ORAL ARGUMENT NOT YET SCHEDULED

No. 13-5281

United States Court of Appeals
For the District of Columbia Circuit

AMERICAN MEAT INSTITUTE, *et al.*,
Plaintiffs–Appellants,
v.
UNITED STATES DEPARTMENT OF AGRICULTURE, *et al.*,
Defendants–Appellees,
and
UNITED STATES CATTLEMEN'S ASSOCIATION, *et al.*,
Intervenors for Defendants–Appellees.

On Appeal from the United States District Court for the District of Columbia in Case No. 1:13-cv-1033-KBJ (Hon. Ketanji Brown Jackson)

BRIEF FOR INTERVENORS FOR DEFENDANTS-APPELLEES UNITED STATES CATTLEMEN'S ASSOCIATION, NATIONAL FARMERS UNION, AMERICAN SHEEP INDUSTRY ASSOCIATION, AND CONSUMER FEDERATION OF AMERICA

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CERTIFICATE OF PARTIES, RULINGS, AND RELATED CASES AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Circuit Rule 28(b), the undersigned counsel for Intervenors for Defendants-Appellees in the above-captioned matter submits this Certificate of Parties, Rulings, and Related Cases.

A. Parties and Amici.

Intervenors for Defendants in the court below and Appellees in this Court are the United States Cattlemen's Association, National Farmers Union, American Sheep Industry Association, and Consumer Federation of America.

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, the undersigned counsel further submits that:

The United States Cattlemen's Association ("USCA") is a national organization committed to presenting an effective voice for the U.S. cattle industry and promoting ranching in the United States. USCA works to promote the interests of cattlemen in the United States on issues such as the Country of Origin Labeling ("COOL") program. USCA has no parent company, and no publicly owned corporation has a 10% or greater ownership interest.

National Farmers Union ("NFU") is a national organization representing the interests of farmers and ranchers across the United States. NFU works to protect and enhance the economic well-being and quality of life for family farmers,

ranchers, fishermen, and rural communities by advocating the policy positions developed by its members at a grass-roots level on issues such as COOL. NFU has no parent company, and no publicly owned corporation has a 10% or greater ownership interest.

The American Sheep Industry Association ("ASI") is the national trade organization for the U.S. sheep industry, working to protect the interests of all sheep producers. ASI has been involved in the development of COOL regulations, concerned over customer confusion between foreign and domestic lamb, a commodity covered in the COOL statute and regulations. ASI has no parent company, and no publicly owned corporation has a 10% or greater ownership interest.

Consumer Federation of America ("CFA") is an association of non-profit consumer organizations advancing consumer interests through research, advocacy, and education. CFA advocates pro-consumer policies at the national and state levels of legislature as well as at government agencies and the courts. CFA has been involved in the development of COOL regulations to protect consumers' right to know the origin of their food. CFA has no parent company, and no publicly owned corporation has a 10% or greater ownership interest.

Plaintiffs in the court below and Appellants in this Court are the American Meat Institute, American Association of Meat Processors, Canadian Cattlemen's Association, Canadian Pork Council, Confederacion Nacional de Organizaciones Ganaderas, National Cattlemen's Beef Association, National Pork Producers Council, North American Meat Association, and Southwest Meat Association.

Defendants in the court below and Appellees in this Court are the United States Department of Agriculture; Agricultural Marketing Service; Tom Vilsack, in his official capacity as Secretary of the United States Department of Agriculture; and Anne L. Alonzo, in her official capacity as Administrator of the Agricultural Marketing Service.

Additionally, Food and Water Watch; Ranchers Cattlemen Action Legal Fund, United Stockgrowers of America; South Dakota Stockgrowers Association; and Western Organization of Resource Councils have moved to participate as *amicus curiae* in support of Appellees and Intervenors for Defendants-Appellees; the Court has not yet issued a decision on this motion.

B. Rulings under Review.

References to the rulings at issue appear in the Brief for Appellants.

C. Related Cases.

This case has not been previously before this Court or any other appellate court. Counsel is not aware of any related cases currently pending in this Court or any other court.

/s/ Terence P. Stewart
Terence P. Stewart

Counsel to Intervenors for Defendants-Appellees

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GLOSSARY OF ABBREVIATIONS

AMA	Agriculture Marketing Act
AMS	United States Department of Agriculture's Agricultural Marketing Service
COOL	Country of Origin Labeling
FSIS	United States Department of Agriculture's Food Safety and Inspection Service
USDA	United States Department of Agriculture
WTO	World Trade Organization

BRIEF FOR INTERVENORS FOR DEFENDANTS-APPELLEES

INTRODUCTION

United States Cattlemen's Association, National Farmers Union, American Sheep Industry Association, and Consumer Federation of America (collectively "intervenors") respectfully submit this Brief in *American Meat Institute, et al. v. United States Department of Agriculture, et al*., Court No. 1:13-5281.

STATUTES AND REGULATIONS

Except for the regulations contained in the Addendum I to this Brief, all applicable statutes, *etc*., are contained in the addendum to the Appellants' Brief.

STATEMENT OF THE FACTS

Appellants' Brief at 7-15 provides the facts of this case in general; however, intervenors disagree with appellants' statements at pages 8-9 that Congress' "primary aim" in the 2002 COOL amendments was to limit use of "United States" designations and that AMS's 2003 regulation "went much farther than the statute." These are appellants' opinions, not facts. Additionally, appellants misstate that the 2003 regulation required all meat labels list all "born, raised, and slaughtered" locations. The 2003 regulation required steps occurring in the United States be listed and allowed, but did not require, their individual listing otherwise. JA198.

SUMMARY OF ARGUMENT

The district court, denying preliminary injunctive relief, held that the movants failed to demonstrate irreparable injury and were unlikely to succeed on

the merits. Appellants come no closer to making these necessary showings now. First, the disclosure requirements at issue are allowable under *Zauderer* because they are reasonably related to the government's interest in addressing consumer confusion. Second, the labeling requirements and elimination of commingling flexibility are entitled to *Chevron* deference as the agency's reasonable interpretation of issues not unambiguously addressed in the Statute but within the authority granted the agency. Third, appellants have not shown that any costs to them for complying with the Final Rule rise to the level of irreparable injury necessary to support the extraordinary remedy of a preliminary injunction.

ARGUMENT

I. Standard of Review.

The district court's weighing of the factors involved in, and its ultimate denial of, a preliminary injunction are reviewed for abuse of discretion, legal conclusions are reviewed *de novo*, and findings of fact are reviewed for clear error. *In re Navy Chaplaincy*, 697 F.3d 1171, 1178 (D.C. Cir. 2012). When there is a close question of constitutional law, the district court's decision should be left intact, as a decision on a close question will very rarely be an abuse of discretion. *See Ashcroft v. Am. Civil Liberties Union*, 542 U.S. 656, 664-66 (2004); *Gordon v. Holder*, 721 F.3d 638, 644-45 (D.C. Cir. 2013).

II. Appellants Have Failed to Show a Likelihood of Success on Their Claims.

A. The Final Rule Does Not Violate the First Amendment.

1. The Final Rule Is Subject to Zauderer *Scrutiny, Not* Central Hudson.

The district court analyzed the Final Rule under the *Zauderer* "reasonableness" standard for two reasons. *See* JA1147. First, because "the Final Rule mandates 'purely factual and uncontroversial' disclosures about where an animal was born, raised, and slaughtered," JA1152 (citing *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1986)), and, second, because "the Final Rule sufficiently establishes that the regulation was intended to address the possibility of consumer confusion regarding the origin of covered commodities." JA1155.

Appellants argue that the district court erred by applying the wrong standard of scrutiny, claiming that the court should have applied heightened scrutiny under *Central Hudson*. Appellants' Brief at 18-19. Appellants are mistaken. The district court applied the appropriate standard–*Zauderer* scrutiny.

In the realm of commercial speech, the Supreme Court has recognized a distinction between laws that impose disclosure requirements and laws that prohibit speech outright. *See Zauderer*, 471 U.S. at 650. For commercial speech restrictions, courts apply a heightened scrutiny established in *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). For laws that

mandate disclosure of "purely factual and uncontroversial information" of a commercial nature, courts apply a lesser level of scrutiny akin to rational basis review, as the "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *See Zauderer*, 471 U.S. at 651 (emphasis added). Thus, "'warning[s] or disclaimer[s] might be appropriately required … in order to dissipate the possibility of consumer confusion or deception.'" *Id.* (quoting *In re R.M.J.*, 455 U.S. 191, 201 (1982)).

A factual disclosure requirement does not violate the First Amendment if reasonably related to furthering the government's interest in enacting the requirement. *See id.* This Circuit has said that the *Zauderer* standard applies where the government's interest in the disclosure requirement is "in avoiding misleading or incomplete commercial messages." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1213 (D.C. Cir. 2012) [hereinafter *RJR*] (internal quotations and citations omitted).[1] The district court correctly determined that the Final Rule met all of these requisites for application of *Zauderer* scrutiny.

[1] Other circuits have applied *Zauderer* in other situations as well, *i.e.*, where the government's interest was not necessarily related to preventing consumer deception. *See RJR*, 696 F.3d at 1227 n.6 (dissent of Rogers, C.J.); *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509, 556 (6th Cir. 2012) ("*Zauderer*'s framework can apply even if the required disclosure's purpose is something other than or in addition to preventing consumer deception"); *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 133 & n.21 (2d Cir.

Appellants do not dispute that the Final Rule mandates "'purely factual and uncontroversial' disclosures" and "thus satisfies this prerequisite to *Zauderer's* application." JA1152. Instead, they challenge the district court's finding that "the Final Rule sufficiently establishes that the regulation was intended to address the possibility of consumer confusion regarding the origin of covered commodities." JA1153.

a. The government's interest in preventing consumer confusion is not* post hoc *rationalization.

Appellants argue that the court erred because it allegedly "read an anti-deception rationale into the Final Rule that AMS had not articulated," and that this rationale is impermissible "post hoc rationalization." Appellants' Brief at 20, 25. Appellants are mistaken. "An agency that provides further explanation of its decision during the course of litigation is not always engaging in impermissible *post hoc* rationalization." *Grossmont Hospital Corp. v. Sebelius*, 903 F. Supp. 2d 39, 58 n.10 (D.D.C. 2012) (citing *Nat'l Oilseed Processors Ass'n v. Browner*, 924 F. Supp. 1193, 1204 (D.D.C. 1996), *aff'd in part and remanded sub nom. Troy*

2009) (*Zauderer*'s holding was broad enough to encompass nonmisleading disclosure requirements); *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (*Zauderer* is not limited to cases of potentially deceptive advertising); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) (upholding compelled disclosure not intended to prevent consumer confusion or deception *per se*, but to better inform consumers about products they purchase).

Corp. v. Browner, 120 F.3d 277 (D.C. Cir. 1997)). Here, the anti-deception rationale described by the district court is, if anything, a permissible *post hoc* explanation because it relies on a "more detailed explanation" of the rationale underlying the Final Rule rather than a "new rationale." *Nat'l Oilseed*, 924 F. Supp. at 1204.

The government's interest in correcting misleading speech and preventing consumer deception and confusion has always been an underlying rationale for the COOL statute and regulations. Congress intended the law to provide consumers with more information about the origin of their food so they could make informed buying decisions. *See* S. Rep. No. 107-117, 107th Cong., 1st Sess. 93-94 (2001) ("[The 2002 Farm Bill] provides consumers with greater information about the food they buy."); S. Rep. No. 110-220, 110th Cong., 1st Sess. 198 (2007) ("[The 2008 amendments were intended] to provide consumers with additional information regarding the origin of certain covered commodities."). It is intuitive that one purpose of providing more origin information to consumers is to lessen confusion occasioned by potentially misleading or nonexistent labels.[2] Congress

[2] Indeed, addressing consumer confusion or deception is inherently part of the *raison d'etre* for country-of-origin labeling requirements generally. For example, the purpose of the U.S. customs law requiring all imported articles be marked with their country of origin is to inform ultimate purchasers so they are not deceived about the origin of goods. *See* 19 U.S.C. § 1304. The U.S. Court

recognized that such confusion was particularly acute in the case of meat products, many of which may bear USDA inspection stamps but no origin information. Legislators noted that this "creates a false impression about the origin of USDA grade meat." 107th Cong. Rec. H1538 (daily ed. Apr. 24, 2002) (statement by Rep. John Thune in the debate leading to the passage of the 2002 COOL law).

Consistent with this rationale, FSIS codified its regulations requiring origin labels to conform to AMS's COOL regulations at 9 C.F.R. § 317.8(b)(40), under the section addressing, inter alia, "[f]alse or misleading labeling or practices ..." 9 C.F.R. § 317.8.

In issuing the 2013 Final Rule, AMS stated the "purpose of COOL is to provide consumers with information upon which they can make informed shopping choices," and "to provide consumers with more specific information." JA518. The district court noted that AMS "explicitly stated" that disclosure of production step information was required "to provide consumers with 'more specific information on which to base their purchasing decisions,'" and that the language

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of Customs and Patent Appeals (predecessor to the Federal Circuit) said the purpose of such labeling was that the consumer "may, by knowing where the goods were produced, be able to buy or refuse to buy them…." *United States v. Friedlaender & Co.*, 27 C.C.P.A. 297, 302 (1940). If the marking was inaccurate, the purchaser "would be *deceived* in buying as the product of one country the product of another which he did not want." *Id.* at 303 (emphasis added).

used in the Final Rule indicated that "consumer confusion was the major driver behind the rule's promulgation." JA1154. The district court further noted that interested public commenters in the rulemaking process supported the revised regulation because it would provide more information to consumers. *See* JA1154, citing JA511 ("AMS received 453 comments, including four petitions signed by more than 40,000 individuals, which indicated that the proposed rule makes labels more informative for consumers.").[3]

Finally, the mere fact that the Final Rule does not recite the exact words "deceive" or "mislead" does not undermine the district court's conclusion. There is no support for such a formulaic, "magic words" approach. While this Court referred specifically to "misleading" and "deceptive" communications as those subject to less-stringent *Zauderer* scrutiny in *RJR*, 696 F.3d at 1213-14, it did so to distinguish those government interests from the very different government interest at issue in that case, which was to dissuade consumers from smoking. *Id*. at 1218. *RJR* does not stand for the proposition that a disclosure regulation aimed at providing more accurate and specific information to consumers must recite the words "deceive" or "mislead" to be eligible for *Zauderer* scrutiny.

[3] Notably, both the WTO dispute panel and the Appellate Body also recognized that an objective of COOL is to reduce consumer confusion. JA467 (para. 451 & n.915).

The case law does not support such a restrictive approach. Indeed, *Zauderer* explained that disclosure requirements are allowable to counter not only possible consumer deception but also "consumer confusion." *Zauderer*, 471 U.S. at 651 (quotation marks and citations omitted). The Supreme Court has also described regulations aimed at aggressive sales practices and those requiring disclosure of beneficial consumer information as subject to a less strict standard of review. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996). The Court has also explained that regulations may permissibly "correct omissions that have the effect of presenting an inaccurate picture." *In re R.M.J.*, 455 U.S. at 201 (citation omitted). Thus, the district court did not abuse its discretion when it determined that the intent to address the possibility of consumer confusion was clear in the Final Rule, even if the specific terms "deceive" or "mislead" were not used. JA1154-55.

In short, the district court did not impermissibly read a *post hoc* anti-deception rationale into the Final Rule. The district court's conclusion that the Final Rule was enacted to serve the government's interest in preventing consumer confusion, and thus is subject to *Zauderer* scrutiny, should therefore be upheld.

b. The* Zauderer *standard is not limited to voluntary advertisements and may apply to revised regulations.

Appellants argue that *Zauderer* does not apply to this case because *Zauderer* is limited to cases involving "voluntary" advertisements and further "does not

apply to disclosure requirements that merely revise prior disclosure requirements." Appellants' Brief at 27-28. Both arguments fail. While the facts in *Zauderer* happened to concern the regulation of voluntary advertisements, this does not mean that the principles of *Zauderer* do not apply to compelled disclosures outside of the voluntary advertising context or to agency revisions of such disclosure requirements. Indeed, *Zauderer* has been applied in both situations.

First, courts have applied *Zauderer* to disclosure requirements outside of the context of voluntary advertising. For example, in *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, the Second Circuit applied *Zauderer* scrutiny to uphold a Vermont statute that required manufacturers of some mercury-containing products to label the goods regarding their mercury content and proper disposal. 272 F.3d at 107, 115-16. Similarly, in *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, the Second Circuit, applying *Zauderer*, upheld a New York City regulation that revised existing menu regulations to require all chain restaurants to disclose the calorie content of meal items on menus and menu boards. 556 F.3d at 121. These cases show that *Zauderer* may be applied to analyze compelled disclosures in contexts other than voluntary advertising.

Second, this Court's decision in *Spirit Airlines* shows that *Zauderer* may be applied when an agency revises a regulation concerning compelled disclosures. There, the Department of Transportation ("DOT") revised a regulation that had

required airlines to disclose "the entire price to be paid by the customer," but allowed airlines to list the base fare, taxes, and fees separately without listing the total. The revised regulation required airlines to explicitly and most prominently disclose the total price of the fare. *Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 687 F.3d 403, 408-09 (D.C. Cir. 2012). One reason DOT revised its existing rule was to prevent consumer confusion; thus, this Court applied *Zauderer* and upheld the DOT's revised regulation. *Id.* at 408-409.

In sum, *Zauderer* may be applied where an agency revises its own prior disclosure requirements and where those requirements compel disclosure outside of the context of voluntary advertising.[4]

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[4] Appellants' citation to *United Foods* is also inapposite. Appellants' Brief at 28. In *United Foods*, the Court did not "decline to apply *Zauderer*," as appellants claim (Appellants' Brief at 28), because the Court was not faced with the question of whether to apply *Zauderer*. The question there was whether the government may require people to subsidize speech which with they disagree. *United States v. United Foods, Inc.*, 533 U.S. 405, 410 (2001). In *dicta*, the Court referred to *Zauderer* merely to point out that its decision was not "inconsistent" with *Zauderer*. *Id.* at 416. Because *Zauderer* was not at issue, *United Foods* does not state a rule regarding the scope of *Zauderer*.

Appellants' references to *Milavetz* and *RJR* are also unavailing. Appellants' Brief at 28-29. Neither case states a rule that the application of *Zauderer* scrutiny is limited to compelled disclosures involving *voluntary* commercial advertisements. Appellants err in asserting the existence of a general rule from the specific factual contexts of those cases.

2. The Final Rule Is Permissible Under Zauderer *Because It Is Reasonably Related to Preventing Consumer Confusion and Deception.*

Compelled disclosure in commercial speech of purely factual and uncontroversial information complies with the First Amendment if it is "reasonably related" to the government's interest in preventing consumer deception or confusion. *Zauderer*, 471 U.S. at 651. This Court has ruled that *Zauderer* may be satisfied when "a self-evident–or at least 'potentially real'–danger" of consumer confusion exists. *RJR*, 696 F.3d at 1214. The government need not produce evidence that confusion has or will occur where the possibility of deception is self-evident or where, based on experience and common sense, the likelihood of deception is hardly speculative. *Spirit Airlines*, 687 F.3d at 413.

The district court found "experience and common sense dictate[ ] that there was a likelihood of consumer confusion under the prior COOL program." JA1154. The district court offered as an example the fact that the 2009 regulation permitted muscle cuts from ninety-nine strictly U.S.-origin cattle to be individually labeled as "Product of the United States and Mexico" if even one Mexican animal was processed the same day as the ninety-nine U.S. cattle. JA1153. The district court also found that statements in the Final Rule evidenced the agency's intent to prevent consumer confusion. JA1154-55. This Court has held that a trial court's findings regarding the deceptiveness of commercial speech are findings of fact that must be upheld unless "clearly erroneous." *F.T.C. v. Brown & Williamson*

Tobacco Corp., 778 F.2d 35, 41 (D.C. Cir. 1985). Appellants have failed to demonstrate that the district court's findings of fact regarding the consumer confusion addressed by the Final Rule are clearly erroneous, and the district court's findings are supported by the underlying record. Thus, these findings must be upheld.

Appellants first argue that the risk of deception under the prior labeling regime cannot be self-evident, because it would have been irrational for the agency to adopt such a regime. Appellants' Brief at 35. But agencies are not required to achieve perfection and foreclose all possible deception in every disclosure rule. *Zauderer*, 471 U.S. at 651 n.14. To the contrary, courts routinely uphold changes to regulations and policies based on agency experience. *Nat'l Cable & Telecomms. Ass'n. v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005); *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 863-64 (1984). The Final Rule is such a change based on AMS's experience with COOL.

Second, appellants claim the district court's conclusion is undermined by the fact that the COOL regime permits less precise labeling of other products that are commingled. Appellants' Brief at 36-37, 39. These differences flow from the COOL statute itself, which requires more precise labeling of muscle cuts finished in the United States than it does of other products, rather than from the challenged

regulation. Furthermore, the government is entitled to regulate disclosure problems in a piecemeal fashion. *Zauderer*, 471 U.S. at 651 n.14.

Third, appellants claim that the previous flexibility to list countries in any order on cuts from Category B and C cows that were processed on the same day posed no risk of deception. Appellants' Brief at 37. However, appellants' example only highlights the confusion under the prior regulations: labeling Category B and C cuts identically as "Product of the U.S. and X" obscured the dramatically different histories of the animals. The Category C animal would have been only slaughtered in the United States, while the Category B animal could have been raised on a U.S. ranch for years. 7 U.S.C. § 1638a(a)(2)(B)-(C). With identical origin labeling on both cuts, a U.S. consumer would be misled into believing that both cuts had an equal connection to U.S. production and would be unable to choose which actually better fit the consumer's preferences.

Webster's dictionary gives among the definitions of "confuse" "to combine without order" and "to fail to distinguish between." Webster's New Universal Unabridged Dictionary 429 (1996). This is precisely what the prior regime did: permit cuts with different origin characteristics to bear a label that combines origins without order and prevent consumers from distinguishing between them. Additionally, as the district court illustrated, the commingling of Category A and Category B cuts creates similar confusion, as ninety-nine U.S. cattle processed on

the same day as one Mexican cow would all be labeled as "Product of the United States and Mexico," preventing the consumer from distinguishing the strictly U.S. product. *See* JA1153. The Final Rule corrects this problem by requiring that all cuts with distinct U.S. processing histories be differentiated by their labels. The Final Rule's modifications are aimed directly at addressing potential consumer confusion.

Finally, appellants argue that the prior regulations were not misleading, because if consumers valued more accurate information the market would voluntarily provide more specific labels. Appellants' Brief at 37-38. This argument is misplaced. The inquiry under *Zauderer* is whether the government regulation is reasonably related to preventing deceptive or confusing commercial speech. Appellants cite no support for the contention that the government must also show that consumers are so desirous of more accurate messages that their purchasing power alone could result in greater disclosure. Courts do not require the government to await a market correction to justify regulation. Further, the record shows that the power in the U.S. meat production industry is heavily concentrated among relatively few meat processors. JA628, JA632. Market failures are common among such oligopolistic, top-heavy industries. Indeed, the record before the agency directly supported the conclusion that consumers valued

more accurate and precise origin information than what was required under the 2009 rule, even if the market did not provide it. JA586-87, JA606.

In conclusion, appellants have failed to demonstrate that the district court's findings of fact regarding the governmental interest served by the Final Rule were clearly erroneous. Moreover, appellants do not appear to contest the district court's determination that the Final Rule is "reasonably related" to that interest, much less raise any argument showing clear error in the district court's determination that the Final Rule is in fact reasonably related to that interest. JA1156-57. Thus, this Court should affirm the district court's findings that the Final Rule is reasonably related to the government's interest in preventing consumer confusion and deception.

3. If the Court Determines that Central Hudson *Scrutiny Applies, It Should Remand to the Trial Court to Decide in the First Instance.*

Appellants argue that the Final Rule fails First Amendment scrutiny under *Central Hudson*. Appellants' Brief at 30-34. If the Court determines that *Central Hudson* provides the appropriate level of scrutiny, the Court should remand the preliminary injunction determination to the district court to permit it to apply *Central Hudson* scrutiny and make the required factual and legal determinations in the first instance. *Cf. Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 305 (D.C. Cir. 2006) [hereinafter *CFGC*] (remanding to the district court, which had only considered one factor, because "without any conclusions of law as

to the three remaining factors, we are unable to determine whether the district court properly carried out this function [of balancing the four factors].").

4. *Even if the Court Applies* Central Hudson *Scrutiny in the First Instance, the Final Rule Directly Advances a Substantial Government Interest and Is Not More Extensive than Necessary.*

Appellants argue that the government interests served by the Final Rule are not substantial, that the Final Rule does not directly advance or reasonably fit these interests, and thus that the Final Rule fails First Amendment scrutiny under *Central Hudson*. Appellants' Brief at 30-34.

As a preliminary matter, we note that appellants do not challenge the constitutionality of the COOL statute or the 2009 COOL rule. In *Nat'l Cable & Telecomms. Ass'n v. FCC*, this Court reviewed a challenge to an order specifying how a carrier should obtain customers' approval to use information that is collected pursuant to, and the use of which is limited by, statute. 555 F.3d 996, 997 (D.C. Cir. 2009). In examining the First Amendment claim, the Court explained that, by not challenging the constitutionality of the underlying statute, "petitioners necessarily concede . . . that the government has a substantial interest in protecting the privacy of customer information and that requiring customer approval advances that interest." *Id.* at 1000. Similarly, here, by conceding the constitutionality of the statute and 2009 rule, the appellants concede that the

governmental interest served by the statute and 2009 rule is substantial and directly advanced by those measures.

The governmental interest served by the 2013 Final Rule is the same substantial interest served by the statute and the 2009 rule: to provide additional, and more accurate, information to consumers regarding the origin of their food. This is clear from the factual findings of the trial court regarding the 2013 rule, JA1154-55, as well as the legislative and regulatory history of the COOL law and regulations reviewed above. Appellants do not contest that this is the interest served by the 2013 Final Rule. Appellants' Brief at 31-32. Instead, they appear to argue that even if this interest may be substantial in some cases, it is not in this case, because the government has not identified any real or material benefit that will result from providing the specific information required in the 2013 Final Rule. *Id*. Their argument is without merit.

The Final Rule materially and directly advances the government's interest in providing additional and more accurate information to consumers regarding the origin of their food. The labels mandated by the Final Rule list specific production steps and the countries in which those steps occurred, while the prior labeling regime did not. JA510. The new labels ensure that meat is labeled with the specific origin information that pertains to the animal from which the meat was actually derived, rather than information regarding all possible origins of every

animal processed on the same day as the animal from which it was derived; the prior rule did not. JA511. In short, if the more general mandates of the statute and the less specific labels in the 2009 rule materially and directly advanced the government's substantial interest in increasing consumer information, which the appellants concede they did, the 2013 Final Rule directly and materially advances that substantial interest even further.

Appellants also challenge the second substantial interest served by the 2013 Final Rule, fulfilling the international trade obligations of the United States. To the extent that appellants contest whether this is a substantial interest, compliance with international obligations is a recognized interest of the U.S. Government. *See Golan v. Holder*, 132 S. Ct. 873, 894 (2012). And the regulation advances and is narrowly tailored to this interest. Congress has statutorily delegated the decision of whether and how to bring U.S. laws, regulations, and practices into compliance with adverse WTO decisions to Congress and the Executive Branch. 19 U.S.C. § 3533(g). AMS enacted the 2013 Final Rule following the statutory process, through which the Executive Branch and the relevant Congressional committees were consulted, to develop a regulation that would comply with the WTO ruling to the extent desired by the government. JA1112. A claim that the regulation does not advance or is not tailored to the government's interest of complying with the WTO ruling belies the very process by which the regulation was developed.

Accord Boos v. Barry, 485 U.S. 312, 329 (1988) (finding that, as "Congress no longer considers this statute necessary to comply with our international obligations[,]" the contention that the statute was narrowly tailored was "gravely weakened").

Accordingly, the Final Rule satisfies the requirements under the *Central Hudson* test and appellants' claims to the contrary must fail.

B. The Final Rule Is a Legitimate Exercise of Statutory Authority and Is Entitled to Deference.

The district court found that appellants failed to show a likelihood of success on their claims that the Final Rule contravenes the statute. The district court rejected the claim that appellants were likely to show that AMS could not require specific origin information on labels and could not regulate commingling. Instead, the district court held that Congress' apparent intent was to develop a uniform system for determining the country of origin for muscle cuts of meat in various situations and to authorize AMS to implement regulations to ensure origin information was conveyed to consumers. JA1161-62.

The district court reasonably interpreted the different subsections of the AMA as creating two separate obligations: (1) that each animal be designated among four categories to determine what countries qualify as country of origin; and (2) a separate obligation to inform customers of country of origin information.

JA1165. The district court reasonably concluded that the statute did not restrict what origin information labels could be required to bear. JA1167.

Further, the district court found appellants unlikely to succeed on their claim that Congress intended to protect the practice of commingling: the labeling of muscle cuts with the countries of origin for all the animals processed at a facility on one day. JA1170. The court held that AMS's elimination of the allowance for commingling in labeling was consistent with Congress' intent to provide more origin information to consumers. JA1184. The court ruled that it would likely find that the elimination of commingling flexibility and the modified labeling requirements in the Final Rule were legitimate exercises of AMS's authority, consistent with the AMA, and due deference under *Chevron*. JA1169, JA1181-82.

1. The District Court Correctly Found that Process Step Labeling Requirements Do Not Conflict with the Statute.

The district court found that the Final Rule's requirement that labels contain "born, raised, and slaughtered" information "is entirely reasonable" and likely due "great deference." JA1169. Appellants' arguments against this reasoning fail. Where an animal was born, raised, and slaughtered is the information Congress explicitly selected as determinative of the country of origin for muscle cuts. Appellants argue Congress unambiguously intended to disallow any requirement that this same information be shared with consumers. This argument has no basis in the statute, which is silent as to what precise information labels should include.

AMS's decision to require that labels include certain born, raised, and slaughtered information is a reasonable interpretation of the statute and entitled to *Chevron* deference.

Appellants argue the district court erred by interpreting terms differently in the different subsections of the statute dealing with different duties. Appellants' Brief at 49-50. But the same term may take different meanings in the same statute when dealing with different issues. *See Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932) ("It is not unusual for the same word to be used with different meanings in the same act…."); *NetCoalition v. S.E.C.*, 715 F.3d 342, 350 (D.C. Cir. 2013). The term "country of origin" is explicitly given different meanings for the various designated categories of this statute. *See* 7 U.S.C. § 1638a(a)(2)(A)-(D).

Appellants argue Congress intended there should be no specific label information other than a list of countries involved in production. Appellants are mistaken. Had Congress intended to limit AMS's authority on this point, it would have said so; particularly as Congress explicitly limited AMS's authority on other points of COOL. 7 U.S.C. §§ 1638a(d)(2)(B) & 1638a(f)(1). *See Vill. of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 661 (D.C. Cir. 2011) ("Congress obviously knew how to limit the [agency's] authority [in one subsection]…since it did so in [other] subsections…."). The only unambiguous

requirements of COOL are that muscle cuts be designated according to production steps and that information on origin be relayed to consumers. Congress gave AMS the authority to implement the precise rules to achieve this. *See* 7 U.S.C. §§ 1638c(b) and 1638(8). This implementation authority is "a very good indicator of delegation meriting *Chevron* treatment." *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001).

2. Congress Gave AMS Authority to Address Commingling.

Appellants seek to avoid a proper *Chevron* analysis by arguing that AMS's elimination of the commingling allowance is a usurpation of authority rather than an application of the statute. However, as the Supreme Court has recently made explicit, the question of an agency's interpretation of its authority is a *Chevron* question. *City of Arlington, Tex. v. FCC*, 133 S. Ct. 1863, 1870-71 (2013).

Appellants argue *Chevron* step-two is not implicated every time an agency action is not explicitly negated by statute. Appellants' Brief at 44, 50. But this does not mean that step-two is never or is not typically implicated in this situation. Indeed, *Chevron* focuses on areas of statutory silence, *i.e.*, statutory gaps. To prevail at *Chevron* step-one, plaintiffs "must show that the statute unambiguously forecloses the [agency's] interpretation." *Vill. of Barrington*, 636 F.3d at 661. Appellants fail that high standard.

Appellants' reliance on *Ragsdale* is misplaced. Appellants' Brief at 42. In *Ragsdale*, the agency rule, which allowed recovery for certain violations of employee-leave rules absent a showing of prejudice, was found contrary to an express statutory requirement that prejudice be shown. *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 86 (2002); *see Doe v. United States*, 372 F.3d 1347, 1359 (Fed. Cir. 2004) (stating the *Ragsdale* decision was due to the conflict between the regulations and the express statutory directive). This sharply contrasts to the situation here, where Congress did not express any requirement on commingling. *See Mobile Commc'ns Corp. of Am. v. FCC*, 77 F.3d 1399, 1406 (D.C. Cir. 1996) (stating the conclusion reached in *Railway Labor Executives' Ass'n*—that an agency lacked authority to issue a regulation when not authorized by statute—is not applicable where the agency's interpretation of its authority does not conflict with the language and structure of the statute).

Commingling is unavoidably linked to labeling and to the authority granted AMS; it is not a separate issue of "production". Any implementation of the COOL statute must resolve whether cuts falling into the different categories established by Congress must bear distinct labels or not. Before the district court, appellants' counsel agreed that the elimination of commingling flexibility is a necessary outgrowth of AMS's current reform of the labeling regime. JA1083-84. Appellants' attempt to recast commingling as a fully separate issue is a red herring,

seeking to avoid the proper *Chevron* step-one question: did Congress, explicitly or implicitly, authorize AMS to regulate labeling of commingled product? As Congress at a minimum was silent on this precise question (and a more reasonable interpretation is that Congress implicitly authorized AMS to determine this question), *Chevron* step-one is met. And, as AMS made a reasonable interpretation of its authority to address commingling, it is entitled to deference under *Chevron* step-two.

Appellants essentially argue that Congress created four distinct categories for muscle cuts with different processing histories, and, by remaining silent on whether cuts from different categories can share a label, unambiguously intended to forbid the regulation of such commingling. But congressional silence often signals the opposite of a restriction on authority. *Catawba Cnty., N.C. v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) ("Silence…may signal permission rather than proscription."). Such unstated delegations of authority are properly reviewed under *Chevron*: "Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit." *Chevron*, 467 U.S. at 844; *see Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1230 (D.C. Cir. 1994).

Further, appellants' reliance on a prior agency interpretation of the statute is misplaced, as it only serves to emphasize that this is a *Chevron* step-two question. First, an agency may reasonably change its interpretation and still receive *Chevron*

deference. *See Chevron*, 467 U.S. at 863; *Mead*, 533 U.S. at 229; *Nat'l Cable*, 545 U.S. at 981. And none of the prior agency materials appellants cite refers to a clear congressional answer on commingling, but instead use language revealing the agency was even then interpreting the statute. For example, the Kesselman letter refers to how USDA's then-counsel believed the "overall structure and purpose" of the statute "supports our reading of the statute." JA531-32.

Additionally, AMS used its authority to issue specific commingling rules in the 2009 regulation, allowing commingled labeling only on cuts "commingled during a production day." JA204, JA205-06. But appellants' current argument would hold that even this rule was illegitimate because AMS lacked any authority to limit commingling to single-day production. As the district court noted, the same-day commingling practices that appellants now seek to protect are "a creature of regulation," born from the very agency authority appellants now try to refute. JA1172.

As the district court recognized, AMS's elimination of commingling flexibility and the process step labeling requirements are an "entirely reasonable" application of the statute and meet Congress' purpose of providing "consumers with more information about the origins of their meat, not less." JA1169, JA1184; *see* JA1184 n.25 (listing multiple statements from Congress on this intent). Appellants' disagreements with the Final Rule do not negate the deference due

AMS in its application of the authority granted it by Congress. "When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail." *Chevron*, 467 U.S. at 866. Appellants' failure to show that the Final Rule is contrary to statute is a failure to show a likelihood of success on the merits and weighs heavily against the preliminary injunction appellants seek.

III. Appellants Have Not Demonstrated that a Preliminary Injunction Is Warranted Based on the Existence of Irreparable Injury.

Appellants assert they are entitled to preliminary relief based on a First Amendment violation and alleged economic harm. Appellants' Brief at 51-56. Neither assertion survives scrutiny.

A. A Claim of Irreparable Injury Based on a Claimed First Amendment Violation Fails Absent a Likelihood of Success.

Appellants assert that harm stemming from an alleged First Amendment violation is, in and of itself, sufficient to warrant preliminary relief. Appellants' Brief at 51-52. However, as the district court properly recognized, JA1200, an alleged First Amendment violation does not mandate relief where, as here, the movant has not demonstrated a likelihood of success on the merits of such a claim. *See Kiyemba v. Obama*, 561 F.3d 509, 513 (D.C. Cir. 2009) (preliminary relief is improper when the moving party shows no likelihood of success on the merits).

B. Appellants Have Not Shown that the Alleged Economic Harms Are Certain and Great.

The district court found that appellants had not demonstrated irreparable harm because the declarants provided only speculative and unsubstantiated allegations, failed to show that the alleged harms threatened the declarants' viability, and did not establish that the alleged harms stemmed from the 2013 regulation. JA1201-10. The district court's finding should be affirmed. Appellants' declarations are insufficient to establish that appellants will suffer irreparable injury, and appellants have not otherwise demonstrated that their alleged economic harms constitute irreparable injury.

1. Non-recoverable economic losses are not per se *irreparable.*

Appellants assume that any non-recoverable economic loss necessarily equals irreparable injury. This Court, apparently, has not directly addressed the issue of whether a non-recoverable economic loss is *per se* irreparable.[5] Although

[5] This Court has affirmed denials of a preliminary injunction where the district court found that irreparable injury was not demonstrated despite an allegation of irretrievable economic losses, but both cases reviewed only the likelihood of success on the merits prong and did not discuss irreparable injury. *Sandoz Inc. v. FDA*, 439 F. Supp. 2d 26 (D.D.C. 2006), *aff'd* No. 06-5204, 2006 WL 2591087 (D.C. Cir. Aug. 30, 2006); *Apotex Inc. v. FDA*, No. Civ.A. 06-06274 2006 WL 1030151 (D.D.C. Apr. 19, 2006), *aff'd* 449 F.3d 1249 (D.C. Cir. 2006). In two other cases this Court found that the inability to recover monetary relief was sufficient to constitute irreparable injury, but these cases concerned challenges to the government's distribution of funds. Thus, the funds that would

appellants cite *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62 (D.D.C. 2010) in support of their proposition that unrecoverable economic loss is necessarily irreparable, this Court did not adopt a *per se* rule in that case. Appellants' Brief at 53-54. In *Smoking Everywhere*, the trial court reviewed a motion for a preliminary injunction where the FDA denied importation of e-cigarettes into the United States. Because these products accounted for "all, or virtually all," of movants' revenue, the trial court explained, "the potential for economic loss absent preliminary injunction is sufficiently grave to threaten plaintiffs' very existence. Therefore, the Court is satisfied that plaintiffs have shown the necessary irreparable harm." *Smoking Everywhere*, 680 F. Supp. 2d at 76-77. The trial court then added that even if the alleged harm did not threaten plaintiffs' existence, it would still be irreparable because it was not recoverable. *Id.* at 77 n.19.[6] On appeal, this Court affirmed the district court, explaining with

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be non-recoverable were the basis for the dispute and, in the absence of an injunction, movants' claims would be moot. *Ambach v. Bell*, 686 F.2d 974 (D.C. Cir. 1982) (per curiam); *Population Inst. v. McPherson*, 797 F.2d 1062 (D.C. Cir. 1986) (per curiam).

[6] Other district court decisions have explicitly addressed the idea in *Smoking Everywhere* that any unrecoverable economic harm is irreparable injury and explained that "not only is such a rule not the law of this Circuit, but it would also effectively eliminate the irreparable harm requirement." *Air Transp. Ass'n of Am., Inc. v. Export-Import Bank of the U.S.*, 840 F. Supp. 2d 327, 335-36 (D.D.C. 2012) (citing *Nat'l Shooting Sports Foundation, Inc. v. Jones*, No. 11-1401, 2011 WL 3875241, at *3 n.5 (D.D.C. Sept. 2, 2011)). The *Air Transp.*

respect to irreparable injury that the FDA's denial of the products' entry "obviously destroyed the firm's ability in the United States to recover its costs for purchase or production of e-cigarettes." *Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010). Thus, this Court's affirmance was based on the effect of the economic harm, not on a mechanistic rule that any non-recoverable harm satisfies the test.

Indeed, a *per se* rule that non-recoverable economic harm is irreparable would be contrary to this Court's acknowledgement that "the injury must be *both* certain *and* great**. . . .**" *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1984) (emphasis added). Similarly, a preliminary injunction is an "extraordinary" remedy; a *per se* rule, however, would find irreparable injury in almost any action brought against a governmental entity. For example, in *A.O. Smith Corp. v. F.T.C.*, in vacating the district court's granting of a preliminary injunction, the Third Circuit noted:

> Any time a corporation complies with a government regulation that requires corporation action, it spends money and loses profits; yet it could hardly be contended that proof of such an injury, alone, would satisfy the requisite for a preliminary injunction.

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court stated that economic injury rises to irreparable injury only when it threatens the existence of the business. *Id.* at 336.

530 F.2d 515, 527 (3d Cir. 1976) (footnotes and internal citations omitted); *see Am. Hosp. Ass'n v. Harris*, 625 F.2d 1328, 1331 (7th Cir. 1980); *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005); *Constructors Ass'n of W. Pa. v. Kreps*, 573 F.2d 811, 819 (3d Cir. 1978).

In sum, the district court's decision correctly required that the alleged economic harm be sufficiently severe to constitute irreparable injury.

2. Appellants have not demonstrated that, absent an injunction, it is likely they would be irreparably injured.

The movant has a high burden to demonstrate the existence of irreparable injury. *See CFGC*, 454 F.3d at 297. Injury "must be both certain and great; it must be actual and not theoretical. Injunctive relief 'will not be granted against something merely feared as liable to occur at some indefinite time.'" *Wis. Gas Co.*, 758 F.2d at 674 (quoting *Connecticut v. Massachusetts*, 282 U.S. 660, 674 (1931)). The movant must provide "proof that harm has occurred in the past and is likely to occur again, or proof indicating that the harm is certain to occur in the near future[]"; irreparable harm is not demonstrated by "[b]are allegations of what is likely to occur . . . ." *Id.* The mere "*possibility* of irreparable harm" is not enough. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis added). The district court's finding that appellants' declarations do not meet the high irreparable injury standard was reasonable, as appellants'

declarations consist of unsupported fears and speculation and are not based on credible evidence.

First, appellants' declarations provide internally inconsistent and contradictory statements. Mr. Attebury alleges lost revenues, claiming that his Mexican cattle were sold at a discount because of the 2009 regulation, JA533, but contradicts this by stating: "I routinely get premiums paid to me based on the quality of beef and the total yield of beef from my cattle." JA1009. Likewise, Messrs. Attebury, Rogers, and Peters assert they receive less from packers for Mexican cattle but cannot pay less for foreign-born cattle they buy. JA1009, JA1024, JA1026. But appellants' rancher declarants—Mr. Unrau and Mr. Hinojosa—claim they must sell their cattle at a discount, JA579, JA1034, thus contradicting Messrs. Attebury, Rogers, and Peters' claims of economic harm.

Mr. Rubin alleges he would incur compliance costs, but states that "we will have to pass on the additional costs of compliance to our customers." JA575. Thus, any costs his business might incur would not be borne by the company. Moreover, given the small amount of cattle produced by Dallas City (approximately 150 cattle daily), JA572, the company could presumably switch to processing only one "category" of meat and avoid any of the costs he claims will be incurred.

Similarly, Mr. Karwal states that, because of the 2013 Final Rule, he will have to pay more for U.S. pigs, but expects that there will be an "oversupply" of U.S.-born pigs "when U.S. pig production returns to its prior level." JA553-554. In other words, any increased costs resulting from buying U.S.-born pigs would not only be temporary (as an oversupply would bring prices down), but would also be the result of swings and uncertainty in the market, which can be caused by a number of factors, and are not a result of the 2013 regulation. Given the inconsistencies present within and among these declarations, they do not, on their face, provide a credible basis for a finding of irreparable injury.

Second, appellants' declarations are contradicted by government data. Mr. Unrau states that, as a result of the 2009 regulation, demand for his Canadian-born cattle decreased because "[r]etailers did not want to incur the costs and burdens of tracking commingled products…." JA579. However, USDA data demonstrate that from 2007 to 2012 the net farm value (*i.e.*, the net price paid for beef to cattle producers) increased by 31.5%, JA955, and U.S. import statistics show that during the same time the average price of Canadian cattle ready for slaughter increased at an even faster rate, JA1137. The higher price increase of Canadian cattle discredits the claim that demand for beef from Canadian-born cattle decreased due to the 2009 regulation. Additionally, as noted above, various declarants assert that the 2009 regulation resulted in discounts on Mexican-born cattle. As the 2009

regulation would have presumably affected Canadian- and Mexican-born cattle in the same manner, the higher price increase seen in Canadian-born cattle indicates that any price decreases seen with respect to Mexican-born cattle are the result of non-regulation factors.

Third, appellants' declarations are contradicted by intervenors' declarations. While appellants' declarants assert that discounts are paid for Mexican cattle because of the 2009 regulation, JA533, JA563, JA568, intervenors' declarant Mr. Sumption explains that Mexican cattle "tend to receive less in the market . . . due to the breed of cattle, how the cattle tend to grade (amount of choice), and quality of feed supply . . . ." JA642. Likewise, Mr. Sears states, "we purchase cattle based on how we predict they will grade at slaughter, which determines the price we think we will receive for the cattle." JA636. In other words, grade and quality—not origin—dictate prices.

Appellants' declarants also assert that the need to further segregate cattle will result in increased costs. JA579, JA1015-16, JA1028-29, JA1034. However, intervenors' declarant Mr. Sears, who has fed U.S., Canadian, and Mexican cattle, explains that any increased segregation done in response to the 2013 Final Rule would not likely add significant costs for either feedlots—because they already segregate based on seller or owner—or slaughterhouses—because they could purchase "lots that were of a single COOL origin[,]" as feedlots would already be

segregating cattle. JA637. Thus, when considering other record evidence, the statements by appellants' declarants do not provide a credible basis for a finding of irreparable injury.

Finally, the extent of the economic harms claimed by appellants' declarants is also unsupported or contradicted by public information. While many of the appellants' declarants provide an alleged amount of lost income from the 2009 regulation, JA533, JA563, JA568, or anticipated costs of complying with the 2013 Final Rule, JA540, JA558-60, JA574, none of the declarants explain how such losses or increased costs compare to their overall operations or how they comport with other declarants' contradictory claims. Thus, even if the claims made are viewed as true, they do not provide the Court with a factual record to determine the significance of the harm.

Appellants' declarants also speculate about what they fear or theorize will happen to their businesses. JA535-36, JA553-54, JA565-66, JA570-71, JA573-74, JA580, JA1035. But, absent information about the companies' overall operations, the Court has no way to determine whether the alleged injuries, present or future, represent significant harm or threaten the companies' viability. In fact, for two of the companies that provided anticipated compliance costs, public data demonstrate that the alleged harm would not likely be significant. Mr. Holbrook estimates a compliance cost for Tyson from the 2013 regulation of $70 million. JA540. In

2012, however, Tyson had sales totaling $33,278 million (*i.e.*, estimated compliance costs are less than 0.5% of sales), JA664. Moreover, SEC and investor relations materials from Tyson never indicate that the 2009 regulation or the 2013 regulation is a material event for the company or will have any effect on corporate performance and profitability. *See* JA738, JA837, JA878, JA892, JA927, JA1116.

Mr. McDowell similarly outlines costs he believes AB Foods will have to incur due to the 2013 Final Rule. JA558-60. However, AB Foods' parent company, Agri Beef, is vertically integrated, operates feeding operations and a processing plant, markets and sells high-quality products to specialty retailers as well as to 15 export markets, and had sales totaling $750 million in 2011. JA933, JA940. AB Foods' declarant certainly expresses fear about the results of the 2013 regulation, but there is no publicly-available information showing the company encountered any significant costs in complying with the 2009 regulation or that the steps they claim they would need to undertake under the 2013 regulations are realistic or would actually be required. Certainly, two to three months after the regulation went into effect (and halfway through the implementation period), AB Foods has not pointed to any actual costs incurred to implement the 2013 regulation. Thus, appellants have not demonstrated that the alleged harms rise to the level of severity necessary to demonstrate irreparable injury.

In short, as correctly found by the district court, appellants' declarations do not provide sufficient proof that irreparable injury is likely to occur absent an injunction.[7]

* * * *

[7] The third factor, the balance of harms, also weighs against appellants. Granting an injunction could cause the United States to be deemed out of compliance with its international obligations, leading to potentially large retaliatory sanctions. JA1111. The district court concluded that retaliation was unlikely if an injunction issues based on a representation at oral argument that Canada and Mexico have agreed not to seek retaliation until the WTO issues a decision on the Final Rule. *Id*. Canada has already requested a compliance panel on the basis of its concerns with the Final Rule, but that request also cites its disagreement with the United States as to whether a measure to come into compliance even exists. JA1057, JA1060. Retaliation can be authorized if the United States is found to be out of compliance with its obligations for any reason, JA1060, including if the Final Rule has been enjoined and the COOL regime reverts to the 2009 regulations already found inconsistent with U.S. obligations. On the final factor, the district court found the public interest weighs against an injunction due to appellants' failure to show a likelihood of success on the merits of their claims.

CONCLUSION

For the foregoing reasons, intervenors respectfully request that the Court affirm the district court's order denying the motion for a preliminary injunction.

Respectfully submitted,

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Dated: October 23, 2013

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

AMI v. USDA, Court No. 13-5281

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that the foregoing Brief for Intervenor for Defendants-Appellees complies with the 8,750 world count limitation in the Order of this Court of September 16, 2013. The foregoing Brief contains 8,682 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and D.C. Circuit Rule 32(a)(1).

I further certify that the foregoing Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). The foregoing Brief has been prepared in Microsoft Word 2010 using Times New Roman, 14-point font.

/s/ Terence P. Stewart
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CERTIFICATE OF SERVICE

AMI v. USDA, Court No. 13-5281

I hereby certify that on October 23, 2013, the foregoing Brief for Intervenors for Defendant-Appellees was electronically filed using the CM/ECF system, which will send notification of the filing by electronic mail to the following:

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ADDENDUM I

APPLICABLE REGULATIONS

PART 65—COUNTRY OF ORIGIN LABELING OF BEEF, PORK, LAMB, CHICKEN, GOAT MEAT, PERISHABLE AGRICULTURAL COMMODITIES, MACADAMIA NUTS, PECANS, PEANUTS, AND GINSENG

Subpart A—General Provisions

DEFINITIONS

COUNTRY OF ORIGIN NOTIFICATION

RECORDKEEPING

Subpart B [Reserved]

AUTHORITY: 7 U.S.C. 1621 *et seq.*

SOURCE: 74 FR 2704, Jan. 15, 2009, unless otherwise noted.

Subpart A—General Provisions

DEFINITIONS

§ 65.100 Act.

Act means the Agricultural Marketing Act of 1946, (7 U.S.C. 1621 et seq.).

§ 65.105 AMS.

AMS means the Agricultural Marketing Service, United States Department of Agriculture.

§ 65.110 Beef.

Beef means meat produced from cattle, including veal.

§ 65.115 Born.

Born in the case of chicken means hatched from the egg.

§ 65.120 Chicken.

Chicken has the meaning given the term in 9 CFR 381.170(a)(1).

§ 65.125 Commingled covered commodities.

Commingled covered commodities means covered commodities (of the same type) presented for retail sale in a consumer package that have been prepared from raw material sources having different origins.

§ 65.130 Consumer package.

Consumer package means any container or wrapping in which a covered commodity is enclosed for the delivery and/or display of such commodity to retail purchasers.

§ 65.135 Covered commodity.

(a) *Covered commodity* means:
(1) Muscle cuts of beef, lamb, chicken, goat, and pork;
(2) Ground beef, ground lamb, ground chicken, ground goat, and ground pork;
(3) Perishable agricultural commodities;
(4) Peanuts;
(5) Macadamia nuts;
(6) Pecans; and
(7) Ginseng.
(b) Covered commodities are excluded from this part if the commodity is an ingredient in a processed food item as defined in § 65.220.

§ 65.140 Food service establishment.

Food service establishment means a restaurant, cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, or other similar facility operated as an enterprise engaged in the business of selling food to the public. Similar food service facilities include salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.

§ 65.145 Ginseng.

Ginseng means ginseng root of the genus Panax.

§ 65.150 Goat.

Goat means meat produced from goats.

§ 65.155 Ground beef.

Ground beef has the meaning given that term in 9 CFR 319.15(a), i.e., chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, and containing no more than 30 percent fat, and containing no added water, phosphates, binders, or extenders, and also includes products defined by the term "hamburger" in 9 CFR 319.15(b).

§ 65.160 Ground chicken.

Ground chicken means comminuted chicken of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

§ 65.165 Ground goat.

Ground goat means comminuted goat of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

§ 65.170 Ground lamb.

Ground lamb means comminuted lamb of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

§ 65.175 Ground pork.

Ground pork means comminuted pork of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

§ 65.180 Imported for immediate slaughter.

Imported for immediate slaughter means imported into the United States for "immediate slaughter" as that term is defined in 9 CFR 93.400, i.e., consignment directly from the port of entry to a recognized slaughtering establishment and slaughtered within 2 weeks from the date of entry.

§ 65.185 Ingredient.

Ingredient means a component either in part or in full, of a finished retail food product.

§ 65.190 Lamb.

Lamb means meat produced from sheep.

§ 65.195 Legible.

Legible means text that can be easily read.

§ 65.205 Perishable agricultural commodity.

Perishable agricultural commodity means fresh and frozen fruits and vegetables of every kind and character that have not been manufactured into articles of a different kind or character and includes cherries in brine as defined by the Secretary in accordance with trade usages.

§ 65.210 Person.

Person means any individual, partnership, corporation, association, or other legal entity.

§ 65.215 Pork.

Pork means meat produced from hogs.

§ 65.218 Pre-labeled.

Pre-labeled means a covered commodity that has the commodity's country of origin and the name and place of business of the manufacturer, packer, or distributor on the covered commodity itself, on the package in which it is sold to the consumer, or on the master shipping container. The place of business information must include at a minimum the city and state or other acceptable locale designation.

§ 65.220 Processed food item.

Processed food item means a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity, or that has been combined with at least one other covered commodity or other substantive food component (e.g., chocolate, breading, tomato sauce), except that the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the

preparation of the product for consumption, would not in itself result in a processed food item. Specific processing that results in a change in the character of the covered commodity includes cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g., salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (e.g., emulsifying and extruding). Examples of items excluded include teriyaki flavored pork loin, roasted peanuts, breaded chicken tenders, and fruit medley.

§ 65.225 Produced.

Produced in the case of a perishable agricultural commodity, peanuts, ginseng, pecans, and macadamia nuts means harvested.

§ 65.230 Production step.

Production step means, in the case of beef, pork, goat, chicken, and lamb, born, raised, or slaughtered.

§ 65.235 Raised.

Raised means, in the case of beef, pork, chicken, goat, and lamb, the period of time from birth until slaughter or in the case of animals imported for immediate slaughter as defined in § 65.180, the period of time from birth until date of entry into the United States.

§ 65.240 Retailer.

Retailer means any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act of 1930 (7 U.S.C. 499a(b)).

[78 FR 31385, May 24, 2013]

§ 65.245 Secretary.

Secretary means the Secretary of Agriculture of the United States or any person to whom the Secretary's authority has been delegated.

§ 65.250 Slaughter.

Slaughter means the point in which a livestock animal (including chicken) is prepared into meat products (covered commodities) for human consumption. For purposes of labeling under this part, the word harvested may be used in lieu of slaughtered.

§ 65.255 United States.

United States means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, the Northern Mariana Islands, and any other Commonwealth, territory, or possession of the United States.

§ 65.260 United States country of origin.

United States country of origin means in the case of:

(a) Beef, pork, lamb, chicken, and goat:
(1) From animals exclusively born, raised, and slaughtered in the United States;
(2) From animals born and raised in Alaska or Hawaii and transported for a period of not more than 60 days through Canada to the United States and slaughtered in the United States; or
(3) From animals present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States.
(b) Perishable agricultural commodities, peanuts, ginseng, pecans, and macadamia nuts: from products produced in the United States.

§ 65.265 USDA.

USDA means the United States Department of Agriculture.

COUNTRY OF ORIGIN NOTIFICATION

§ 65.300 Country of origin notification.

In providing notice of the country of origin as required by the Act, the following requirements shall be followed by retailers:
(a) *General*. Labeling of covered commodities offered for sale whether individually, in a bulk bin, carton, crate, barrel, cluster, or consumer package must contain country of origin as set forth in this regulation.
(b) *Exemptions*. Food service establishments as defined in § 65.135 are exempt from labeling under this subpart.
(c) *Exclusions*. A covered commodity is excluded from this subpart if it is an ingredient in a processed food item as defined in § 65.220.
(d) *Labeling Covered Commodities of United States Origin*. A covered commodity may bear a declaration that identifies the United States as the sole country of origin at retail only if it meets the definition of United States country of origin as defined in § 65.260. The United States country of origin designation for muscle cut covered commodities shall include all of the production steps (i.e., “Born, Raised, and Slaughtered in the United States”).
(e) *Labeling Muscle Cut Covered Commodities of Multiple Countries of Origin from Animals*

Slaughtered in the United States. If an animal was born and/or raised in Country X and/or (as applicable) Country Y, and slaughtered in the United States, the resulting muscle cut covered commodities shall be labeled to specifically identify the production steps occurring in each country (e.g., "Born and Raised in Country X, Slaughtered in the United States"). If an animal is raised in the United States as well as another country (or multiple countries), the raising occurring in the other country (or countries) may be omitted from the origin designation except if the animal was imported for immediate slaughter as defined in § 65.180 or where by doing so the muscle cut covered commodity would be designated as having a United States country of origin (e.g., "Born in Country X, Raised and Slaughtered in the United States" in lieu of "Born and Raised in Country X, Raised in Country Y, Raised and Slaughtered in the United States").

(f) *Labeling Imported Covered Commodities*. (1) Perishable agricultural commodities, peanuts, pecans, ginseng, macadamia nuts and ground meat covered commodities that have been produced in another country shall retain their origin, as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale.

(2) Muscle cut covered commodities derived from an animal that was slaughtered in another country shall retain their origin, as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale (e.g., "Product of Country X"), including muscle cut covered commodities derived from an animal that was born and/or raised in the United States and slaughtered in another country. In addition, the origin declaration may include more specific location information related to production steps (i.e., born, raised, and slaughtered) provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

(g) *Labeling Commingled Covered Commodities*. In the case of perishable agricultural commodities; peanuts; pecans; ginseng; and macadamia nuts: For imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with covered commodities sourced from a different origin that have not been substantially transformed (as established by CBP) in the United States, and/or covered commodities of United States origin, the declaration shall indicate the countries of origin in accordance with existing Federal legal requirements.

(h) *Labeling Ground Beef, Ground Pork, Ground Lamb, Ground Goat, and Ground Chicken*. The declaration for ground beef, ground pork, ground lamb, ground goat, and ground chicken covered commodities shall list all countries of origin contained therein or that may be reasonably contained therein. In determining what is considered reasonable, when a raw material from a specific origin is not in a processor's inventory for more than 60 days, that country shall no longer be included as a possible country of origin.

(i) Remotely Purchased Products. For sales of a covered commodity in which the customer purchases a covered commodity prior to having an opportunity to observe the final package (e.g., Internet sales, home delivery sales, etc.), the retailer may provide the country of origin notification either on the sales vehicle or at the time the product is delivered to the consumer.

[74 FR 2704, Jan. 15, 2009, as amended at 78 FR 31385, May 24, 2013]

§ 65.400 Labeling.

(a) Country of origin declarations can either be in the form of a placard, sign, label, sticker, band, twist tie, pin tag, or other format that allows consumers to identify the country of origin. The declaration of the country of origin of a product may be in the form of a statement such as "Product of USA," "Produce of the USA", or "Grown in Mexico," may only contain the name of the country such as "USA" or "Mexico," or may be in the form of a check box provided it is in conformance with other Federal labeling laws.

(b) The declaration of the country of origin (e.g., placard, sign, label, sticker, band, twist tie, pin tag, or other display) must be legible and placed in a conspicuous location, so as to render it likely to be read and understood by a customer under normal conditions of purchase.

(c) The declaration of country of origin may be typed, printed, or handwritten provided it is in conformance with other Federal labeling laws and does not obscure other labeling information required by other Federal regulations.

(d) A bulk container (e.g., display case, shipper, bin, carton, and barrel) used at the retail level to present product to consumers, may contain a covered commodity from more than one country of origin provided all possible origins are listed.

(e) In general, country abbreviations are not acceptable. Only those abbreviations approved for use under Customs and Border Protection rules, regulations, and policies, such as "U.K." for "The United Kingdom of Great Britain and Northern Ireland", "Luxemb" for Luxembourg, and "U.S. or USA" for the "United States of America" are

acceptable. The adjectival form of the name of a country may be used as proper notification of the country of origin of imported commodities provided the adjectival form of the name does not appear with other words so as to refer to a kind or species of product. Symbols or flags alone may not be used to denote country of origin.

(f) Domestic and imported perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng may use State, regional, or locality label designations in lieu of country of origin labeling. Abbreviations may be used for state, regional, or locality label designations for these commodities whether domestically harvested or imported using official United States Postal Service abbreviations or other abbreviations approved by CBP.

RECORDKEEPING

§ 65.500 Recordkeeping requirements.

(a) *General*. (1) All records must be legible and may be maintained in either electronic or hard copy formats. Due to the variation in inventory and accounting documentary systems, various forms of documentation and records will be acceptable.

(2) Upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location.

(b) *Responsibilities of suppliers*. (1) Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must make available information to the buyer about the country(ies) of origin of the covered commodity. This information may be provided either on the product itself, on the master shipping container, or in a document that accompanies the product through retail sale. In addition, the supplier of a covered commodity that is responsible for initiating a country(ies) of origin claim, which in the case of beef, lamb, chicken, goat, and pork is the slaughter facility, must possess records that are necessary to substantiate that claim for a period of 1 year from the date of the transaction. For that purpose, packers that slaughter animals that are tagged with an 840 Animal Identification Number device without the presence of any additional accompanying marking (i.e., "CAN" or "M") may use that information as a basis for a U.S. origin claim. Packers that slaughter animals that are part of another country's recognized official system (e.g., Canadian official system, Mexico official system) may also rely on the presence of an official ear tag or other approved device on which to base their origin claims. Producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction. In the case of cattle, producer affidavits may be based on a visual inspection of the animal to verify its origin. If no markings are found that would indicate that the animal is of foreign origin (i.e., "CAN" or "M"), the animal may be considered to be of U.S. origin.

(2) Any intermediary supplier handling a covered commodity that is found to be designated incorrectly as to the country of origin shall not be held liable for a violation of the Act by reason of the conduct of another if the intermediary supplier relied on the designation provided by the initiating supplier or other intermediary supplier, unless the intermediary supplier willfully disregarded information establishing that the country of origin declaration was false.

(3) Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly (i.e., including but not limited to growers, distributors, handlers, packers, and processors), must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction.

(4) For an imported covered commodity (as defined in § 65.300(f)), the importer of record as determined by CBP, must ensure that records: provide clear product tracking from the port of entry into the United States to the immediate subsequent recipient and accurately reflect the country of origin of the item as identified in relevant CBP entry documents and information systems; and must maintain such records for a period of 1 year from the date of the transaction.

(c) *Responsibilities of retailers*. (1) In providing the country of origin notification for a covered commodity, in general, retailers are to convey the origin information provided by their suppliers. Only if the retailer physically commingles a covered commodity of different origins in preparation for retail sale, whether in a consumer-ready package or in a bulk display (and not discretely packaged) (i.e., full service meat case), can the retailer initiate a multiple country of origin designation that reflects the actual countries of origin for the resulting covered commodity.

(2) Records and other documentary evidence relied upon at the point of sale to establish a covered commodity's country(ies) of origin must either be maintained at the retail facility or at another location for as long as the product is on hand and provided to any duly authorized representative of USDA in accordance with § 65.500(a)(2). For pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product's origin and no additional records documenting origin information are necessary.

(3) Any retailer handling a covered commodity that is found to be designated incorrectly as to the country of origin shall not be held liable for a violation of the Act by reason of the conduct of another if the retailer relied on the designation provided by the supplier, unless the retailer willfully disregarded information establishing that the country of origin declaration was false.

(4) Records that identify the covered commodity, the retail supplier, and for products that are not pre-labeled, the country of origin information must be maintained for a period of 1 year from the date the origin declaration is made at retail.

Subpart B [Reserved]

ADDENDUM II

UNPUBLISHED DISPOSITIONS

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Apotex, Inc., **Plaintiff.** **v.** **FOOD AND DRUG ADMINISTRATION, et al.,** **Defendants,** **and**	**Civil Action No. 06-0627 (JDB)**
TEVA PHARMACEUTICALS USA, INC., **Intervenor-Defendant,** **and** **RANBAXY PHARMACEUTICALS, INC.,** **Intervenor-Defendant.**	

MEMORANDUM OPINION

Plaintiff Apotex, Inc. ("Apotex") seeks a temporary restraining order and preliminary injunction to prevent defendants Food and Drug Administration ("FDA"), Michael O. Leavitt in his capacity as the Secretary of Health and Human Services, and Andrew Von Eschenbach in his capacity as the Acting Commissioner of Food and Drugs, from granting final approval under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), 21 U.S.C. § 355, to intervenor-defendants Teva Pharmaceuticals USA, Inc. ("Teva") and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), based upon their Abbreviated New Drug Applications ("ANDA") for pravastatin sodium ("pravastatin"), the generic version of the branded drug

Pravachol®. Although this action was actually filed prematurely in advance of the FDA's most recent decision, it is now effectively a challenge to the April 11, 2006 decision by the FDA issued to Apotex. For the reasons that follow, the Court will deny plaintiff's motion.

BACKGROUND

I. Prior Proceedings

This action stems from an earlier case ("Teva III") in which Teva sued defendants pursuant to the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) ("APA"), and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA"), challenging the determination that the dismissal of a previous action in the United States District Court for the Southern District of New York, Apotex Inc. v. Bristol-Myers Squibb Co., No. 1:04-CV-2922 (S.D.N.Y.) ("Apotex-BMS litigation"), had triggered the 180-day exclusive marketing period to which Teva might otherwise be entitled under the provisions of the Hatch-Waxman Act. See Teva Pharms. USA, Inc. v. FDA, 398 F. Supp. 2d 176, 179 (D.D.C. 2005) ("Teva III Dist. Ct. Mem. Op.").[1] Apotex, the plaintiff here, was an intervenor-defendant in Teva III, and vigorously opposed Teva's effort to prevent the FDA from granting final approval to any other ANDA for

[1]The Hatch-Waxman Act provides a 180-day period of generic exclusivity to the first company that files an ANDA containing a "paragraph IV certification" for a patent connected to the branded version of the drug. See 21 U.S.C. § 355(j)(5)(B)(iv). A paragraph IV certification alleges that the relevant patent is either invalid or will not be infringed by the proposed ANDA product. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The exclusivity period begins on the earlier of two dates: (1) "the date on which the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application"; or (2) "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed." See § 355(j)(5)(B)(iv)(II). At issue here is the latter triggering-even, referred to as the "court-decision trigger." For a full discussion of the intricate statutory landscape established by the Hatch-Waxman Act, see this Court's earlier opinion and the FDA's April 11, 2006 administrative decision.

generic pravastatin in the relevant dosage form and strength. See generally 398 F. Supp. 2d 176. The complex factual background giving rise to Teva III -- including the underlying Apotex-BMS litigation -- is discussed in detail in this Court's October 21, 2005 decision and FDA's April 11, 2006 administrative decision on remand, and will not be repeated in full here.

At the request of the parties, the motion for preliminary injunction in Teva III was consolidated with a trial on the merits pursuant to Fed. R. Civ. P. 65(a)(2), and the Court treated the proceeding as "akin [to a motion for] summary judgment." Id. at 181 & n.1. On October 21, 2005, this Court ruled that because the Apotex-BMS litigation was dismissed for lack of subject matter jurisdiction at the request of the plaintiff in that case (Apotex), it constituted a private settlement agreement between the parties and, accordingly, was not "a decision of a court . . . holding the [relevant] patent . . . to be invalid or not infringed," as required by the plain language of the Hatch-Waxman Act and applicable FDA regulations, and, in this Court's view at the time, as contemplated by two prior decisions of the D.C. Circuit: (1) Teva Pharms. USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999) ("Teva I"), and (2) Teva Pharms. USA, Inc. v. FDA, 2000 WL 1838303 (D.C. Cir. 2000) (unpublished disposition) ("Teva II"). See 398 F. Supp. 2d at 187-192.[2] Hence, the Court concluded that FDA's decision was "arbitrary, capricious, or otherwise not in accordance with law" under the APA and granted Teva's motion for a preliminary injunction. Id. at 179, 192. Apotex and the FDA then appealed this Court's ruling to the D.C. Circuit. Apotex moved this Court for a stay pending appellate review in the D.C. Circuit, but the motion was denied because, based upon the circumstances at the time, Apotex faced no

[2]The factual background for, and decisions in, Teva I and Teva II are detailed in this Court's October 21, 2006 decision and the FDA's April 11, 2006 administrative decision.

impending likelihood of irreparable injury and the balance of hardships did not tip decidedly in its favor. See Teva Pharms. USA, Inc. v. FDA, 404 F. Supp. 2d 243, 244-46 (D.D.C. 2005).

Before the D.C. Circuit, the FDA stated that its administrative decision was based on the view that Teva I and Teva II constituted substantive rules of law establishing that dismissals of declaratory judgment actions for lack of subject matter jurisdiction are court decisions within the language of the Hatch-Waxman Act. See Teva Pharms. USA, Inc. v. FDA, 441 F.3d 1, 5 & n.5 (D.C. Cir. 2006) ("Teva III"). The FDA represented that if it had understood that Teva I and Teva II stood only for the proposition that FDA had not sufficiently articulated the rationale in support of its administrative conclusions, then it would have reached the same conclusion as this Court reached in Teva III Dist. Ct. Mem. Op. See Pl.'s Exh. D. FDA's counsel all but promised that, on remand, FDA would adopt a "textual approach" to the statute, pursuant to which it would find that the Apotex-BMS dismissal did not qualify as a "decision of a court" and, accordingly, did not trigger the 180-day exclusivity period.

On March 16, 2006, the D.C. Circuit held that FDA had in fact operated under an erroneous interpretation of law -- namely, that Teva I and Teva II set forth substantive rules of law regarding what constitutes a "decision of a court" within the meaning of the Hatch-Waxman Act. See Teva III, 441 F.3d at 5. According to the panel, Teva I and Teva II did nothing more than reaffirm and apply the long-standing axiom of administrative law that agency action must be supported by thorough, reasoned decisionmaking. See id. Because "'[a]n order may not stand if the agency has misconceived the law,'" id. (citing SEC v. Chenery Corp., 318 U.S. 80, 94 (1943)), the panel vacated the Teva III Dist. Ct. Mem. Op. and remanded the case to this Court, with instructions to vacate FDA's agency decision and then remand to the FDA so that it could fulfill

its statutory mandate to "'bring its experience and expertise to bear in light of competing interests at stake' and make a reasonable policy choice." Id. at 5 (quoting PDK Labs., Inc. v. DEA, 362 F.3d 786, 797-98 (D.C. Cir. 2004)). The panel clearly expressed a desire for bona fide agency action that would explicitly articulate a specific rationale -- oral representations during arguments before courts could not suffice as a substitute. Id. (stating that "[t]he FDA's 'stated rationale for its decision is erroneous' and 'we cannot sustain its action on some other basis [it] did not mention,'" and describing the agency's statutory mandate and noting that it had not yet been fulfilled) (citing PDK Labs., 362 F.3d at 798). The D.C. Circuit also recalled that FDA had attempted to adopt a textual approach in Teva I, and hinted that, on remand, the agency would be expected to address the concerns expressed in Teva I regarding the reasonableness of such an approach. Id. at 5 n.5.

II. FDA's Decision on Remand

On remand, the FDA reconsidered its earlier decision in light of Teva III's pronouncement that Teva I and Teva II were purely procedural in nature. In a fifteen-page, single-spaced decision letter issued on April 11, 2006, the agency adopted a textual approach to the statute, under which, based upon the plain language of the Hatch-Waxman Act, only a decision of a court holding on the merits that a particular patent is invalid, not infringed, or unenforceable would suffice to trigger the 180-day exclusivity period. See Pl.'s Exh. A at 2, 6. The agency began by analyzing the meaning of the word "holding," referring to the definition adopted by the Seventh Edition of Black's Law Dictionary: "[a] court's determination of a matter of law pivotal to its decision; a principle drawn from such a decision." Id. at 6-7 (citing BLACK'S LAW DICTIONARY at 737 (7th ed. 1999)). Based on this definition, the FDA concluded that, to be sufficient, the "holding must be evidenced by a statement on the face of the court's decision demonstrating that the court has

made a determination on the merits [as to the] invalidity, noninfringement, or unenforceability [of the relevant patent]." Id. at 7. Under this approach, the determination must address one or more of the actual "elements or grounds of a claim or defense [of patent invalidity, noninfringement or unenforceability]; the substantive considerations to be taken into account in [making that] deci[sion], as opposed to extraneous or technical points, esp[ecially] of procedure." Id. (citing BLACK'S LAW DICTIONARY, supra, at 1003).

FDA then assessed the first of three concerns expressed by the D.C. Circuit in Teva I and referred to in footnote five of Teva III -- whether a textual interpretation of the statute (as contrasted with the estoppel-based interpretation that Apotex advocates)[3] would lead to absurd results that undermine the purpose of the statute. Id. Recognizing that, in light of Teva III, the preference for an estoppel-based approach allegedly embodied in Teva I no longer constrains its decisionmaking process, FDA concluded that a textual approach is preferable because it gives substantive effect to the words chosen by Congress. Id. at 8. The estoppel-based approach would, in FDA's view, "render[] the terms 'decision,' 'holding,' and 'invalid or not infringed' superfluous, in contravention of accepted canons of statutory construction." Id. (citing Bailey v. United States, 516 U.S. 137, 146 (1995)). The agency further expressed a concern that an estoppel-based approach would impose a large administrative burden by requiring it to resolve complex factual issues under the law in the absence of meaningful guidance from the courts. Id. at 8. FDA reasoned that the determination of whether one party is estopped from suing another is dependent upon a multifaceted composite of factual considerations and the legal consequences that flow

[3]The many contours, drawbacks, and advantages of the estoppel approach are detailed in this Court's earlier decision.

therefrom, which it is admittedly "ill-equipped" to evaluate. Id. at 8, 9. Based upon its previous experience, FDA characterized the estoppel-based approach as arduous and impractical, often leading to uncertain and inconsistent results, and, as illustrated by the instant case, "inexorably spawn[ing]" perpetual litigation that undermines the statute's purpose of providing lower-cost generic alternatives to the public in an expedient fashion. Id. at 9. FDA concluded that following a textual interpretation of the statute, on the other hand, greatly improves the likelihood of industry certainty by facilitating consistency, dispenses with the inherent subjectivity that plagues an estoppel-focused analysis, and reduces the administrative burden by enabling the agency to look at the four corners of a court order to determine whether the exclusivity clock has been triggered. Id. at 9.

Addressing the second concern raised in Teva I, FDA considered whether a textual approach would be consistent with its regulation, 21 C.F.R. § 314.107(c)(1), recognizing unenforceability as a "separate basis for a court decision trigger." See id. at 9. The plain language of the regulation, FDA concluded, parallels the terms of the statute: the exclusivity clock is triggered as of "[t]he date of a decision of a court holding the relevant patent invalid, unenforceable, or not infringed." § 314.107(c)(1); Pl.'s Exh. A at 10. Essentially, the only difference between the language of the regulation and that of the statute is that the former expressly provides for patent challenges based upon alleged unenforceability, whereas the latter does not. Pl.'s Exh. A at 10. Thus, "[e]ven if a patentee's representations have the apparent effect of rendering a patent unenforceable vis-a-vis a particular ANDA applicant, in the agency's view, a holding of unenforceability must result from a court's consideration of that issue on the merits, rather than FDA's evaluation of the effect of a patentee's statement." Id. at 10 (emphasis in

original). From FDA's perspective, then, an estoppel-based approach "turns the statutory language on its head, by compelling FDA -- rather than a court" to "make a 'decision' and a 'holding' of unenforceability." Id.

Turning to the final issue raised by Teva I, FDA discussed two perceived inconsistencies in its prior decisionmaking, specifically: (1) how the conclusion that it reached in Teva I could be justified under the "case-by-case" approach allegedly adopted by the agency in its earlier guidance document; and (2) how it could have reached a different conclusion with respect to the court action at issue in Teva I and the court action at issue in another case, Granutec, Inc. v. Shalala, 139 F.3d 889, 1998 WL 153410 (4th Cir. Apr. 3, 1998) (unpublished disposition). With respect to the guidance document, FDA pointed to "dramatic[] change[s]" in the regulatory landscape that have occurred since it considered the dismissal at issue in Teva I. Pl.'s Exh. A at 10. The Teva I opinion "suggested that [the agency] had failed to adopt any particular interpretation of the statute . . . [or] 'abide[] by the commitments it made in the [guidance document]." Id. at 10-11. Subsequently, FDA had proposed a new approach, under which exclusivity would be forfeited if the clock had not been triggered within a particular amount of time. Id. at 11. The proposed rule was withdrawn in 2002 "in part due to [FDA's] belief that the Teva I 'holding was directly at odds with the [triggering-period] approach.'" Id. Thereafter, Congress significantly changed the 180-day exclusivity provision through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), and FDA thought it unwise to waste precious resources drafting a regulation that would become less important in light of the MMA and perhaps be

"vulnerable to challenge if it diverged from Teva I." Id.[4] The agency concluded its analysis by stating that it "is [now] independently interpreting the statute in accordance with the direction of the Teva III court" and adopting an interpretation that it considers "fully consistent with the statutory language and the extensive regulatory and judicial history concerning the agency's treatment of the court decision trigger issue." Id.

On the second consistency point, the dismissals at issue in Teva I and Granutec were both predicated on statements made by the manufacturers of the branded drugs, which functioned to estop those companies from being able to file suit for patent infringement in the future. FDA reached different conclusions in those cases, determining that the dismissal underlying Teva I did not trigger the exclusivity period but the one in Granutec did. According to FDA, its conclusions are not irreconcilable, and they are consistent with the textually-based approach that the agency now espouses. Id. at 12. The Granutec dismissal was a court-issued memorandum decision that granted a motion for partial summary judgment on the basis that the relevant patent was not infringed. Id. at 12 (citing Glaxo, Inc. v. Boehringer Ingelheim Corp., No. 95-CV-01342 (D. Conn. Oct. 7, 1996)). A grant of partial summary judgment is, in FDA's view, a holding on the merits. Id. In contrast, the dismissal underlying Teva I was purely jurisdictional in nature, because it was based upon a determination that, in light of the statements made by the manufacturer of the branded drug, the non-movant (Teva) lacked a reasonable apprehension that it would be sued for infringement of the relevant patent. Id. (citing Teva I, 182 F.3d at 1004). In FDA's words, "once the court recognized that it lacked jurisdiction, it appropriately refused to

[4]The pre-MMA version of the statute applies to this case, and all statutory citations to the Hatch-Waxman Act and the FDCA are to the pre-amendment version of the statute.

decide the merits of the case and granted . . . the motion to dismiss." Id. Hence, FDA does not consider the Teva I dismissal to be a "decision of a court" under a textual interpretation of the statute, but does consider the Granutec dismissal based on a grant of partial summary judgment to be one. Id.

Next, FDA explained how the textual approach was more consistent with congressional intent. To begin with, although the textual approach could theoretically slow the entry of lower-cost generic drugs into the marketplace by more jealously safeguarding exclusivity entitlements, FDA noted that it also facilitates patent challenges "overall." Id. at 13. The estoppel approach, on the other hand, interprets the court-decision trigger more broadly, which may at first blush appear to further the underlying purpose of the statute by making generic products available to consumers at an expedited pace, id. at 13, but actually diminishes the value of the exclusivity entitlement and, accordingly, deters pharmaceutical companies from challenging patents, id. at 12, 13. By creating the exclusivity entitlement, the FDA observed, Congress manifested a belief that some incentive in addition to the prospect of earlier generic market entry was required in order to encourage pharmaceutical companies to undertake the risks and burdens of pursuing patent challenges. Id. at 12, 13. A narrower interpretation of the court-decision trigger (as provided by the textual approach) makes it harder to trigger the exclusivity periods, thereby preserving their value to pharmaceutical companies and, in FDA's view, leaving in place the incentive that Congress saw fit to create. Id. at 13.

Put another way, FDA recognized that each approach furthers certain policy objectives while undercutting others. Id. The agency pointed to the instant litigation involving Apotex and Teva as an example of the creative legal maneuvering in which pharmaceutical companies have

repeatedly engaged, flip-flopping between diametrically opposed positions in various litigation actions based upon their financial interests. Id. at 13-14. This behavior, FDA concluded, will occur "whenever the potential financial rewards are sufficiently high," and "a standard less objective and clear than the 'holding-on-the-merits' standard" would increase the opportunities for such disputes. Id. at 14. Because such contests are lengthy and costly, they often delay the entry of generic drugs into the market. Id. "It is in the public's interest, as well as FDA's own interest," FDA continued, "to have exclusivity triggering determinations governed by a legal regime that is clear and easily administered." Id. at 14. In its view, the estoppel approach "offers no guarantee of more rapid generic drug approvals, only a high likelihood of delay due to litigation, and the prospect that this area of law will remain unnecessarily unstable, thus undermining marketplace certainty and interfering with business planning and investment." Id.

Finally, FDA addressed the application of the textual approach to the facts of Teva III, and determined that the underlying Apotex-BMS dismissal is not a "decision of a court" because it contains no "'holding' that the subject patents are invalid, not infringed or unenforceable" and the face of the dismissal is devoid of any court determination touching on any of the patents at issue. Id. Like the dismissal at issue in Teva I, the Apotex-BMS dismissal is (by its own terms) wholly jurisdictional, FDA concluded, and does not constitute a "holding on the merits." See id. On this rationale, FDA determined that the "180-day exclusivity for pravastatin was not triggered by the [Apotex-BMS] dismissal" and proclaimed that "[a]bsent a material change in circumstances, FDA intends to approve only those ANDAs eligible for 180-day exclusivity for pravastatin when the [relevant] patent . . . expires on April 20, 2006. Approvals of all other pravastatin ANDAs will be delayed for 180 days after exclusivity has been triggered." Id.

III. The Current Proceeding

Taking note of the proverbial "writing on the wall," Apotex initially filed the complaint in this action and a motion for a temporary restraining order on April 5, 2006, in advance of FDA's remand decision. See generally Compl.; Pl.'s Mot. T.R.O. Teva was added as an intervenor-defendant on April 10, 2006. Apotex Inc. v. FDA, Civil Action No. 06-0627, dkt. no. 10 (D.D.C. Apr. 10, 2006) (Order). In its April 5th motion, Apotex argued that the representations of government counsel at the oral argument on appeal -- and in FDA's appellate briefs -- constituted "final agency action" on the basis of which it was entitled to pursue relief in this Court under 5 U.S.C. § 705. See Pl.'s Mot. T.R.O. at 12-13; see also Compl. at 13 ¶ 53. Unpersuaded -- and wary of potential jurisdictional complications -- this Court directed Apotex to re-file its motion following the release of the impending agency decision. On April 11, 2006, FDA issued its remand decision. See generally Pl.'s Exh. A. Three days later, on April 14, 2006, Apotex re-filed its motion, this time choosing also to pursue a preliminary injunction immediately. See Pl.'s Mot. T.R.O. & Prelim. Inj. Ranbaxy filed a motion to intervene on April 12, 2006, arguing that it was the first to file an ANDA containing a paragraph IV certification for one particular dosage of Pravachol® -- hence, Ranbaxy contended that it was entitled to the contested exclusivity period. See Ranbaxy Mot. Interv. as Defs. at 1. The Court granted Ranbaxy's motion the same day. Apotex Inc. v. FDA, Civil Action No. 06-0627, dkt. no. 16 (D.D.C. Apr. 12, 2006) (Order). The FDA and intervenor-defendants responded to Apotex's motion on April 18, 2006, and all parties have agreed that this matter should be addressed as a preliminary injunction request. Armed with the final agency decision, plaintiff's motion, and the memoranda of all parties, the Court will now address the merits of plaintiff's contentions.

LEGAL STANDARDS

When considering a motion for preliminary injunction or temporary restraining order, a court must weigh four factors: (1) the prospective irreparable injury to the movant in the event that the requested relief is denied; (2) the possibility of harm to other parties in the event that the relief is granted; (3) the likelihood that the movant will prevail on the merits; and (4) the public interest. See, e.g., Mova Pharms. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998).[5] "These factors interrelate on a sliding scale and must be balanced against each other," Davenport v. Int'l Bd. of Teamsters AFL-CIO, 166 F.3d 356, 360-61 (D.C. Cir. 1999), such that a particularly strong showing with respect to one may compensate for a weaker showing with respect to another, CityFed Fin. Corp. v. OTS, 58 F.3d 738, 747 (D.C. Cir. 1995). Specifically, the "likelihood of success on the merits" inquiry is inversely proportional to the "degree of irreparable harm" inquiry -- that is, a court may grant the sought-after relief when the movant is very likely to succeed on the merits, in the face of a lesser degree of potential irreparable injury. Cuomo v. U.S. Nuclear Reg. Comm'n, 772 F.2d 972, 974 (D.C. Cir. 1985).

Whether plaintiff is likely to prevail on the merits is, under the circumstances of this case, informed by the deferential standards of review under the APA. Pursuant to the relevant provisions of the APA, a court may vacate FDA's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law," 5 U.S.C. § 706(2)(A), or in excess of statutory authority, 5 U.S.C. § 706(2)(C). Agency actions are entitled to much deference, and the

[5]Plaintiff has also moved for a stay pending appeal in the event that it does not prevail before this Court. That request is analyzed under the same four-pronged legal framework that applies to the motion for temporary restraining order and preliminary injunction. See Teva Pharms. USA, 404 F. Supp. 2d at 245 (citing Washington Area Metro. Auth. Comm'n v. Holiday Tours, 559 F.2d 841, 843-44 (D.C. Cir. 1977)).

standard of review is narrow. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The reviewing court is not permitted to substitute its judgment for that of the agency. See id. That is, it is not enough for the agency decision to be incorrect -- as long as the agency decision has some rational basis, the court is bound to uphold it. See id. The court may only review the agency action to determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Id.

The familiar framework of Chevron USA, Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), applies here. At step one of Chevron, the Court first must inquire whether the statute "speaks clearly 'to the precise question at issue.'" Chevron, 467 U.S. at 842-43. If so, then the analysis proceeds no further -- the Court must "give effect to the unambiguously expressed intent of Congress." Id.; see also Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997) (if text is plain and unambiguous, then the analysis ends there). If, however, the statute is not clear in relation to the specific issue before the Court, then under Chevron step two, the Court must consider whether FDA's interpretation is supported by a "permissible construction" of the statute. Chevron, 467 U.S. at 843. But the Court will only reach the second inquiry under Chevron if it determines that the statute is "silent or ambiguous with respect to the specific issue" presented. Id. The "[e]xistence of ambiguity is not enough per se to warrant deference to the agency's interpretation. The ambiguity must be such as to make it appear that Congress either explicitly or implicitly delegated authority to cure that ambiguity." Am. Bar Ass'n v. FTC, 430 F.3d 457, 469 (D.C. Cir. 2005); see also Michigan v. EPA, 268 F.3d 1075, 1082 (D.C. Cir. 2001). Hence, under the Chevron step two deferential analysis, if the statute is "ambiguous in such a way as to make the [FDA's] decision worthy of deference," then this Court should "uphold the [FDA's]

interpretation of the ambiguous statute as long as that interpretation is 'permissible,' that is, if it is 'reasonable.'" Am. Bar Ass'n, 430 F.3d at 468 (quoting Chevron, 467 U.S. at 843, 845).

When the agency decision is based upon its interpretation of the statute that it is charged with administering, a court's deference to the agency is at its apex. See United States v. Mead, 533 U.S. 218, 226-27 (2001). Because FDA is interpreting its own statute here (the FDCA), the appropriate degree of deference will be determined based upon the circumstances surrounding that interpretation. See id. at 227-31. An agency will receive utmost deference if "it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." Mead, 533 U.S. at 226-27. The FDCA, pursuant to 21 U.S.C. § 371(a), grants explicit authority to FDA "to promulgate regulations for the efficient enforcement of" the statute. Similarly, the Hatch-Waxman Amendments permit FDA to promulgate regulations that are "necessary for the administration" of those amendments. See 21 U.S.C. § 355 note, Pub. L. No. 98-417, 105, 98 Stat. 1585, 1597 (1984).

As the D.C. Circuit noted in Teva III, it is the responsibility of FDA "to 'bring its experience and expertise to bear in light of competing interests at stake' and make a reasonable policy choice." 441 F.3d at 5 (quoting PDK Labs., Inc., 362 F.3d at 797-98). Frequently, the D.C. Circuit has given Chevron deference to FDA's interpretation of the FDCA and the agency's implementing regulations. See Novartis Pharms. Corp. v. Leavitt, 435 F.3d 344, 349 (D.C. Cir. 2006) (stating that "FDA interpretations of the FDCA receive deference, as do its interpretations of its own regulations unless plainly erroneous or inconsistent with the regulations"); Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1281 (D.C. CIr. 2004); Purepac Pharm. Co. v.

Thompson, 354 F.3d 877, 883 (D.C. Cir. 2004).[6] It makes no difference, moreover, that an administrative determination is embodied in a decision letter, as here, rather than in a rulemaking or formal adjudication; Chevron deference still applies. See Mylan, 389 F.3d at 1279-80.

ANALYSIS

I. Whether Plaintiff is Likely to Prevail on the Merits of its Argument that the Apotex-BMS Dismissal Triggered the 180-Day Exclusivity Period for Pravastatin

To obtain emergency injunctive relief, plaintiff need not prevail on each factor of the four-pronged calculus. See Teva Pharms., 404 F. Supp. 2d at 245 (citing Holiday Tours, Inc., 559 F.2d at 843-44). Nevertheless, the case law in this Circuit indicates that the "likelihood of success on the merits" inquiry is the most salient consideration, because a plaintiff's failure to prevail on that prong necessitates an unusually strong showing as to the remaining three factors in order "to turn the tide in [its] favor." Davenport, 166 F.3d at 366. Hence, the Court will tackle this step in the analysis first. As noted above, whether plaintiff is likely to succeed on the merits is an assessment that is governed by the Chevron framework.

A. Chevron Step One

At step one of Chevron, the Court must first consider whether the relevant statutory provision, § 355(j)(5)(B)(iv)(II), is silent or ambiguous with respect to the issue presented. The provision appears, at first blush, to use language that is sufficiently uncomplicated to lend itself to but one interpretation of the qualifying event: a "decision of a court . . . holding the patent . . .

[6]The FDA is entitled to the same "substantial deference" whether this Court is viewed as assessing the agency's interpretation of its statute or its implementing regulation. See Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994); U.S. Air Tour Ass'n v. FAA, 298 F.3d 997, 1005 (D.C. Cir. 2002).

invalid or not infringed." § 355(j)(5)(B)(iv)(II). Any superficial simplicity, however, is deceptive. The Court is well aware of the confusion that this language has caused. One need not look very far to discover that there is considerable room for debate regarding what constitutes a "decision" or "holding." See, e.g., Teva III, 441 F.3d at 3, 4; Teva I, 182 F.2d at 1007-08. It seems, then, that careful, inventive lawyering has rendered uncertain what might otherwise have appeared straightforward and unambiguous. See Teva I, 182 F.3d at 1007-08 (noting that a "'decision' can take several forms" and the word "'holding' . . . is also susceptible to interpretation"). To be sure, the language of the statute does not foreclose the textual or holding-on-the-merits approach adopted by the FDA; nor does it require the estoppel-based interpretation that plaintiff so vehemently urges. See id. at 1012 (noting that the estoppel approach is not the only permissible construction of the court-decision trigger). But the latent ambiguity inherent in the terms "decision" and "holding" is sufficient to render the provision ambiguous. In fact, the FDA itself has previously acknowledged that the holding-on-the-merits approach is arguably more narrow than the language of § 355(j)(5)(B)(iv)(II) supports. See id. at 1011.

In this Court's view, the holding-on-the-merits approach arises more naturally from the statutory language than does the estoppel approach, and, accordingly, is the better interpretation. But that is not the proper inquiry. At Chevron step one, the mere possibility of more than one meaning, in a given context, for a statutory word or phrase is sufficient to warrant further inquiry into the agency's deliberative process. Under such circumstances, "'the text and reasonable inferences from it [do not] give a clear answer against'" either interpretation. See Cal. Indep. Sys. Operator Corp., 372 F.3d at 402 (quoting Brown v. Gardner, 513 U.S. 115, 120 (1994)). "In determining whether a statutory provision speaks directly to the question before [it, a court must]

consider it in context." See Holly Sugar Corp. v. Johanns, 437 F.3d 1210, 1213 (D.C. Cir. 2006) ((citing FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132-33 (2000)). Here, it simply cannot be said that the FDA's approach is the only reasonable way to interpret the statute -- the statute never specifies that the "decision" and "holding" rendered by the court must be "on the merits" of the dispute. Hence, the provision is ambiguous, and the Court will proceed to step two of the Chevron analysis. Certainly, that assessment is consistent with the thrust of the D.C. Circuit's observations in Teva I and Teva III.

B. Chevron Step Two

1. Whether the FDA's Approach is a Permissible Construction of the Statute

At step two of Chevron, the threshold inquiry is whether the holding-on-the-merits approach may reasonably be divined from the text of the statute. See Chevron, 467 U.S. at 843. This Court readily concludes that it may: by its plain terms, the language of the provision requires a "decision of a court . . . holding the patent . . . invalid or not infringed," and makes no mention of notions of estoppel. A natural, and therefore permissible, construction of this language is that it requires a judicial decision addressing the merits of the patent infringement or invalidity action. Indeed, in so concluding, FDA has correctly commenced its analysis with the plain language of the statutory provision. See Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002); Group Life & Health Ins. Co. v. Royal Drug Co., 440 U.S. 205, 210 (1979).

2. Whether the FDA's Approach is the Product of Reasoned Agency Decisionmaking

The Court must also consider whether the approach taken by the FDA is supported by reasoned agency decisionmaking. See Teva II, 2000 WL 1838303, at *2. Apotex argues that the

FDA's April 11, 2006 decision is identical to the views FDA espoused in Teva I and Teva II. Because the holding-on-the-merits approach was, in Apotex's view, rejected by the D.C. Circuit in Teva I and Teva II, and rejected by Judge Kollar-Kotelly of this Court on remand, it allegedly follows that it should likewise be deemed insufficient here. But Teva I and Teva II must be construed in light of Teva III, which states clearly that the D.C. Circuit neither invalidated the holding-on-the-merits interpretation that FDA now advocates nor established a substantive rule of law regarding the proper construction of the court-decision trigger. See Teva III, 441 F.3d at 3-4. Teva I and Teva II were purely procedural in nature, and they held only that "the FDA's conclusion [was] 'arbitrary and capricious inasmuch as [it] [took] an inconsistent position in another case and failed to explain adequately the inconsistency.'" Id. at 4 (citing Teva I, 182 F.3d at 1004) (emphasis added).[7] Hence, plaintiff's suggestion that the holding-on-the-merits approach itself is arbitrary and capricious is misleading -- it was the agency's failure to justify that approach under the law that was deemed arbitrary and capricious, not the approach itself. Because the FDA had suddenly reversed course and failed to follow the case-by-case method that it purportedly adopted in its earlier guidance document "without justification" and based on nothing more than a

[7]Apotex also relies on certain language in Teva I that it characterizes as a categorical recognition by the D.C. Circuit that dismissals like the Apotex-BMS dismissal are qualifying triggering events. See Pl.'s Mot. T.R.O. &. Prelim. Inj. at 17; see also Teva I, 182 F.3d at 1009 (stating that "the [Teva I] dismissal appears to meet the requirements of a triggering 'court decision' because th[e dismissing] court had to make a predicate finding with respect to whether [the manufacturer of the branded drug] would ever sue . . . for infringement in order to conclude that there was no case or controversy between the parties"). The problem with this argument is that, in the wake of Teva III, the language has little continuing force: its function was to identify weaknesses in the agency's logic that remained unaddressed as a result of the failure to engage in considered analysis. The language cannot be considered a determinative statement of law regarding the types of dismissals that would satisfy the statute; rather, it must be understood as an invitation for FDA to grapple with certain issues on remand.

desire for administrative ease, see Teva I, 182 F.3d at 1011, the FDA's ultimate conclusion could not be sustained as the product of a reasoned agency decisionmaking process, see Teva II, 2000 WL 1838303 at *2. Thus, in Teva I the FDA failed even to establish that it was entitled to deference under Chevron -- it "offered no particular interpretation of [the court-decision trigger] provision, relying instead on its authority to interpret the provision narrowly until it promulgate[d] a new rule." 182 F.2d at 1007.

The outcome in Teva I and Teva II rested on the FDA's abdication of its responsibility "to bring its experience and expertise to bear" upon the court-decision trigger interpretation. Teva III, 441 F.3d at 5 (quoting PDK Labs, Inc., 362 F.3d at 797-98). This Court is not convinced, however, that the FDA has similarly "failed to adequately explain" its conclusion here. The FDA's April 11, 2006 remand decision is not, as Apotex claims, "indistinguishable" from the agency's actions in Teva I and Teva II. This time, the FDA has not relied solely on administrative concerns. Rather, the record reveals that the FDA "brought its experience and expertise to bear," utilizing its resources and fulfilling its statutory mandate by carefully considering the statute's text, see Pl.'s Exh. A at 7, balancing the advantages and drawbacks of each approach, considering the competing policy interests that underlie the statute, examining the possible implications of congressional intent, and ultimately exercising its delegated discretion to choose from among the available options, see id. at 8-10, 12-14. As the FDA has acknowledged, neither the holding-on-the-merits approach nor the estoppel approach is without complication or idiosyncracy. Both approaches may, in theory, function to undercut legislative policy and congressional intent in some regard. However, the holding-on-the-merits approach offers benefits that the estoppel approach does not. Primarily, it preserves the incentive for companies to undertake the very

substantial risks and costs associated with patent challenges; it is congruent with the intent of Congress as expressed through the plain language of the statute; it facilitates certainty and consistency on an industry-wide basis; it offers heightened ease of administration;[8] and it reduces opportunities for lengthy, costly, and repetitive litigation. By facilitating patent challenges and reducing complex litigation, the holding-on-the-merits approach actually furthers the very policy that Apotex claims it undermines -- the goal of getting more low-cost generic products into the hands of consumers as quickly as possible. FDA's April 11, 2006 decision therefore constitutes a much more thorough, considered, and comprehensive analysis than the agency undertook in Teva I or Teva II. In any event, the choice between competing policy concerns is for the agency, not this Court, to make, and here FDA has properly adopted an interpretation that hews closely to the terms chosen by Congress to express its legislative judgment. See Teva Pharms. Indus., Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005).

3. Whether the FDA's Approach is Reasonable in Practice

The reasonableness of the agency's approach in practice plays an important part in the Chevron step two analysis. See Associated Gas Distribs. v. FERC, 899 F.2d 1250, 1261-63 (D.C. Cir. 1990); cf. Teva I, 182 F.3d at 1011 (stating that the FDA must interpret the court-decision

[8]It is perfectly appropriate for the agency to consider administrative convenience as one component of the overall mix of factors when developing an interpretive approach. See Teva II, 2000 WL 1838303, at *1 (quoting Teva Pharms., USA, 1999 WL 1042743, at *5); see also Clinton Mem'l Hosp. v. Shalala, 10 F.3d 854, 860 (D.C. Cir. 1993). The problem in Teva I and Teva II was that the agency attempted to insulate its otherwise unexplained action solely on that basis. See Teva II, 2000 WL 1838303, at *2 (quoting Teva Pharms., USA, 1999 WL 1042743, at *5). Here, in contrast, the agency has articulated many reasons for its decision to abandon the case-by-case method, reject the estoppel approach, and adopt the holding-on-the-merits approach. Under such circumstances, the Court "ha[s] no business second-guessing the agency." Teva II, 2000 WL 1838303, at *4 (Edwards, J., concurring in part and dissenting in part).

trigger clause of Hatch-Waxman in a manner that "avoid[s] absurd results and further[s] the statute's purpose"). An approach that is practically infeasible may thus prove not to be a permissible construction of the statute. For many of the same reasons that the holding-on-the-merits approach is supported by reasoned agency decisionmaking, it is also reasonable in practice.

Plaintiff's argument that the approach "nullif[ies] the crucial declaratory judgment mechanism for ANDA applicants," Pl.'s Mot. T.R.O. & Prelim. Inj. at 26, does not warrant a contrary conclusion. As long as the party filing the declaratory judgment action meets the "case or controversy" requirements of Article III (meaning that it has a reasonable apprehension of suit by the branded product manufacturer), that party may seek a court decision that qualifies as a triggering event under the statute. The holding-on-the-merits approach does not "nullify[] the crucial declaratory judgment mechanism," then, it only nullifies the manipulation of that mechanism, which has facilitated numerous sham lawsuits akin to the Apotex-BMS litigation.

As the FDA's remand decision acknowledged, the holding-on-the-merits approach is not perfect, but neither is the estoppel approach advocated by Apotex. For example, the estoppel approach completely ignores the language of the statutory provision, which requires a decision of a court with an actual holding. Pl.'s Exh. A at 8. The FDA has correctly noted that parties may be estopped for any number of reasons, based upon various considerations, which may be wholly unrelated to patent infringement, unenforceability, or invalidity. To make estoppel the pivotal focus is essentially to amend the statute's text, effectively deleting the words "holding the [relevant] patent . . . invalid or not infringed." Such an approach would "contraven[e] accepted cannons of statutory construction," id. (citing Bailey, 516 U.S. at 146), because, as the Court

discussed supra, it would run counter to the seemingly clear language of the statute.[9]

Plaintiff may well be correct that "some degree of legal analysis is unavoidable in the context of the court-decision trigger." See Teva II, 2000 WL 1838303, at *1 (quoting Teva Pharms., USA, 1999 WL 1042743, at *5). But the holding-on-the-merits approach does not entirely eradicate legal analysis; it merely focuses that analysis. Instead of engaging in the broader, more amorphous, subjective, and labor-intensive inquiries associated with estoppel (including what constitutes a reasonable apprehension of suit, what is sufficient to eradicate such an apprehension, and what is sufficient to prevent such an apprehension from ever arising in the first place), the FDA will instead concern itself with the more focused issues of what constitutes a holding "on the merits" of the patent suit, and whether that holding is the result of a court decision, rather than a decision or agreement of the parties.

Even if, as plaintiff contends, the estoppel approach is less imperfect than the holding-on-the-merits approach, that does not render the FDA's approach impermissible. See Am. Bar Ass'n, 430 F.3d at 468. The act of analyzing competing policy concerns against the backdrop of the statutory landscape that Congress has placed in its charge is the quintessential function of an administrative agency. See, e.g., Teva Pharms. Indus., 410 F.3d at 54. It is precisely the province of the agency to choose from among the permissible constructions and competing policy interests of a statute after assessing the benefits and disadvantages of each, and the Court may not

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[9]This observation does not conflict with the Court's earlier conclusion that the provision's text is not sufficiently unambiguous to end the inquiry at Chevron step one. The ambiguity in the language is latent in nature, arising from the fine legal distinctions that may be drawn when interpreting the meaning of individual words like "decision" and "holding." Hence, while the language is ambiguous when judged by Chevron step one standards, it does, nonetheless, lend itself strongly and naturally to the FDA's interpretation, and not the estoppel approach urged by Apotex.

substitute its judgment for that of the agency. See Am. Bar Ass'n, 430 F.3d at 468; see also Chevron, 467 U.S. at 866 (stating that "[t]he responsibilit[y] for assessing the wisdom of such policy choices . . [is] not [a] judicial one[]"); cf. Teva III, 441 F.3d at 4-5. Under Chevron's highly deferential standard, it matters not which is the better or even the correct interpretation, as long as the one advocated by the FDA is not entirely irrational. See Am. Bar Ass'n, 430 F.3d at 468. This is particularly so in an administrative context that, like the one currently before the Court, is admittedly fraught with complications and conflicts. See Barnhart, 535 U.S. at 222. Here, the FDA has been given substantial authority over an ambiguous statute in this complex arena, and has chosen a method that it believes properly strikes the delicate balance between competing legislative policies, thereby filling the gap left by Congress. See Teva III, 441 F.3d at 4 (citing Chevron, 467 U.S. at 843-44). Under such circumstances, the deference to which the agency is entitled is at its apex, see Mead, 533 U.S. at 226-27, and the Court cannot conclude that the FDA has acted irrationally or outside the scope of its authority, see Cal. Indep. Sys. Operator Corp., 372 F.3d at 399-400 (citing Chevron, 467 U.S. at 843-44; Motion Picture Ass'n of Am., Inc. v. FCC, 309 F.3d 796, 801 (D.C. Cir. 2002)). "[S]o long as [the FDA's] interpretation is 'permissible,' that is, if it is 'reasonable,'" it must be upheld under Chevron. Am. Bar Ass'n, 430 F.3d at 468 (quoting Chevron, 467 U.S. at 843, 845). Operating, as it must, within these well-settled principles, the Court concludes that the FDA's interpretation of its statute and implementing regulation is reasonable.

C. Whether the FDA's Remand Decision Adequately Addresses the Concerns Expressed in Teva I

In Teva III, the D.C. Circuit noted that

> the FDA states that in the absence of any perceived Teva I constraint, it would employ a 'textual' approach to interpreting the statute, and would take the position that dismissals of declaratory judgment actions are not court decisions holding a patent to be invalid or not infringed . . . . The agency took a similar position in Teva I, but failed to provide adequate explanation. In this litigation the FDA still has not answered the questions put to it by the Teva I court.

441 F.3d at 5 n5. Apotex argues that this language constitutes a requirement that the FDA, on remand in Teva III, reconcile the result that it reached in Teva I and Teva II under the cae-by-case method adopted in the earlier guidance document; reconcile the result that it reached in Teva I and Teva II, as well as the result that it has reached regarding the Apotex-BMS dismissal, with the result that it reached in Granutec; and explain how its departure from the estoppel approach is permissible in light of its regulation including a decision as to unenforceability as a possible triggering event. Apotex also submits that the FDA's remand decision has left these questions unanswered yet again.

As a threshold matter, Apotex is mistaken regarding the effect of the D.C. Circuit's statement in Teva III. It would be nonsensical if that language required the FDA to reconcile the results that it reached in Teva I, Teva II, and Granutec, or to justify the result that it reached here regarding the Apotex-BMS dismissal under the now-defunct case-by-case method. At the time of those earlier decisions, the FDA had committed itself to using the case-by-case method while it awaited promulgation of a new, final rule. In Teva I and Teva II, however, the FDA decided to apply the holding-on-the-merits approach, and did not explain its departure from the case-by-case method. The concerns expressed by the D.C. Circuit in Teva I were predicated upon the improper rejection of the case-by-case method and considerations of estoppel in favor of the holding-on-the-merits approach in the absence of any justification for the departure. Now, however, the

agency has explicitly rejected the case-by-case method, as well as the estoppel approach, in favor of the holding-on-the-merits approach, and that rejection has been fully explained in the April 11, 2006 decision letter. Teva III explicitly opened the door for the FDA to do this -- the FDA stated, at oral argument and in its briefs, that it would adopt the holding-on-the-merits approach if it were free to do so. Following these representations, the D.C. Circuit issued the Teva III opinion, which held that neither Teva I, Teva II, nor any other circuit precedent required the FDA to use the estoppel approach or the case-by-case method. As long as the FDA explained adequately its reasons for doing so, it could adopt whatever approach it preferred. The necessary corollary is that Teva III recognized the agency's authority to reject other approaches, including the one previously followed. Accordingly, decisions rendered under the case-by-case method when it was still viable have little, if any, bearing on assessments made under the new holding-on-the-merits approach, and it makes little sense to require the FDA to justify its decision here under the case-by-case method when that method is no longer being employed.

Instead, the Court interprets the language in Teva III as an admonishment to the agency that while it is free to reject certain approaches and adopt the one that it prefers, it must explain adequately its reasons for doing so, and it must reconcile any currently relevant aberrations that may be created as a result (including any inconsistency with the still-effective regulation on unenforceability). Teva III merely reminded the agency that it cannot commit the same sins as it did in Teva I. In any event, even if Apotex's interpretation of that language were correct, the Court is convinced that the FDA has satisfied its responsibilities in its remand decision. To begin with, the agency has explained why its decision is not arbitrary or capricious in light of its previous guidance document -- the guidance document is no longer viable. Because the FDA is

no longer required, by its own commitment, to make a case-by-case assessment based on considerations of estoppel, it is permissible for the FDA to reach a conclusion under its new approach that might not have been supported under a case-by-case assessment. Simply put, the guidance document can no longer be considered the frame of reference for proper agency action.

Moreover, the FDA has adequately articulated how the holding-on-the-merits approach is consistent with its implementing regulation. The language of the regulation parallels the language of the statute, except that the regulation adds the word "unenforceable" to the statutory terms "invalid or not infringed." By its plain terms, then, the regulation requires nothing less, and nothing more, than what the statute requires. The FDA has reasonably determined that both the statute and the regulation require a decision of a court that is a holding on the merits regarding the patent action. It cannot convincingly be argued that there is any incongruity between the regulation and the statute, such that it would be improper under the regulation to utilize a holding-on-the-merits approach that is reasonably supported by the terms of the statute itself. Both the statute and the regulation reflect the intent of Congress for the exclusivity clock to be triggered only by a judicial determination that the relevant patent is invalid, not infringed, or unenforceable.

Hence, neither a private agreement between litigants that procures a voluntary dismissal of a declaratory judgment action (like the Apotex-BMS dismissal), nor a determination by the FDA regarding whether or not the branded drug manufacturer is estopped from pursuing a patent action will satisfy the statute's requirements as also embodied in the regulation. Apotex's argument that the agency has "elevated the form of the dismissal over its substance," Pl.'s Mot. T.R.O. & Prelim. Inj. at 21, thus begs the question: Congress chose to focus on the nature of the dismissal, rather than its practical effect, by specifying a court decision with a holding. That is the legislative

scheme that Congress created, and the agency's holding-on-the-merits approach furthers that scheme. The relevant inquiry under the FDA's reasonable interpretation of the statute and regulation is not whether there is estoppel as a result of a given court proceeding, but rather whether the court has itself rendered a decision that holds -- on the merits -- that the relevant patent is invalid, not infringed, or unenforceable. Apotex's dissatisfaction with the way in which the agency's approach affects its interests in generic pravastatin does not offer the Court a sufficient basis to disturb the legislative scheme reasonably adopted by the FDA.

Finally, the agency has adequately explained why the court action at issue in Granutec was a triggering event, whereas the Apotex-BMS dismissal is not. The Granutec court granted partial summary judgment, through a memorandum opinion, in one party's favor on the basis of representations that had estoppel effect. By its very nature, summary judgment requires the weighing of substantive arguments and necessitates legal analysis -- the court is required to determine that there is no genuine dispute of material fact, and the moving party is entitled to prevail as a matter of law. See Fed. R. Civ. P. 56(c). Of course, under the FDA's April 11, 2006 decision, estoppel is no longer the relevant inquiry -- the focus is now on whether there is a court decision and what it holds. However, the result previously reached in Granutec would, as FDA concluded, be the same under the holding-on-the-merits approach that applies today.[10] In Granutec, the court was called upon to make a factual and legal finding with respect to the substantive arguments presented on the issue of patent invalidity, infringement, or

[10]In its opposition memorandum, defendant-intervenor Teva submits as well that Granutec has been superseded by statute, such that a partial grant of summary judgment would no longer qualify as a triggering event because it is not a "decision of a court" within the meaning of the statute pursuant to the MMA. See Teva Mem. Opp'n at 14.

unenforceability. This did not happen in the Apotex-BMS litigation. As this Court articulated in its prior decision, the Apotex-BMS dismissal was nothing more than a private settlement agreement between the parties, which required no court action whatsoever and lacked the requisite judicial imprimatur to constitute a "decision of a court." See 398 F. Supp. 2d at 190-91. It was a "decision," in essence, by the parties. The court was not called upon to make any substantive determinations, and its signature upon the face of the order added nothing of substance. See id. at 189-92. The same outcome would have been reached whether or not the court signed the document, because the action that made the document effective was taken by the parties, not by the court. See id. In contrast, the parties in Granutec could never have obtained the outcome in that case -- partial summary judgment -- without a court decision addressing the merits.

With respect to the results reached by the agency in Teva I and Teva II (prior to the D.C. Circuit's decisions in those cases), there is no inconsistency with the holding-on-the-merits approach. As the D.C. Circuit recognized, the dismissal at issue in those cases was not a holding on the merits. See Teva I, 182 F.3d at 1009 (recognizing that the "dismissal was not a judgment on the merits after consideration of evidence presented by the parties"). Hence, it would not qualify as a triggering event under the approach that applies as of April 11, 2006. The D.C. Circuit rejected the FDA's conclusion in this regard because the agency itself had made estoppel the focal point of the analysis, and the dismissal at issue in Teva I and Teva II did have preclusive effect. See id. Hence, the dismissal was, at the time, a qualifying triggering event, and the FDA's unexplained refusal to recognize it as such was improper. See id.

Not only did the agency's fifteen-page, single-spaced remand decision thoughtfully deconstruct the multifaceted implications of the estoppel and holding-on-the-merits approaches,

but it also sufficiently addressed each of the three concerns raised in Teva I and recalled in Teva III. There is no "want of reasoned decisionmaking" here. See Teva II, 2000 WL 1838303, at *2. Moreover, the agency's remand decision represents a permissible construction of the statute as a matter of textual interpretation as well as practice. Apotex is, accordingly, unlikely to prevail on the merits of its claim that the FDA acted arbitrarily, capriciously, in excess of statutory authority, or otherwise not in accordance with law when it determined that the Apotex-BMS dismissal is not a qualifying triggering event under § 355(j)(5)(B)(iv)(II).

II. Whether Plaintiff Will Suffer Irreparable Harm if Relief is Not Granted

The irreparable injury requirement erects a very high bar for a movant. See Varicon Int'l v. OPM, 934 F. Supp. 440, 447 (D.D.C. 1996). A plaintiff must show that it will suffer harm that is "more than simply irretrievable." Gulf Oil Corp. v. Dept. of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981). In this jurisdiction, harm that is "merely economic" in character is not sufficiently grave under this standard. See Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); Boivin v. US Airways, Inc., 297 F. Supp. 2d 110, 118 (D.D.C. 2003); Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 42 (D.D.C. 2000). To successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to "cause extreme hardship to the business" or threaten its very existence. Gulf Oil, 514 F. Supp. at 1025; see also Wisconsin Gas, 758 F.2d at 674; Experience Works, Inc., 267 F. Supp. 2d at 96; Sociedad Anonima Vina Santa Rita v. Dep't of Treasury, 193 F. Supp. 2d 6, 14 (D.D.C. 2001). To warrant emergency injunctive relief, the harm alleged must be certain, great, actual, and imminent. See Wisconsin Gas, 758 F.2d at 674. Moreover, because Apotex has not established a likelihood of success on the merits, its showing of irreparable harm must be very

strong. See Cuomo, 772 F.2d at 974; Davenport, 166 F.3d at 366.

The Court is not convinced that Apotex can satisfy these standards. To be sure, if Apotex is correct that all generic exclusivity connected to pravastatin has already been triggered and extinguished, then it probably stands to lose a significant sum of money unless it is granted emergency injunctive relief. But if, as the FDA has concluded (reasonably, this Court believes), intervenor-defendants are statutorily entitled to benefit from a period of generic exclusivity that has not yet been triggered, then Apotex faces no harm whatsoever because the denial of emergency injunctive relief leaves its position untouched.

Apotex has never contended that it has a statutory entitlement to generic exclusivity; it has never claimed that it was the first to file an ANDA containing a paragraph IV certification with respect to one of the Pravachol® patents. Rather, Apotex merely submits that it stands to lose approximately $9.9 million dollars in sales over the course of one year if intervenor-defendants are permitted to exercise their statutory exclusivity entitlements. The Court will assume the accuracy of that dollar estimate for the moment, putting aside the FDA's contention that the relevant time period for the calculation of losses is only from the point when the intervenor-defendants launch their products on April 20, 2006 to the time that the case is resolved on the merits, probably just a few months. Even so, the harm that Apotex allegedly faces cannot be called anything other than "merely economic." Apotex "produces more than 260 generic pharmaceuticals in approximately 4000 dosages and formats which, in Canada, are used to fill over 60 million prescriptions a year -- the largest amount of any pharmaceutical company in [Canada]." See http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes (last visited Apr. 18, 2006). Moreover, Apotex reaps annual revenues that total approximately $700

million USD. Id. (boasting annual revenue of more than $800 million in Canadian currency). Under the circumstances, it hardly seems possible that a $9.9 million loss in sales over a year would cause extreme hardship, much less threaten the company's very existence, and Apotex has not established (or even contended) that it would.

Apotex's speculative sales loss thus remains an economic loss that does not meet the irreparable harm standard. So, too, its concerns about a lost market share fall well short of the serious, irretrievable damage to its business required to warrant a preliminary injunction, particularly when one considers that the actual relevant period for assessing harms is probably only a few months. And even assuming that Apotex has adequately established a cognizable irreparable injury, the Court cannot conclude that the balance of hardships tips decidedly in its favor because, as discussed below, each of the intervenor-defendants stands to lose a much greater sum if the launch of their generic products is delayed. Particularly where Apotex has made a very weak showing of likely success on the merits, that balance of harms is fatal to its request for emergency injunctive relief.

III. Whether the Intervenor-Defendants Will Suffer Irreparable Harm if Emergency Injunctive Relief is Granted

In the event that Apotex receives the emergency injunctive relief that it seeks, the intervenor-defendants will be prevented from marketing their generic products on April 20, 2006. Both Teva and Ranbaxy are, the FDA has determined, entitled to enjoy a 180-day period of generic marketing exclusivity. Each company is prepared to launch on April 20, 2006, and estimates that it will suffer lost profits that far exceed the losses that Apotex allegedly faces over a

longer period of time. Specifically, Teva contends that a delay as short as seven days could cost it "tens of millions of dollars," and Ranbaxy anticipates losses totaling fifteen to twenty million dollars within the first six months of marketing. See Teva Mem. Opp'n at 20; Ranbaxy Mem. Opp'n at 16. But unlike the harm that Apotex allegedly faces, the potential injury that the intervenor-defendants face is not "merely economic." Rather, they stand to lose a statutory entitlement, which is a harm that has been recognized as sufficiently irreparable. See, e.g., Mova, 140 F.3d at 1067 n.6. Once the statutory entitlement has been lost, it cannot be recaptured.

Moreover, although intervenor-defendants are entitled to an exclusivity period of 180 days under the statute, in reality they will only enjoy an exclusivity period of approximately sixty days. On June 23, 2006, the patent for a branded drug by the name of Zocor® will expire. Generic versions of that drug (simvastatin) will then enter the market. Simvastatin and pravastatin are in the same drug class, have very similar treatment indications, and are, for all practical purposes, interchangeable for many patients. According to some reports, Pravachol® users are currently being advised to switch to Zocor® in anticipation of the arrival of generic simvastatin. See Interv.-Def.'s (Ranbaxy) Exhs. C, D. Intervenor-defendants estimate, not unreasonably, that the launch of generic simvastatin will diminish the value of the 180-day exclusivity period for generic pravastatin. Additionally, the manufacturer of Pravachol®, BMS, has already entered into agreements pursuant to which it will launch an "authorized generic" product on April 20, 2006.[11] This product will compete directly with the products marketed by intervenor-defendants. If intervenor-defendants are prevented from entering the market at the same time as the authorized

[11]An "authorized generic" or "brand generic" is a generic version of the branded drug that is produced by, or in partnership with, the same company that manufactures the branded drug. See generally Teva Pharms., 410 F.3d at 52-53.

generic, then they stand to lose a portion of the market that BMS will have already acquired. Hence, each day after April 20, 2006 that intervenor-defendants are foreclosed from marketing their generic pravastatin products will result in further erosion of the statutory entitlement and additional lost profits and market share. In light of the considerable economic injury facing intervenor-defendants, and the less substantial injury to Apotex, the balance of hardships clearly tips against granting Apotex the emergency injunctive relief that it seeks.

IV. Where the Public Interest Lies

Where, as here, the FDA is administering a statute that has been placed within its charge, and has no financial interest in the outcome, its interest is deemed to be aligned with that of the public. The public interest would not, as Apotex claims, be furthered by a court order preserving the alleged status quo. Such an order would effectively constitute a constructive extension of the brand manufacturer's patent (and period of pediatric exclusivity). That monopoly is set to end on April 20, 2006, and there are two pharmaceutical companies that are ready and willing to make generic alternatives to Pravachol® available to consumers on that date. The purpose of the relevant statutory provisions is to expedite and increase the availability of generic substitutes. If this Court were to grant Apotex's motion, then the public would be forced to wait until this litigation is completely resolved (at some unidentified point in the future) before it is able to benefit from low-cost versions and widespread availability of pravastatin. The fact that BMS, as the manufacturer of Pravachol®, plans to release an authorized generic on that date does not indicate otherwise. To be sure, an authorized generic may provide some benefit to the public in the form of reduced costs and greater product availability. But, as Teva notes, those benefits are

not likely to be as great as the ones that flow from real generic competition. The authorized generic faces no significant market pressure because the manufacturer is, essentially, competing with itself. Accordingly, it lacks a sufficiently strong incentive to undercut the pricing of the branded product. A third-party generic seeks to attract the consumers of the branded product, but the authorized generic naturally seeks (to a degree) to maintain a customer base for its more profitable branded product. Hence, the public interest is most directly furthered by the launch of generic pravastatin on April 20, 2006.[12]

CONCLUSION

For the foregoing reasons, plaintiff's motion for a temporary restraining order and preliminary injunction is denied. Apotex has also sought an injunction pending appeal. The legal analysis that applies to a request for a stay or injunction pending appeal is identical to that for a temporary restraining order or preliminary injunction and, accordingly, Apotex has failed to establish that the balance of harms or its likelihood of success on the merits favors the issuance of such relief. Nevertheless, in order to allow the Court of Appeals, if so requested, to determine whether it will exercise its discretion to grant an injunction pending appeal, this Court will grant that injunction for a brief period, through 5:00 p.m. on April 21, 2006. A separate order has been issued on this date.[13]

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[12]Apotex claims that the public interest is furthered by "faithful application of the laws." This is undoubtedly true, but it is of little aid here. In the Court's opinion, the holding-on-the-merits approach adopted by the FDA is more faithful to the statutory language, preferable from a policy standpoint, and facilitates consistency and industry certainty -- all things that amount to a "faithful application of the law."

[13]FDA requested that this proceeding be consolidated, under Fed. R. Civ. P. 65(a)(2), with a proceeding on the merits. The parties agreed to such a course of action with respect to the proceedings before this Court in Teva III. However, in light of the compressed time schedule

/s/ John D. Bates
JOHN D. BATES
United States District Judge

Dated: April 19, 2006

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with respect to the current proceedings, the Court is reluctant to do so in the absence of consent by all parties. Accordingly, the FDA's request is denied.

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Not Reported in F.3d, 2006 WL 2591087 (C.A.D.C.)

United States Court of Appeals,
District of Columbia Circuit.

A. SANDOZ INC., Appellant
v.
FOOD & DRUG ADMINISTRATION, et al., Appellees

No. 06-5204.
Aug. 30, 2006.

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BEFORE: GINSBURG, Chief Judge, and GRIFFITH and KAVANAUGH, Circuit Judges

ORDER

PER CURIAM

*1 Upon consideration of the motion for summary affirmance, the response thereto, and the reply; and the motion to expedite consideration of this appeal, the responses thereto, and the reply, it is

ORDERED that the motion for summary affirmance of the district court's denial of a preliminary injunction be granted. The merits of the parties' positions are so clear as to warrant summary action. See *Taxpayers Watchdog, Inc. v. Stanley*, 819 F.2d 294, 297 (D.C.Cir.1987) (per curiam). As mandated by the district court's decision in *Ranbaxy Labs., Ltd. v. Leavitt*, No. 05-1838 (D.D.C.2006), the Food and Drug Administration (FDA) approved the Abbreviated New Drug Applications (ANDAs) filed by two manufacturers of generic simvastatin. In the district court, the appellant moved for a preliminary injunction to restrain the FDA from issuing those approvals. The appellant also sought (apparently in the alternative) to enjoin the FDA from delaying final approval of the appellant's generic simvastatin. When considering a request for injunctive relief, a court must weigh: (1) the movant's likelihood of success on the merits; (2) irreparable injury to the movant; (3) injury to other interested parties; and (4) the public interest. See *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C.Cir.1977). Because the FDA refused to approve appellant's ANDA for generic simvastatin during the 180-day period of marketing exclusivity for two other simvastatin manufacturers mandated by the district court's decision in *Ranbaxy*, the district court properly concluded that appellant's claim was not sufficiently likely to succeed on the merits and denied the motion for a preliminary injunction. We express no opinion here as to whether the district court's opinion in *Ranbaxy* was correct; that issue is before this panel in a separate appeal (No. 06-5154). It is

FURTHER ORDERED that the motion to expedite consideration of this appeal be dismissed as moot.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or petition for rehearing en banc. See Fed. R.App. P. 41(b); D.C.Cir. Rule 41.

C.A.D.C.,2006.
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Judges

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- Kavanaugh, Hon. Brett M.
United States Court of Appeals, District of Columbia Circuit
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