobacco product is a *de facto* manufacturing standard. They present the following *reductio ad absurdum*: if the City can ban tobacco products because they have a certain characteristic (like being flavored) or because they are manufactured in a certain way (for instance using a flavoring process), then the City could effectively impose more stringent manufacturing standards than the FSPTCA. All the City would need to do is establish its own manufacturing standards for tobacco products, and ban any products that do not meet the City's standards, even if those same products would meet federal manufacturing standards. In this way (the argument continues), the City could undermine the division of jurisdiction intended by the FSPTCA, which vests exclusive control over manufacturing standards in the Federal government.

Thus, Plaintiffs conclude that any sales ban should be treated as "relating" to a "tobacco product standard," and therefore as falling within the scope of the Preemption Clause, in order to avoid the result just described – de facto City control over tobacco product manufacturing standards. Congress has determined that, while *flavored cigarettes* should not be made (see 21 U.S.C. § 387g(a)(1)(A)), *smokeless flavored tobacco* can and should be made. The City's attempt to ban the "manufacture" of smokeless tobacco by refusing to permit its sale except in tobacco bars thus conflicts with the FSPTCA.

This argument is predicated on the false premise that there is no relevant distinction between a sales prohibition and a manufacturing standard. The language, structure and purpose of the statute defeat this proposition entirely. The Preservation Clause says sales restrictions, and even prohibitions, are within the States' reserved powers. Id. § 387p(a)(1). Only *manufacturing*

standards are remitted to federal control. Although the Preemption Clause raises the issue of whether a local sales restriction might be preempted if a tobacco product standard related to sales were promulgated by the FDA, see U.S. Smokeless Tobacco, 703 F. Supp. 2d at 340-41, 344, the Saving Clause makes plain Congress' intention that sales restrictions not be preempted in the absence of federal regulatory action – and no such regulation has been imposed. The effect of the Saving Clause is to compel the Court to read the reference to State requirements "relating to tobacco product standard" in the Preemption Clause narrowly to refer only to the kinds of manufacturing and fabrication set forth the actual tobacco product standards, 21 U.S.C. § 387g, or whatever sales restrictions the FDA may later see fit to impose, see id. § 387g(a)(4)(B)(v).

Thus, it is Congress, not this Court, that has distinguished between restrictions going to the manufacturing (the making) of tobacco products, on the one hand, and restrictions relating to their sale or distribution to persons of any age, on the other. If Plaintiffs have a theoretical problem with that distinction, they should take it up with Congress.

In any event, Plaintiffs' theory – that a sales ban amounts to a manufacturing standard – is specious. How a thing is made and whether and where it can be sold are entirely different issues, in theory and as a matter of fact. The FDA has no power to ban all sales of smokeless tobacco products (see id. 387g(d)(3)), but is permitted to regulate the way smokeless tobacco is made. The Ordinance does not prevent Plaintiffs from making a flavored smokeless tobacco, or from performing that fabrication in whatever way they wish – as long as they do so consistently with federal standards. Rather, it simply prohibits Plaintiffs from selling those products in New York City anyplace except a tobacco bar. That the Ordinance does not restrict manufacturing is made plain by the fact that the Ordinance on its face would allow Plaintiffs to manufacture flavored smokeless tobacco within City limits.

There is a second false premise in Plaintiffs' argument. They contend that Congress has in effect determined that flavored smokeless tobacco ought to be manufactured and sold, and that the Ordinance conflicts with that determination. For evidence of this determination, they rely on the FSPTCA's ban on the manufacture flavored cigarettes. 21 U.S.C. § 387g(a)(1). Congress' failure to ban the making of flavored smokeless tobacco, they reason, indicates Congress' intent "to permit[] the manufacture *and sale* of non-cigarette tobacco products with characterizing flavors." Pl.'s Br. at 10 (emphasis added). Since, if Congress or the FDA says that a class of product must not be banned, or must be sold, the City cannot pass an ordinance banning its sale, the passage of the Ordinance here conflicts with the Congressional determination and is therefore preempted.

But Congress' decision to ban the manufacture of flavored cigarettes does not amount to a directive that smokeless tobacco (whose manufacture is not banned) be sold in every type of outlet everywhere in the country. Again, the statute's division of regulatory responsibility is clear. Congress and the FDA say what can be made, and how it must be made; and the States and their subdivisions decide what being made can be sold, where and to whom. If Plaintiffs were correct that everything Congress allows to be made must be sold everywhere, then the language of the Preservation and Savings Clauses reserving to the States the power to restrict sales and distribution would be meaningless. All decisions about sales and distribution would necessarily be in the federal government's hands, exercised through manufacturing restrictions – or, worse, as in this case, the absence of such restrictions.

Plaintiffs' argument is therefore at odds with the language, structure and purpose of the FSPTCA.

Nor can they salvage it by asking the Court to read into the Saving Clause a limitation that allows local control only over the "time, place, and manner" of tobacco product sales, prohibiting local product bans on sales. Plaintiffs' limitation is an effort to give meaning to the statutory language their reading otherwise erases, but it is not persuasive.

First, such a limitation is found nowhere in the provisions on which they rely. "[T]he FSPTCA grants states and localities the power to regulate sales – without qualification." U.S. Smokeless Tobacco, 703 F. Supp. 2d at 344. As the City points out, Congress knew how to include "time place and manner" restrictions in the FSPTCA. See 15 U.S.C. § 1334(c) (allowing States power to make time place and manner restrictions for advertising), added by FSPTCA § 203.

Second, Plaintiffs' limitation to time, place, and manner sales restrictions is inconsistent with what I have already found to be the essential division of regulatory power in the statutory scheme. See supra.

Finally, such a limitation on local power to regulate sales and distribution does not make any sense. If Plaintiffs are concerned that local governments will enact *de facto* manufacturing standards by passing product bans, it is hard to see how that fear is alleviated by allowing a sales restriction that, for example, forbids sales except on Sundays, between two and three pm, from licensed dealers only, and to customers between the ages of 62 and 63. Indeed, if the line Plaintiffs would draw is at outright bans, then Ordinance does not run afoul of it, since sale is permitted of flavored smokeless tobacco in some places (tobacco bars) at all times. See N.Y. City Admin. Code § 17-715.

The line drawn by plain language and apparent structure of the FSPTCA is much simpler. The law says that local tobacco restrictions of any sort are preempted when they are inconsistent

with federal tobacco product standards, but that local sales and distributions restrictions are not preempted except when contradicted by a specific federal regulatory provision. Thus, until the FDA determines that flavored smokeless should be sold everywhere, or subject only to certain specific restrictions, the City is free ban it here.

Plaintiffs' remaining arguments fail once the foregoing premises are rejected.

Plaintiffs correctly point out that the final category of regulation referred to in the Saving Clause – fire safety standards – is the only one that involves a true "tobacco product standard" – i.e., a regulation affecting the manufacture or fabrication of tobacco products. Plaintiffs are also correct that this confirms what the Preemption Clause says outright: Congress did not generally intend for States to regulate with respect to other tobacco product standards. But insofar as the Ordinance does not impose any "tobacco product standard," and is not in conflict with any federally-imposed standard, these observations avail Plaintiffs nothing.

Plaintiffs also make much of the second "relating to" phrase in the Saving Clause, emphasized below:

> Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or *relating to* fire safety standards for tobacco products.

21 U.S.C. § 387p(2)(B) (emphasis added).

But, as explained in the PI Order, that additional phrase is necessary because all of the categories other than fire safety standards are modified by the phrase "of any age." 703 F. Supp. 2d at 345. Moreover, as Plaintiffs themselves point out, the only category in the Saving Clause that actually might impose a manufacturing standard is the fire safety category. It therefore makes sense to set it off from the others. In any event, the inclusion of that second phrase does

not by any stretch of logic reflect a Congressional intent to save only local laws restricting the time, place, or manner of tobacco sales.

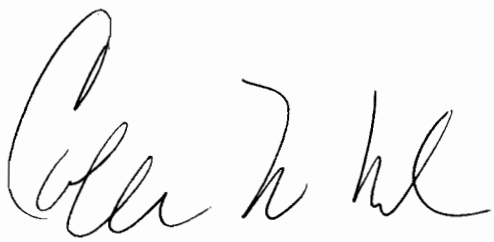
Finally, Plaintiffs try to find meaning in the fact that the Preservation Clause purports to reach both sales restrictions "and prohibitions," while the Saving Clause reaches only sales restrictions. Compare 21 U.S.C. § 387p(1), with id. § 387p(2)(B). Plaintiffs would conclude from this that prohibitions are preempted and never saved. But as the Preemption Clause is itself silent regarding sales prohibitions, it seems far more likely that prohibitions are preserved and never preempted, and therefore need never be saved. Insofar as the latter inference is more consistent with the statute's language, structure, and purpose, I opt for it.

CONCLUSION

For the foregoing reasons, and for those stated in the PI Order, Plaintiffs' motion for summary judgment (No. 30) is DENIED, the City's cross-motion (No. 35) is GRANTED, and the complaint in this matter is dismissed.

The clerk is directed to remove the motions at docket numbers 30 and 35 from the Court's active motion list, and to terminate the case from the docket.

Dated: November 15, 2011



U.S.D.J.

BY ECF TO ALL COUNSEL