THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438
Appellate Case No. 2012-206987

State of South Carolina ex rel. Alan Wilson in his capacity as Attorney General of the State of South Carolina,.....Respondent,

v.

Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc., ... Defendants.

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc., is.....Appellant.

Reply in Support of
Petition for Rehearing

Appellant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen") respectfully submits this reply memorandum in support of its Petitions for Rehearing of the Court's opinion in *State of South Carolina* ex rel. *Alan Wilson, in his capacity as Attorney General of the State of South Carolina v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P.*, Op. No. 27502 (S.C. Sup. Ct. filed Feb. 25, 2015) (Shearouse Adv. Sh. No. 8 at 31).

I.
INTRODUCTION

The State's Opposition to Janssen's Petition for Rehearing ("Opp'n") urges the Court to disregard the Legislature's requirement that it look to Federal Trade Commission standards for determining what constitutes an unfair or deceptive trade practice under the South Carolina Unfair Trade Practices Act ("SCUTPA"). Instead, the State would have the Court allow the Attorney General to seek penalties for conduct that violates neither the Federal Trade Commission Act nor the unfair trade practice acts of other states where the legislatures, like the South Carolina Legislature, have directed their courts to follow FTC standards. The result would contravene SCUTPA's express statutory directive and would subject businesses operating in South Carolina to liability where the Legislature has determined it should not exist. Because the Court overlooked or misapprehended the Legislature's mandate, Janssen's Petition for Rehearing is the proper vehicle "to aid the Court in deciding correctly [the] case heard by it." *Arnold v. Carolina Power & Light Co.*, 168 S.C. 163, 172, 167 S.E.2d 234, 238 (1933).

The State also asks the Court to write the regulated activity exemption out of SCUTPA where, in the State's view, FDA regulations required Janssen to use the "changes being effected" (CBE) process to move hyperprolactinemia risk information to

the Warnings section of Risperdal's FDA-approved label. The State argues that FDA regulations required Janssen to use the CBE process notwithstanding the absence of any new risk information about hyperprolactinemia, but the State's argument is wrong, for three reasons. First, it contradicts SCUTPA's plain language, which precludes liability for activities a federal or state regulator has approved. Second, it contradicts the FDA's own determination that its CBE regulation has always conditioned the availability of the CBE process on the existence of new risk information warranting a label change. Contrary to the State's argument, the FDA made clear when it amended the CBE regulation in 2009 that it intended only to "affirm" that preexisting requirement. Third, allowing the State to override the regulated activity exemption by asserting non-compliance with FDA drug labeling regulations would violate the federal Food, Drug and Cosmetic Act's prohibition against state enforcement of those regulations, *see* 21 U.S.C. § 337(a).

The State's other arguments are equally flawed. The State urges the Court to ignore the likelihood that the jury's verdict against Janssen on the labeling claim was based solely on conduct predating the limitations period, contending that Janssen waived the right to argue that the Court overlooked the implications of its statute of limitations holding because Janssen did not offer a jury verdict form at trial that anticipated this Court's ultimate ruling. But South Carolina law did not require Janssen to propose a verdict form that would be applicable only in the event it prevailed on appeal. Where, as here, the Court's opinion overlooks an issue created by its decision, the proper remedy is rehearing. The State also argues that Janssen waived the right to contest the Court's incorrect estimate of the number of Risperdal samples distributed during the limitations period because Janssen did not anticipate this Court would, first, hold that the limitations period

for the State's labeling claim began on January 24, 2004, and second, estimate the number of samples during the limitations period by relying on data from 1998-2007, when separate evidence showed the actual number. Again, South Carolina law imposes no such duty on litigants, and the proper remedy is rehearing. Finally, the State asserts that record evidence supports imposition of $72,744,000 in penalties for 36,372 Risperdal sales calls occurring between November 2003 and July 2004, arguing that "ample evidence" supports a finding that all 36,372 constituted separate SCUTPA violations. But the cited evidence belies the State's contention—confirming there is no evidence concerning what happened during any of the sales calls and that rehearing is required.

The Court should grant Janssen's Petition for Rehearing, withdraw its current opinion and set the matter for argument on the matters raised in the Petition.

II.
ARGUMENT

A. SCUTPA Requires South Carolina Courts to Be Guided By FTC Standards For Unfair or Deceptive Conduct

The State incorrectly argues that South Carolina courts are free to disregard the Legislature's statutory mandate that they "be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to § 5(a)(1) of the Federal Trade Commission Act." S.C. Code Ann. § 39-5-20(b). Like the Court's opinion, the State insists that FTC interpretations are merely "persuasive but not binding." Opp'n 5. But nothing about the Legislature's directive supports the State's view: SCUTPA instructs that the courts "***will be guided***" by FTC interpretations. S.C. Code Ann. § 39-5-20(b) (emphasis added). This Court itself has noted that the Legislature "***specifically instructs*** state courts to be guided" by FTC decisions. *Plowman v. Bagnal*, 316 S.C. 283, 287, 450 S.E.2d 36, 38 (1994) (emphasis added); *see id.* ("The federal act, however, does not create a private

right of action to recover damages. Therefore, although the controlling person doctrine has been extended to actions brought by the Attorney General, we find no authority that the Legislature intended to extend the doctrine to private actions."); *see also State ex rel. McLeod v. VIP Enters., Inc.*, 286 S.C. 501, 504-505, 335 S.E.2d 243, 244-245 (S.C. Ct. App. 1985) (using FTC decisions in attorney general enforcement action under SCUT-PA).

The State does not substantively address the decisions by courts in other states that have been guided by FTC interpretations when so directed by the legislature, and so fails to appreciate the significance of those decisions. Compare Opp'n 5 to Petition at 8-9; *see also Cal-Tech Comms., Inc. v. Los Angeles Cellular Telephone Co.*, 973 P.2d 527 (Cal. 1999) (rejecting amorphous definitions of unfairness such as those that make "vague references to 'public policy'"); *Legg v. Castruccio*, 642 A.2d 906, 917 (Md. Ct. Spec. App. 1994) (holding "FTC's test for unfair trade practices is the appropriate test for Maryland"). By following legislative guidance, those courts gave businesses operating in their states the consistency and predictability state legislatures sought to provide. SCUT-PA requires the same result, but the refusal to follow the Legislature's mandate resulted in liability that should not exist in South Carolina and would not exist in numerous other states with similar statutory provisions.[1]

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[1] *See, e.g.*, Ala. Code § 8-19-6; Conn. Gen. Stat. Ann. § 42-110b; Fla. Stat. Ann. § 501.204(b); Ga. Code Ann. § 10-1-391(b); Haw. Rev. Stat. § 480-2(b); Idaho Code Ann. § 48-604; 815 Ill. Comp. Stat. Ann. 505/2; Me. Rev. Stat. Ann. tit. 5 § 207(1); Md. Code Ann., Com. Law § 13-105; Mass. Gen. Laws Ann. ch. 93A § 2; N.H. Rev. Stat. Ann. § 358-A:13; N.M. Stat. Ann. § 57-12-4; R.I. Gen. Laws § 6-13.1-3; Tenn. Code Ann. § 47-18-115; Tex. Bus. & Com. Code Ann. § 17.46(c); Utah Code Ann. § 13-11-2; Vt. Stat. Ann. tit. 9 § 2453(b); Wash. Rev. Code Ann. § 19.86.920; W. Va. Code Ann. § 46A-6-101(1).

The State does not contest that the Court's refusal to be guided by FTC interpretations changed the outcome of this case. Its brief does not mention this Court's conclusion that the evidence "tended to support Janssen's thesis that its deceptive conduct had no effect on the community of prescribing physicians, for they knew the truth concerning the risks and side effects associated with Risperdal." Op. No. 27502 at 50. Rather than addressing the absence of proof sufficient to satisfy the FTC interpretations on which the jury should have been instructed, the State insists that the trial record supported a jury verdict under the instructions actually given. *See* Opp'n 6. But the question Janssen's Petition raises is not how the evidence might fit the instructions given; the question is whether the jury was properly instructed in the first place. The State's reliance on *Thomas v. Atl. Coast Line R.R. Co.*, 221 S.C. 462, 470, 71 S.E.2d 403, 406 (1952), a personal injury action under the Federal Employers' Liability Act, is thus misplaced. The defendant there did not challenge the trial court's jury instructions; it argued that the trial evidence was insufficient to support the jury's verdict *as instructed.* Where a trial court fails to instruct the jury on the correct liability standards for a plaintiff's claim, it commits reversible error. At a minimum, the trial court's failure to instruct the jury on the correct liability standards for deceptive and unfair practices requires a new trial. *See S.C. Dep't of Transp. v. First Carolina Corp. of S.C.,* 372 S.C. 295, 303, 641 S.E.2d 903, 907-08 (2007) (defective verdict question with prejudicial effect constitutes reversible error); *see also Sulton v. HealthSouth Corp.*, 400 S.C. 412, 419, 734 S.E.2d 641, 645 (2012) (finding verdict form's "overall structure both confusing and prejudicial").

Under the proper standard in this case, the evidence required a verdict for Janssen, not the State. Doctors' pervasive knowledge of Risperdal's risks eliminated the likelihood

of substantial injury to consumers or deception of doctors based on Risperdal's FDA-approved label or the November 2003 DDL. *See* FTC, Policy Statement on Unfairness (Dec. 17, 1980); 15 U.S.C. § 45(n) (act or practice not "unfair" unless "the act or practice causes or is likely to cause substantial injury to consumers"); FTC, Policy Statement on Deception (Oct. 14, 1983) ("practice or representation directed to a well-educated group, such as a prescription drug advertisement to doctors, would be judged in light of the knowledge and sophistication of that group"). Evidence establishing the truth of Janssen's representation that Risperdal carries a lower diabetes risk than its principal competitor Zyprexa further dispels any possibility of injury or deception. On this point, the State's own experts agreed with Janssen, *see* R. 653 (Wirshing: Zyprexa causes twice as much weight gain as Risperdal), R. 1016 (Plunkett: "Zyprexa has a greater risk of producing weight gain and diabetes"), and the State makes no effort to reconcile their opinions with its trial narrative.

Nor does the State take issue with the current view of the FDA, which now agrees with Janssen that Zyprexa carries a greater risk of weight gain and diabetes than Risperdal and requires Zyprexa to carry a stronger diabetes warning on its label. Recognizing that $101 million of the $136 million penalty in this case was based on communications that accurately represented the difference between the two medications, the State advances a waiver argument it never made before. The State argues that Janssen was required to proffer the Zyprexa label at the moment the trial court granted the State's motion *in limine* to exclude it. Opp'n 6, n.1 ("Janssen did not make an offer of proof contemporaneous with the trial court's exclusion"). The State cites no authority for this assertion, and there is none. Janssen did what South Carolina law requires by making a

proffer before the close of evidence to preserve the issue of whether the Zyprexa label was properly excluded. *See* Rule 103(a)(2), SCRE; *see also* R. 2323 (Janssen proffer).

The State takes an identical tack in a footnote addressing the 2004 DDMAC Warning Letter admitted by the trial court. The State sidesteps entirely the critical substantive point that DDMAC applies not FTC standards for unfair or deceptive conduct when reviewing communications by drug manufacturers subject to FDA regulation, but a regulatory standard judging whether communications depart from FDA's approved labeling. *See* 21 U.S.C. §§ 352(a), 321(n). Instead, the State incorrectly argues that Janssen waived its hearsay objection to the 2004 DDMAC letter because its pre-trial and trial hearsay objections were not "sufficiently specific" to preserve the issue for appellate review. Opp'n 7, n.2. But Janssen filed a pre-trial motion *in limine* to exclude the 2004 DDMAC letter as "inadmissible hearsay," R. 7747, and then re-asserted all of its "earlier objections" (including inadmissible hearsay) when the State introduced the DDMAC letter at trial. R. 531.[2]

While it ignores the evidence disproving its core trial allegation, the State defends the Court's reliance on Janssen's 2013 settlement with the federal government, arguing that the Court was "free to take judicial notice" of it. Opp'n 8 (quotation omitted). Here again, the State misses the point: the Court's reliance on the settlement for its conclusion that "the deceptive marketing that gave rise to this action also formed the basis of federal civil and criminal claims ... [that have] thus far resulted in agreed upon penalties in ex-

[2] The State also argues incorrectly that Janssen relies exclusively on Arkansas law to argue that the DDMAC letter was inadmissible hearsay. Janssen's hearsay arguments are based on well-settled South Carolina law, *see* Final Br. of Appellant at 38-40, but the Court did not consider them. Op. No. 27502 at 45-46.

cess of $2 billion" (Op. No. 27502 at 70) was incorrect. The federal settlement encompassed claims relating not only to Risperdal but to other medications, and it focused on alleged off-label marketing, not comparisons of the diabetes risk in Risperdal and Zyprexa. *See* Petition at 15. Were it appropriate for the Court to go outside the record and take judicial notice of Janssen settlements as a measure of assessing the proportionality of the $136 million penalty here, it would need to look at settlements of reasonably comparable claims. Doing so would show just how *disproportionate* the penalty here is to settlements reached with other states. *See, e.g.*, Press Release, Tex. Att'y Gen. (Aug. 30, 2012), *available at* https://www.texasattorneygeneral.gov/oagnews/release.php?id=4137 (37 state settlement at average of $4.89 million per state).

B. SCUTPA's Regulated Activity Exemption Bars the State's Labeling Claim

The Court held that SCUTPA's three-year statute of limitations barred imposition of penalties on the State's labeling claim for conduct occurring prior to January 24, 2004. But the Court overlooked or misapprehended the impact of that holding on the viability of the State's labeling claim under SCUTPA's regulated activity exemption. In particular, the Court did not evaluate whether FDA's "changes being effected" (CBE) process would have allowed Janssen to cure what the State concedes is the only alleged deficiency in Risperdal's label that remained as of the start of the applicable limitations period, namely, the placement of the risk information about hyperprolactinemia. As the Court correctly observed, FDA regulations authorize and require manufacturers to strengthen the warnings in drug labels through the CBE process "[a]s new risks and side effects are discovered." Op. No. 27502 at 35 (citing *Wyeth v. Levine*, 555 U.S. 555, 566 (2009), 21 C.F.R. §§ 201.80(e), 314.80(b), and 314.70(c)(6)(iii)(A),(C); and 73 Fed. Reg. 49605). Because the State alleged the label to be deficient during the limitations period only be-

cause information about hyperprolactinemia risk still appeared under Precautions rather than Warnings, and because the State did not contend that any new information about the risk of hyperprolactinemia emerged after the FDA first approved the hyperprolactinemia precaution in December 1993, Janssen had neither the obligation nor the ability to update the labeling of this risk through the CBE process. SCUTPA's regulated activity exemption therefore bars the State's labeling claim.

In opposition to Janssen's Petition, the State makes no contention that new hyperprolactinemia risk information emerged after the FDA approved Risperdal's label. Rather, it argues that the CBE process required Janssen to update Risperdal's label in the absence of any new information at all. Opp'n 10-11. The State bases this argument on the incorrect assertion that the requirement for new information did not exist until the FDA amended 21 C.F.R. 314.70(c)(6)(iii) in 2009 by adding language indicating that changes in labeling should reflect newly acquired information. *Id.* But the FDA has always made clear that the CBE process is only available to bring forward new risk information.[3] And the 2009 amendment made no change to this aspect of the CBE process. On the contrary, the FDA explained that the amendment was intended to "affirm that a CBE supplement is appropriate to amend the labeling for an approved product only to reflect newly acquired information." 73 Fed. Reg. 49603, 49604 (2008). This affirmation did not impose a new requirement; it simply "clarif[ied] FDA's existing policies." *Id.* at 49605; *see also id.* at

[3] *See* 47 Fed. Reg. 46622-01, 46635 (1982) ("Supplements not requiring prior FDA approval. Although most changes in labeling would require the applicant to submit a supplement and obtain FDA approval before making a change, the following changes in labeling, *which would make available important new information about the safe use of a drug product*, could be made if the applicant submits a supplement when the change is made: Changes that add or strengthen a contraindication, warning, precaution, or statement about an adverse reaction ...") (emphasis added).

49604, 49606, 49608 (same). This Court thus correctly noted that the CBE regulations required Janssen to update Risperdal's label only "[a]s new risks and side effects are discovered." Op. No. 27502 at 35.

Wyeth v. Levine, 555. U.S. 555 (2009), does not hold otherwise. In *Wyeth*, the U.S. Supreme Court accepted that the amendments to the CBE regulation affirmed those existing requirements, but found that Wyeth possessed newly acquired information triggering a duty to update its drug's labeling. 555 U.S. at 569-70. That is not the case here, where the State concedes there was no new information but contends that the label's discussion of hyperprolactinemia risk was wrongly placed based on information "known from the day the drug was developed." R. 857 (testimony of State's expert Dr. Laura Plunkett).

Nor does *Wyeth's* observation that a "manufacturer bears responsibility for ... its label at all times," 555 U.S. at 570-71, render SCUTPA's regulated activity exemption inapplicable. The State suggests that a manufacturer's "responsibil[ity] for the content of its label" means that whenever the State contends that a prescription drug label is inadequate, the label is neither authorized nor approved by FDA and imposition of liability and civil penalties is not barred by the regulated activity exemption. *See* Opp'n 11. Under the State's reasoning, the State may seek penalties for the content of prescription drug labels "from the day [a] drug [is] developed" if it disagrees with the FDA's determination of how risk information should be described or where it should be placed in the label. But this would allow the State to seek penalties in situations where federal law does not permit manufacturers to change the content of FDA-approved labels. The State's position is directly contrary to SCUTPA's regulated activity exemption, which expressly exempts

manufacturers from liability in this circumstance. *See* S.C. Code § 39-5-40(a) (no SCUTPA liability for conduct "permitted under laws administered by [a] regulatory body or officer acting under statutory authority of ... the United States").

Further, interpreting the regulated activity exemption to allow the State to penalize alleged violations of FDA labeling regulations under SCUTPA would violate federal law, *see* 21 U.S.C. 337(a) ("all . . . proceedings for the enforcement, or to restrain violations" of the federal food and drug laws "shall be by and in the name of the United States"); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001) (claims preempted where they would "exert an extraneous pull on the scheme established by Congress"); *Arizona v. United States*, 132 S. Ct. 2492, 2502 (2012) (state law claims are preempted if they "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress") (citation omitted), just as allowing State enforcement of FDA labeling regulations would be barred by statute.

Janssen preserved its regulated activity exemption arguments. At every stage of the proceedings, Janssen argued that SCUTPA's regulated activity exemption barred the State's labeling claim: summary judgment (R. 14-15); directed verdict (R. 8601); renewed directed verdict (R. 8870); JNOV (R. 9031); and on appeal (*see* Final Brief. of Appellant ("Final Br.") at 17-21). The trial court ruled against Janssen, and Janssen specifically appealed from and cited the trial court's rulings in its briefs in this Court. *See id.* at 1, 4, 19 (citing trial court's denial of JNOV motion). It is therefore unsurprising that the State never before argued that Janssen failed to preserve this argument. It is equally unsurprising that the newly-minted waiver argument presented in the State's rehearing opposition is factually and legally unsupported.

The State first cites a series of cases for the idea that "where an issue is not argued within the body of the brief [on appeal] but is only a short conclusory statement, it is abandoned." Opp'n 9 (citation omitted). The body of Janssen's brief argued at length that the regulated activity exemption bars the State's labeling claim, *see* Final Br. at 17-21, and the State's contrary suggestion is frivolous. The State then asserts that Janssen did not "identify any specific trial court rulings claimed to constitute error." (Opp'n 9), but this is simply incorrect: Janssen's brief specifically identified the trial court's order denying JNOV as the place where the trial court wrongly rejected Janssen's arguments concerning the regulated activity exemption. *See* Final Br. at 1; *see also id.* at 3 (directing Court to the record where, at the close of the State's case and again at the close of all the evidence, the trial court denied Janssen's directed verdict motions, citing "(R. p. 1332, line 19-p. 1367, line 18; p. 1722, line 16-p. 1725, line 20; p. 2348, line 2-p. 2365, line 1; p. 2365, line 15-p. 2371, line 25.)").

The State is therefore reduced to arguing that waiver exists because, despite Janssen's identification of the error appealed from in the Statement of Issues and Statement of the Case, which specifically identified the trial court's erroneous ruling on regulated activity exemption error and cited the place in the record where the ruling was made, "the substantive portion of Janssen's Final Brief discussing the regulated activity exemption reveals no instance where Janssen pointed to a specific ruling made in error by the trial court regarding the statute" (Opp'n 9). But nothing in South Carolina law requires an appellant identifying specific rulings in its Statement of Issues and Statement of the Case, on pain of waiver, to repeat those citations in the argument section of the same brief. To preserve an issue on appeal, the brief need only: (1) identify the specific trial

court rulings claimed to constitute error, SCACR 208(b)(4) (*see* Final Br. at 1); (2) provide record references to the relevant rulings, *id.* (*see* Final Br. at 3-4); and (3) specifically argue the issue in the body of the brief, *Ellie, Inc. v. Miccichi*, 358 S.C. 78, 99, 594 S.E.2d 485, 496 (S.C. Ct. App. 2000) (claim must be "argued within the body of the brief") (*see* Final Br. at 17-21). The State's waiver argument is unsupported and rehearing on this issue should be granted.

C. The Court's Statute of Limitations Holding Requires at Minimum a New Trial on the Labeling Claim

The State's argument that Janssen waived its argument that the Statute of limitations requires at minimum a new trial is equally unsupported. Janssen's argument arises only because the Court's statute of limitations ruling has now made clear that the failure to include an earlier diabetes warning—which was the overwhelming focus of the State's case at trial—could not support the verdict on the State's labeling claim. As explained in the Petition, Janssen added the diabetes warning (and the CVAE warning) in 2003, *before* what this Court has now determined to be the beginning of the limitations period. The likelihood that the jury based its verdict on the State's time-barred claim that Janssen should have added the diabetes warning earlier than 2003 requires a new trial.

The State argues that Janssen waived this argument by not submitting a verdict form calling for the jury to make separate liability determinations for each risk on which the State based it claims. But this would have required Janssen to anticipate that this Court would reverse the trial court's refusal to apply the statute of limitations. The State cites no South Carolina authority requiring litigants to submit alternative verdict forms anticipating that a trial court's decision as to the proper scope of the claims in issue would be rejected. Such a submission would be an exercise in futility. A litigant pre-

serves the issue by preserving and appealing the underlying error, in this case the trial court's erroneous refusal to apply the statute of limitations. The State is incorrect that Janssen waived anything by not submitting alternative verdict forms anticipating reversal.

The State alternatively contends that the impact of the statute of limitations decision does not require a new trial due to the "continuing nature of the accrual of labeling violations." Opp'n 12. The State offers no explanation for how the "continuing nature of the accrual" would salvage its claim that Janssen inadequately warned of risks that were updated in the Risperdal label *before* January 24, 2004. The Court specifically held that "labeling violations occurring prior to January 24, 2004 were therefore barred by the statute of limitations." Op. No. 27502 at 59. The only labeling violation alleged to have occurred after January 24, 2004, was the placement of hyperprolactinemia risk information in the Precautions section of the label rather than the Warnings section. That alleged inadequacy is the only potential basis for an adverse jury verdict, yet the trial court's verdict form allowed the jury to base its verdict on alleged violations that ceased before the limitations cutoff date.

The State is also incorrect that the Court has already decided this issue. The Court's opinion contains no discussion of the problem created by application of the limitations bar to the State's claim on the diabetes warning. The very purpose of rehearing is to give the Court an opportunity to consider issues, like this one, that its opinion overlooks or misapprehends. Rule 221(a), SCACR. Rehearing should therefore be granted on this issue.

D. <u>The Court Miscalculated the Penalty on the Labeling Claim</u>

The State does not dispute that record evidence of the actual number of sample boxes distributed during the limitations period shows that number to be 228,447, or

117,007 less than the Court estimated by calculating and applying a daily average from the number of boxes distributed during the longer 1994-April 2007 time period. But rather than joining Janssen's request for the Court to correct this undisputed error, the State advances a specious waiver argument. Alternatively, the State argues, without having requested rehearing on the point, that the Court should revisit its determination that the "$300 penalty per sample box [is] excessive," Op. No. 27502 at 67, and reverse its decision remitting the penalty on the labeling claim to $100 per sample box. Opp'n 13 n.4.

Both arguments should be rejected. The State argues that Janssen did not preserve its argument that the Court incorrectly estimated the number of sample boxes distributed during the limitations period because "Janssen never [before] argued that the number of sample boxes was improperly counted." Opp'n 14. It is astonishing that the State would even make this argument. The sample box count was not an issue at trial because the trial court ruled that Janssen was subject to penalties for the entire 1994-April 2007 period. Janssen provided a count of the total number of sample boxes distributed during that period, and there was no dispute about its accuracy. As the State knows, the sample box count has become an issue on rehearing because this Court's statute of limitations ruling determined, for the first time, that the proper time period in issue begins not in 1994 but on January 24, 2004, and the Court's *sua sponte* attempt to recalculate the correct box count overlooked record evidence showing the Court's calculation to be 50% too high. The State's waiver argument is meritless, and rehearing to correct the error is proper.

The State's alternative argument that the Court should reconsider its remittitur of the excessive $300 per sample box penalty is equally meritless. The request is procedurally improper because the State did not move for rehearing on the point, and the deadline

for doing so has long passed. Rule 221(a), SCACR. And the request is in any event substantively unsupported. The State gives no reason grounded in the record—indeed, no reason at all—why the Court should reconsider its determination that the per box penalty assessed by the trial court was excessive. For both of these reasons, the State's request should be rejected.

E. The Court Overlooked the Absence of Evidence Supporting the Penalties on the Letter Claim for Sales Calls

On the DDL claim, the State asserts that "ample evidence" supports the proposition that Janssen "published the letters on 36,372 sales calls." Opp'n 14. But the State's citations to evidence supposedly supporting this assertion only confirm the merit of Janssen's contention that the Court's opinion overlooked the *absence* of any such supporting evidence. Rehearing is therefore proper.

The State's record citations provide no support for the proposition that Janssen published the DDL on 36,372 sales calls.[4] The citations reflect only the April 2004 Warning Letter, testimony and e-mails about the Warning Letter and the November 2003 DDL, and an isolated page from a training document. Opp'n 14 (citing R. 778-789, 1155-1156, 3107-3111, 3164, 3247-3248, 3792-3794.). None shows that Janssen violated SCUTPA 36,372 times by publishing the DDL at every sales call. None remotely supports a staggering incremental penalty of $72 million—on top of $28 million for the mailing itself—on the basis of anything that occurred on a sales call.

[4] It bears reminding that on the DDL claim, the jury found that Janssen made false and misleading statements only in the DDL. R. 3030-31. The jury did not find, and was not asked to find, that Janssen sales representatives separately made false and misleading statements in sales calls.

The State's case citations are equally inapposite. In *State ex rel. McLeod v. C & L Corp.*, 280 S.C. 519, 313 S.E. 2d 334 (S.C. Ct. App. 1984), abrogated on other grounds by *Murphy v. Owens-Corning Fiberglas Corp.*, 346 S.C. 37, 550 S.E.2d 589 (S.C. Ct. App. 2001), the Court of Appeals affirmed the penalty of $55,000 for eleven violations of SCUTPA by sales representatives. Among the key supporting facts were: (1) "sales of the lots went forward in plain violation of the law" despite county officials having advised the defendant "on more than one occasion" that the conduct at issue was in violation of an ordinance; and (2) the defendant's sales agents brazenly "told prospective buyers whatever they felt the buyers wished to hear in order to conclude a sale." 280 S.C. at 524, 313 S.E. 2d at 337. There is no comparable evidence here. The State introduced no evidence of misrepresentations at *any* sales call. And the record is undisputed that Janssen did not disseminate the DDL after receiving the FDA's Warning Letter. *See* SR.2 (April 28, 2004 letter from Janssen advising FDA that "the November 10, 2003 letter is no longer being disseminated"). The Court nevertheless upheld tens of millions of dollars in additional penalties for this time period. Rehearing on the $72 million sales call penalty should be granted.

III.
CONCLUSION

For the foregoing reasons, rehearing is warranted and the Court should withdraw its current opinion and, after oral argument on the matters raised here, and issue a new opinion consistent with the relief requested by Janssen in its appellate briefing and Petition for Rehearing.

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Columbia, South Carolina
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THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

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APR 20 2015
S.C. Supreme Court

Case No. 2007-CP-42-1438
Appellate Case No. 2012-206987

State of South Carolina ex rel. Alan Wilson in his capacity as Attorney General of the State of South Carolina,.....Respondent,

v.

Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc., ... Defendants.

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc., is.....Appellant.

Proof of Service

I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for Appellant, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) herein below specified by mailing a copy of the same by United States Mail, postage prepaid, to the following address(es):

Pleadings: **Reply in Support of Petition for Rehearing**

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April 20, 2015