

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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**LOUISIANA WHOLESALE DRUG CO., INC.,** :  
**Plaintiff,** :

**against-** :

**SANOFI-AVENTIS, SANOFI-AVENTIS U.S., LLC** :  
**and AVENTIS PHARMACEUTICALS, INC.,** :

**Defendants.** :

**07 Civ. 7343 (HB)**  
**OPINION & ORDER**

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**Hon. HAROLD BAER, JR., District Judge:**

In this action Plaintiff, Louisiana Wholesale Drug Co., Inc. (“LWD” or “Plaintiff”), alleged that Defendants Sanofi-Aventis, Sanofi-Aventi U.S., LLC and Aventis Pharmaceuticals, Inc. (collectively “Defendants” or “Aventis”) violated the antitrust laws, specifically, Section 2 of the Sherman Act, 15 U.S.C. § 2, by filing with the Food and Drug Administration (“FDA”) a sham Citizen Petition designed to delay approval of a generic version of Defendants’ rheumatoid-arthritis drug leflunomide, sold under the name Arava. The case culminated in a jury trial which resulted in a defense verdict after the jury concluded that the Citizen Petition was not “objectively baseless,” the first question of the two-pronged test for determining whether the Citizen Petition was protected by the *Noerr-Pennington* doctrine or actionable under the so-called “sham exception” thereto. *See Professional Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49 (1993) (“*PRE*”). Following the verdict, LWD moved for a judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b) or, alternatively, for a new trial pursuant to Fed R. Civ. P. 59. For the reasons that follow, LWD’s motion is DENIED.

**I. FACTUAL BACKGROUND**

Familiarity with the facts of this litigation, as set forth in prior opinions,<sup>1</sup> is presumed and those facts will not be restated at length here. Leflunomide, a drug that combats rheumatoid arthritis, was developed and patented by Aventis under the market name Arava. Aventis produced 10 mg and 20 mg “maintenance doses” of Arava as well as a 100 mg “loading dose.”

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<sup>1</sup> *See Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2008 WL 169362, 1 (S.D.N.Y. Jan. 18, 2008) (motion to dismiss); *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2008 WL 4580016, (S.D.N.Y. Oct. 14, 2008) (summary judgment).

The Arava label recommends that treatment commence with a “loading dose of one 100 mg tablet per day for 3 days,” and the clinical trials that preceded the original FDA approval of Arava included use of the loading dose in the form of a 100 mg tablet. Eventually, Aventis stopped selling the 100 mg loading dose in pharmacies, but made it available to prescribing doctors free of charge.

On the day that Aventis’ period of patent exclusivity expired, March 10, 2004, several generic drug makers filed Abbreviated New Drug Applications (“ANDA”) to obtain FDA approval to produce generic leflunomide.<sup>2</sup> At trial, Mark Gardella, an Aventis employee and member of the company’s “Life Cycle Maintenance Group,” testified that Aventis learned that generic manufacturers in Canada were producing generic leflunomide in 10 mg and 20 mg maintenance doses, but not the 100 mg loading dose referred to in the Arava label. Trial Transcript (“Tr.”) 154. The FDA is required to keep the existence and contents of ANDAs confidential unless and until approved, and thus Aventis could only speculate that in the United States the generic manufacturers would similarly attempt to gain approval to produce the maintenance dose strengths, but not the loading dose.

On March 31, 2005, Aventis filed a Citizen Petition with the FDA that requested that the FDA not approve any ANDA for generic leflunomide unless the ANDA (1) contained “data from *in vivo* bioequivalence studies confirming that five of [the generic applicant’s] proposed 20 mg leflunomide tablets are bioequivalent to one Arava 100 mg tablet”; or (2) sought “approval of 100 mg leflunomide tablets that are bioequivalent to 100 mg Arava tablets.” P-*Tex* 625. The Citizen Petition referenced provisions of the FDCA and its regulations that provide that an ANDA must show that the label of the generic drug matches that of the branded or “reference listed” drug in all material respects. *See id.* (citing FDCA Section 505(j)(2)(A)(v), 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. §314.94(a)(8)(iv)). The Citizen Petition stated that “omission of the loading dose information [in the generic label] may render the generics less effective than Arava, thereby making the ANDAs unapprovable.” *Id.* The Citizen Petition also noted that while the new drug application (“NDA”) for Arava was pending, the FDA rejected a request by Aventis’

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<sup>2</sup> The Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, requires manufacturers of a new drug product to obtain FDA approval by filing a New Drug Application (“NDA”). In 1984, the Hatch-Waxman amendments to the FDCA created an expedited FDA review process for generic versions of brand name drugs pursuant to which generic manufacturers were permitted to file Abbreviated New Drug Applications (“ANDAs”).

predecessor to permit five 20 mg tablets to serve as an alternative to the 100 mg tablet loading dose without a showing of bioequivalence. *Id.* After one of the generic manufacturers, Kali Laboratories, Inc., submitted comments to the Citizen Petition, Aventis responded to the FDA in a letter dated June 10, 2005, that requested that the FDA not permit generic manufacturers to reference in their label a 100 mg tablet that they did not produce. P-TEX. 128.

The FDA denied the Citizen Petition on September 13, 2005, the same day that it approved the ANDAs for six generic manufactures to produce and sell generic leflunomide, including one manufacturer who did so pursuant to an agreement with Aventis to sell an “authorized generic” version of the drug. In denying the Citizen Petition, the FDA noted that Aventis’ request for relief “seem[ed] to be based on a false premise,” namely that if a generic manufacturer recommended a 100 mg loading dose it must either (1) produce its own 100 mg tablet; or (2) recommend using five 20 mg tablets. P-TEX. 285. Rather, the FDA commented, Aventis “seem[ed] to ignore a third possibility”: that a label for generic leflunomide could recommend a loading dose with reference a 100 mg tablet that the generic manufacturer did not itself make. *Id.* The FDA noted that it is “not uncommon” for makers of brand name drugs, including Aventis, to reference in their labels drugs made by other manufacturers, a procedure that is known as “co-administration.” *Id.*; Tr. 132. The FDA also noted that “there is nothing in the [FDCA] or the regulations that requires an ANDA applicant to seek approval for all available strengths of the [reference listed drug].” *Id.* Finally, the FDA noted that it would require the “labeling for generic leflunomide products to include the labeling approved for [the reference listed drug], Arava, concerning the use of a 100 mg loading dose.” *Id.*

On August 17, 2007, LWD filed suit on behalf of a class of wholesale drug distributors who alleged they were injured by the delayed entry of generic leflunomide to market that they claimed was the direct result of Aventis’ Citizen Petition, an alleged act of monopolization in violation of Section 2 of the Sherman Antitrust Act. The gravamen of LWD’s complaint was that the Citizen Petition was merely a “sham” designed to exploit the FDA’s citizen petition process to delay approval of generic leflunomide and thereby extend the period of Arava’s exclusivity. Aventis countered that the Citizen Petition was protected by the First Amendment and, more specifically, the *Noerr-Pennington* doctrine, which confers antitrust immunity to acts of petitioning government so long as they are not a “sham.” At trial, LWD offered evidence and argument that the relief requested in the Citizen Petition was not only contrary to FDA statutes,

regulations, and practices, but also lacked medical or scientific basis. In response Aventis offered evidence to show that the loading dose issue raised by the Citizen Petition had not previously been addressed by the FDA and that the generic manufacturers themselves were unsure about how to address the issue in their ANDAs. After seven days of trial, the jury returned a verdict for Defendants; the jury concluded that LWD had failed to prove that the Citizen Petition was “objectively baseless,” the first of two sequential inquiries that must be made to determine whether an act of petitioning is a “sham.”

## II. LEGAL STANDARDS

### A. Judgment as a Matter of Law

“Judgment as a matter of law is appropriate when ‘a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue.’ ” *Jarvis v. Ford Motor Co.*, 283 F.3d 33, 43 (2d Cir. 2002) (quoting Fed. R. Civ. P. 50(a)). Thus, in ruling on a motion for judgment as a matter of law, the Court must “consider the evidence in the light most favorable to the party against whom the motion [is] made” and “give that party the benefit of all reasonable inferences that the jury might have drawn in his favor from the evidence.” *Id.* (quoting *Tolbert v. Queens College*, 242 F.3d 58, 70 (2d Cir.2001)) (internal quotation marks omitted). The Court “cannot assess the weight of conflicting evidence, pass on the credibility of witnesses, or substitute its judgment for that of the jury.” *Tolbert v. Queens College*, 242 F.3d 58, 70 (2d Cir. 2001) (quotation marks and citation omitted).

The Second Circuit has instructed that judgment as a matter of law should not be granted unless:

- (1) there is such a complete absence of evidence supporting the verdict that the jury’s findings could only have been the result of sheer surmise and conjecture, or
- (2) there is such an overwhelming amount of evidence in favor of the movant that reasonable and fair minded persons could not arrive at a verdict against the defendant.

*Galdieri-Ambrosini v. Nat’l Realty & Dev. Corp.*, 136 F.3d 276, 289 (2d Cir. 1998) (internal citations and alterations omitted) (quoting *Cruz v. Local Union No. 3 of the Int’l Brotherhood of Electrical Workers*, 34 F.3d 1148, 1154 (2d Cir. 1994)).

### B. Motion for a New Trial

The Court has significant discretion in deciding whether to grant a Rule 59 motion for a new trial. *See, e.g., Amato v. City of Saratoga Springs*, 170 F.3d 311, 314 (2d Cir. 1999). In

determining whether to order a new trial under Rule 59, the Court may independently weigh the evidence. *See, e.g., Song v. Ives Labs, Inc.*, 957 F.2d 1041, 1047 (2d Cir. 1992). A motion for a new trial “may be granted even if there is substantial evidence to support the jury’s verdict.” *Id.* A jury’s verdict, however, should not be disturbed unless it is seriously erroneous:

The trial judge, exercising a mature judicial discretion, should view the verdict in the overall setting of the trial; consider the character of the evidence . . . ; and abstain from interfering with the verdict unless it is quite clear that the jury has reached a seriously erroneous result. The judge’s duty is essentially to see that there is no miscarriage of justice.

*Bevevino v. Saydjari*, 574 F.2d 676, 684 (2d Cir. 1978); *see also Caruolo v. John Crane, Inc.*, 226 F.3d 46, 54 (2d Cir. 2000) (“A motion for a new trial ordinarily should not be granted unless the trial court is convinced that the jury has reached a seriously erroneous result or that the verdict is a miscarriage of justice.”) (quotation marks and citation omitted).

### III. DISCUSSION

#### A. Applicable Law: Petitioning Immunity and the “Sham Exception”

The *Noerr-Pennington* doctrine immunizes from antitrust liability persons who petition government for redress. *PRE*, 508 U.S. 56 (discussing *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *Mine Workers v. Pennington*, 381 U.S. 657 (1965)). But the doctrine does not protect “‘sham’ activities”—*i.e.* petitioning “ostensibly directed toward influencing governmental action [that] is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor.” *Noerr*, 365 U.S. at 144. In *PRE*, the Supreme Court articulated the two-step inquiry that applies to claims of “sham” petitioning or litigation:

First, the [petition] must be objectively baseless in the sense that no reasonable [person] could realistically expect success on the merits. If an objective [petitioner] could conclude that the [petition] is reasonably calculated to elicit a favorable outcome, the [petition] is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. . . . [Second] the court should focus on whether the baseless [petition] conceals an attempt to interfere *directly* with the business relationships of a competitor, through the use of the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.

*PRE*, 508 U.S. at 56 (internal quotation marks, citations and alterations omitted). The two-step inquiry is sequential: “Only if [the] challenged [activity] is objectively meritless may a court examine the [petitioner’s] subjective motivation.” *Id.*<sup>3</sup>

In *PRE*, the Supreme Court framed the inquiry as a question of whether the antitrust defendant had “probable cause to institute legal proceedings,” which would include “actions ‘arguably ‘warranted by existing law’ or at the very least [] based on an objectively ‘good faith argument for the extension, modification or reversal of existing law.’” *PRE*, 508 U.S. at 62, 65 (quoting Fed. R. Civ. P. 11). Thus, “[e]ven in the absence of supporting authority” a litigant or petitioner “is entitled to press a novel [] claim as long as a similarly situated reasonable litigant *could have perceived some likelihood of success.*” *Id.* (emphasis added). As I instructed the jury, to determine whether the Citizen Petition was objectively baseless they were required to decide “whether a reasonable pharmaceutical manufacturer could have realistically expected the FDA to grant [the] relief sought by Sanofi-Aventis in the citizen petition.” Tr. 1398; *see also PRE*, 508 U.S. at 62 (“Under the objective prong of the sham exception . . . [the] sham litigation must constitute the pursuit of claims so baseless that no reasonable litigant could realistically expect to secure favorable relief.”)

#### **B. LWD’s Motion for Judgment as a Matter of Law**

At trial, there was neither such an “overwhelming amount of evidence in favor” of LWD’s contention that the Citizen Petition was objectively baseless nor such a “complete absence of evidence” supporting the contrary view so as to entitle LWD to a judgment as a matter of law. *Galdieri-Ambrosini*, 136 F.3d at 289. In short, there was ample evidence introduced at trial that tended to show that the issue raised by the Citizen Petition was sufficiently novel and unsettled to permit an objectively reasonable drug company to “perceive[] some likelihood” that the FDA would grant the relief requested. *PRE*, 508 U.S. at 62.<sup>4</sup>

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<sup>3</sup> “Of course, even a plaintiff who defeats the defendant’s claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham must still prove a substantive antitrust violation. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.” *PRE*, 508 U.S. at 60-61. Because the jury found that the Citizen Petition was not “objectively baseless,” they were not required to consider the substantive elements of LWD’s monopolization claim under Section 2 of the Sherman Act.

<sup>4</sup> In support of the instant motion LWD argues that I concluded at the summary judgment stage that the Citizen Petition was objectively baseless and that at trial LWD presented the same evidence that was before me at the summary judgment phase and more. (LWD made a similar application prior to trial,

## 1. Defendants' Evidence.

Aventis points to three categories of trial evidence that support the jury's conclusion that the Citizen Petition was not objectively baseless. First, if credited, the trial testimony of certain of Aventis' employee and expert witnesses is sufficient to support a reasonable inference that the loading dose issue raised by the Citizen Petition had not been previously addressed by the FDA. For example, Mary Pendergast, an expert witness called by Defendants to opine upon FDA practices and procedures testified that she "looked at all of the citizen's petitions the FDA had ever answered to see if they've ever answered one involving a loading dose, and they haven't." Tr. 1124. Pendergast, a veteran of the FDA, further testified that she reviewed the labels of other drugs approved by the FDA, together with testimony, speeches and reports "to see if they'd ever dealt with a loading dose and what their instructions were to companies about how to deal with loading doses, and [she] couldn't find anything that told [her] what the answer was." *Id.* at 1124-25. On cross examination, Pendergast again stated that "there was no precedent either way, no guidance either way how to do it," and that "there weren't clear rules." Tr. 1181, 1213. Similarly, Mark Gardella, the employee in Aventis' "Life Cycle Management" group who first

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requesting in its pretrial memorandum that I take the objective baselessness issue away from the jury for the reasons outlined in my summary judgment order. I denied this application. Tr. 4.) In denying Defendants' motion for summary judgment, however, I merely concluded that "there [were] genuine issues of fact with respect to the Defendants' objective basis for filing the [Citizen] Petition." *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2008 WL 4580016, \*5 (S.D.N.Y. Oct. 14, 2008). Furthermore, the statements in my summary judgment opinion that LWD would have me treat as adjudicated facts—such as, for example, the statement that "[n]o reasonable pharmaceutical manufacturer could have expected Aventis' Citizen Petition to succeed on the merits because Aventis ignored the law by requesting relief that was contrary to existing law and precedent" *Id.* at \*4—were made in the context of the summary judgment standard in which all inferences were to be drawn in LWD's favor as the non-moving party. That same standard applies to the instant motion for judgment as a matter of law, but this time Aventis is the non-moving party and thus is entitled to the benefit of all reasonable inferences the jury may have drawn from the trial evidence. *See Runner v. New York Stock Exchange, Inc.*, 568 F.3d 383, 386 (2d Cir. 2009) ("The standard for post-verdict judgment as a matter of law is the same as for summary judgment under Fed.R.Civ.P. 56.") (citation and internal quotation marks omitted). It is no doubt true that where "there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide [the objective baselessness prong] as a matter of law." *PRE*, 508 U.S. at 63. But "as the cases cited by [*PRE*] make clear, the relevant 'predicate facts' are not only the facts determined in the prior lawsuit, but also those facts *tending to 'prove or disprove the existence of probable cause.'*" *In re Relafen Antitrust Litig.*, 346 F.Supp. 2d 349, 361 (D. Mass. 2004) (quoting *Stewart v. Sonneborn*, 98 U.S. 187, 194 (1878) (cited in *PRE*, 508 U.S. at 62). Because I found, at the summary judgment stage, that there were genuine issues pertaining to the "predicate facts" surrounding the Citizen Petition, I declined to take the question of objective baselessness away from the jury before trial and similarly decline to do so here.

conceived of the Arava Citizen Petition, testified that he personally researched FDA precedents and “couldn’t find any prior statements specifically [referring] to a loading dose regimen in regards to [the] generic approval process,” and that this suggested to him that the FDA had not previously addressed the issue. Tr. 156.<sup>5</sup>

Second, the inconsistent approaches to the loading dose issue taken by the generic drug manufacturers who, as Aventis puts it, were “contemplating the same regulatory landscape,” is competent and, perhaps, compelling evidence of not only the unsettled nature of the issue under applicable law, regulations and FDA policy, but also the objective reasonableness of the two options proposed by Aventis in the Citizen Petition, notwithstanding that the FDA ultimately settled on a third. As Pendergast testified, “if four out of the seven companies involved didn’t know what the right answer was, it was reasonable to ask the question.” Tr. 1128-29. For example, the generic manufacturer Barr Laboratories, stated in its initial ANDA that it would provide the loading dose in “blister packs” of five 20 mg tablets of leflunomide but revised its label after the FDA requested that it either remove the reference to “5 X 20 mg” blister packs or submit *in vivo* bioequivalence studies comparing five of the 20 mg tablets to a 100 mg tablet. Tr. at 595; D-TEX. 31, 59. In contrast, a second generic manufacturer, Teva Pharmaceuticals, initially copied the Arava label verbatim to recommend a loading dose “of one 100 mg tablet per day for three days,” but subsequently attempted to revise its label to delete the words “one” and “tablet” from the loading dose reference. Tr. 513-19. Finally, a third generic manufacturer, Apotex, initially proposed labeling language that recommended that “leflunomide therapy be initiated with a loading dose *equivalent* to 100 mg per day for 3 days,” and the company’s representative testified (via deposition designation) that she believed that because Apotex did not manufacture the 100 mg tablet Apotex “needed to satisfy the loading dose itself in some other fashion.” Tr. 815, 819. In sum, the varied approaches taken by the generic manufacturers,

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<sup>5</sup> Plaintiff argues that the alleged novelty of the loading dose issue “cannot provide a reasonable objective basis for the relief requested in the [Citizen Petition] because Aventis did not even make the argument in the [Citizen Petition].” Pls. Mem. at 7. But as framed by the Supreme Court’s decision in *PRE*, the initial inquiry is whether the litigant “had probable cause to sue,” not whether the suit was ably prosecuted or whether the litigant asserted all possible arguments in support of the relief sought. The jury may have considered the fact that the Citizen Petition’s text lacked any reference to the novelty of the issue it presented as bearing on the objective reasonableness of the petition itself, but it is not the Court’s role here to weigh this evidence against the testimony that suggested FDA precedents did *not* clearly address the issue raised in the Citizen Petition.



including, in Barr's case, proposing the very same "5 X 20 mg" loading dose that the Citizen Petition speculated would be used by the generics to satisfy labeling requirements, is competent evidence upon which the jury could have based its conclusion that the Citizen Petition was not objectively baseless.

Third, Aventis introduced at trial evidence that in reviewing the ANDAs for generic leflunomide the FDA took action consistent with some of the views espoused by Aventis in the Citizen Petition itself. For example, in June 2005, after the Citizen Petition was filed, the FDA informed Barr that it had to either withdraw proposal to supply the loading dose in 5 X 20 mg "blister packs" or "submit an in-vivo bioequivalence study comparing 5 of the 20 mg tablets to a 100 mg tablet." *See* D-Ex. 59; Tr. 594-96. Of course, in so doing the FDA did not grant the specific relief sought by Aventis in the Citizen Petition and the June 10, 2005 supplement thereto, but testimony that the FDA was inclined to condition approval of a "5 X 20 mg" loading dose regimen on *in vivo* bioequivalence studies is additional evidence upon which the jury could have reasonably based its determination that the Citizen Petition was not objectively baseless. In short, LWD fails to show that at trial there was such a "complete absence of evidence" to support the jury's verdict that it is entitled to a judgment as a matter of law. *Galdieri-Ambrosini*, 136 F.3d at 289.

## 2. LWD's Evidence

Similarly, LWD fails to show that there was such an "overwhelming amount of evidence in [its] favor" that it is entitled to the relief sought by the instant motion. *Id.* LWD asserts three arguments as to why, in its view, no reasonable jury could have concluded that the Citizen Petition was not objectively baseless. These arguments are unavailing.

First, LWD argues that because FDA regulations neither require an ANDA applicant to seek approval for every dosage strength sold by the brand company nor to demonstrate bioequivalence between different strengths of its own product line it was not reasonable for Aventis to ask the FDA to require the generic manufacturers to either seek approval of a 100 mg loading dose or demonstrate "5 X 20 mg" bioequivalence. *See* Pls.' Mem. 8-10. But the Citizen Petition did not pose such questions to the FDA in the abstract; that is, the Citizen Petition did not ask whether, as a general matter, an ANDA must establish bioequivalence between different dosage strengths of the same drug. Rather, the Citizen Petition raised the specific issue of how

the FDA would ensure compliance with the requirement that a generic label match that of the referenced listed drug if the generics sought approval to reference a “5 X 20 mg” loading dose.

Second, LWD argues that because applicable law mandates that the label of a generic drug be identical to that of the brand drug, Defendants’ attempt to prevent the generic drug-makers from referencing in their label the 100 mg loading dose produced by Sanofi-Aventis was contrary to laws and precedents of which Defendants were well aware. But, if credited, not only did the testimony of Aventis’ employees and experts establish that the FDA had not previously addressed the precise issue raised by the Citizen Petition supplement, but the testimony of at least one generic manufacturer also established that FDA precedent was somewhat unsettled on the question of whether a drug maker could reference in its label a drug it did not itself make.<sup>6</sup> Ultimately, in denying the Citizen Petition, the FDA found examples of co-administered drugs to be compelling analogies to the loading dose issue create by the Arava label. But this does not mean the two situations are so factually indistinguishable that FDA precedents concerning one situation necessarily must apply to the other. In this sense, the FDA’s denial of the Citizen Petition was akin to a court’s rejection of a litigant’s attempt to distinguish a line of case law. In both cases, the tribunal’s decision spells defeat for the litigant but it does not inexorably follow that the litigant’s suit was objectively baseless. *See PRE*, 508 U.S. at 64.

Third and finally, LWD argues that Defendants knew that there was no difference from a safety or efficacy standpoint between the 10 mg and 20 mg “maintenance doses” produced by Sanofi-Aventis and those for which the generic producers sought approval. Consequently, LWD argues, there was no scientific or medical basis for Defendants to request that generic manufacturers either seek approval for a 100 mg loading dose or provide studies that confirm that five 20 mg tablets of generic leflunomide were bioequivalent to a 100 mg tablet of Arava. But LWD’s argument assumes that the only answer to the loading dose question was that upon which the FDA ultimately settled: namely, that the generic labels should reference the 100 mg loading dose manufactured by Aventis. It is true that once the labeling issue is resolved in this

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<sup>6</sup> A representative of Teva, Erickson, testified that his company had received inconsistent guidance from the FDA as to whether it could reference products it was not itself providing:

Q: In the past, FDA had sometimes asked Teva not to make reference to products Teva was not presenting, correct?

A: Yes.

Q: And other times FDA had asked Teva to leave those references in, correct?

A: Yes.

Tr. at 520.

fashion there can be no difference in efficacy between the generic and branded maintenance doses, which must themselves be bioequivalent. But when Aventis posed the question to the FDA the labeling issue had not yet been resolved in this way, and the FDA's rejection of a "5 X 20 mg" loading dose regimen in connection with the Arava NDA suggests a plausible, if ultimately unconvincing, basis for the company to argue that administering the loading dose in such fashion would raise efficacy concerns. As Aventis' director of regulatory affairs, James Parker, testified, "the concern was that if you haven't demonstrated that five twenties or tens is bioequivalent to a 100 loading dose, then how do you know that regimen is going to be safe and effective?" Tr. 351.

In sum, LWD fails to establish that the evidence at trial so overwhelmingly establishes that the Citizen Petition was objectively baseless that it is entitled to a judgment as a matter of law. For this reason, and because Aventis' evidence was sufficient for a reasonable jury to conclude that the Citizen Petition was *not* objectively baseless, LWD's motion for a judgment as a matter of law is DENIED.

#### **C. LWD's Motion for a New Trial**

As discussed above, although the trial court has considerable discretion in ruling on a motion for a new trial pursuant to Fed. R. Civ. P. 59, "[a] motion for a new trial ordinarily should not be granted unless the trial court is convinced that the jury has reached a seriously erroneous result or that the verdict is a miscarriage of justice." *Caruolo*, 226 F.3d at 54. For the reasons set forth above, I cannot conclude that the jury's conclusion was "seriously erroneous" or that the resulting verdict a "miscarriage of justice." *Id.* Consequently, LWD's motion for a new trial is DENIED.

#### **D. LWD's "Renewal" of its Motion for a Directed Verdict**

In its brief in support of the instant motion, LWD seeks to "renew" the "remainder" of its motion for a directed verdict, which was made after LWD put on its case in chief and which requests that the Court direct that a verdict be entered in LWD's favor on the Sherman Act Section 2 claim alleged in the Complaint. Aventis counters that because the instant motion was filed more than ten days after the jury was discharged, LWD's purported "renewal" of the motion is untimely as to any issue other than the objective baselessness of the Citizen Petition. *See* Fed. R. Civ. P. 50(b) (motion for judgment as a matter of law on issues not decided by a verdict must be made not later than 10 days after the jury is discharged); 6(b)(2) (court must not

extend the time to act under Rule 50(b)). In any event, because a finding that the Citizen Petition was objectively baseless is a necessary step along the way to a verdict in LWD's favor and, for the reasons set forth above, I find that there was a sufficient evidentiary basis for the jury to conclude that the Citizen Petition was *not* objectively baseless, LWD's "renewal" of the "remainder" of its motion for a directed verdict is likewise DENIED.

#### IV. CONCLUSION

For the reasons set forth above, Plaintiff LWD's motion for a judgment as a matter of law or, in the alternative, for a new trial is DENIED. The Clerk of the Court is instructed to close this and any open motions and remove them from my docket.

SO ORDERED  
August 28 2009  
New York, New York

  
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U.S.D.J.