

THE STATE OF SOUTH CAROLINA  
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY  
Court of Common Pleas

**RECEIVED**

APR 23 2013

Roger L. Couch, Circuit Court Judge

**S.C. Supreme Court**

Case No. 2007-CP-42-1438

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 MOTION FOR LEAVE TO  
SUPPLEMENT THE RECORD ON APPEAL

In its Return to the Motion for Leave to Supplement the Record on Appeal, the State notes that a copy of the April 28, 2004 letter introduced as P-436 is already in the Record on Appeal as a different exhibit (P-1731) and as an attachment to a motion. P-436, however, should still be made part of the record as that is the specific exhibit to which the State's regulatory expert, Dr. Plunkett, was referred during her testimony about actions Janssen took after it received the Warning Letter, including Janssen's decision not to use certain promotional materials. R. p. 904, lines 1-14; *see also* R. p. 1046, line 14-p. 1047, line 3.

The State also argues that supplementation should not be allowed because Janssen's argument that the November 10, 2003 letter was not distributed on each of the 36,372 sales calls "has not been preserved for appellate review." Ret. at 2. It says that "in the proceedings below and in its appellate briefs, the Appellant has never challenged the relevant timeframe for the Dear Doctor Letter or offered any evidence that it stopped disseminating the letter before it issued a correction letter in July 2004." *Id.* In truth, the issue was properly preserved and was briefed in both the trial court and this Court.

In its Post-Penalty Hearing Brief, Janssen explained that the November 2003 to July 2004 "sales calls include multiple visits to the same South Carolina physicians." R. p. 9431. And, Janssen wrote: "As the State has acknowledged, the letter was not 'published' on repeat visits to a physician. Rather, the use of the November 2003 'Dear Healthcare Provider' letter on sales calls was a 'one and done' event." *Id.* (citations omitted). In its memorandum of law in support of its Motion to Alter or Amend the Judgment and/or for a New Trial, Janssen renewed the argument: "Equally important, when imposing a penalty for every sales call, the Court assumed that the November 2003 mailing was shown at every sales call from November 2003 until July 2004. This assumption, however, is belied by the undisputed evidence of record. As the State provided no evidence whatsoever as to the actual number of 'one and done' sales calls where the November 2003 mailing actually was published, the award based on sales calls in connection with the November 2003 mailing is speculative and must be amended and vacated." R. p. 9469 (internal citations omitted); *see also* R. pp. 9526-27 (Janssen's Reply in Supp. of Its Mot. to Alter or Amend the J. and/or for a New Trial).

Janssen made the same argument in each of its appellate briefs. In its Final Brief, Janssen wrote: “Additionally, the trial court erroneously assumed that the November 2003 letter was published on every sales call made from November 10, 2003 until July 21, 2004. The undisputed record evidence, however, is that the use of the letter on sales calls was a ‘one and done’ event – i.e., the letter was shown to a physician only once, no matter how many sales calls were made on that physician between November 10, 2003 and July 21, 2004.” Final Br. at 51 (citations omitted). Janssen also noted, as it did below, that the 36,372 sales calls included many *repeat* visits to healthcare professionals: “Between November 10, 2003 and July 21, 2004, Janssen sales representatives made Risperdal-related sales calls on 3,149 different South Carolina medical professionals.” *Id.* n.16 (citation omitted). In its Final Reply Brief, Janssen made the argument yet again: “There was no factual or record basis, however, for the conclusion that the November 10, 2003 letter was ‘published’ on every sales call between November 10, 2003 and July 21, 2004. To the contrary, the undisputed testimony at trial was that the distribution of the November 10, 2003 letter by sales representatives was a ‘one and done’ event; the letter was not distributed on repeat visits to a physician. The State does not address this testimony in its brief, and does not even attempt to defend the trial court’s conclusion that the letter was ‘published’ 36,372 times.” Final Reply Br. at 31 (internal citations omitted).

Just as in its briefs in both the trial court and this Court, the State, in its Return, does not point to record evidence supporting its assertion that the November 10, 2003 letter was distributed to healthcare professionals on every one of the sales calls between November 10, 2003 and July 21, 2004. Although the State says that it “presented call

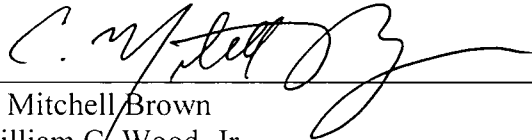
note evidence showing dissemination of the Dear Doctor Letter,” Ret. at 3, that “call note evidence” was nothing more than evidence that sales representatives delivered the letter on their *first* sales call. None of the evidence identified by the State supports the assertion that the letter was delivered or shown on *all* of the 36,372 sales calls for which Janssen was penalized, or that it was delivered or shown *after receipt of the Warning Letter*.

The evidence is all to the contrary. According to P-436, the November 10, 2003 letter was “no longer being disseminated” when Janssen first responded to the Warning Letter, on April 28, 2004. Other evidence introduced at trial established that the letter would be distributed only “one time” – only on the first sales call to each physician after November 10, 2003. Mot., n.\*.

Respectfully submitted,

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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) hereinbelow specified by mailing a copy of the same by United States mail, postage prepaid, to the following address(es):

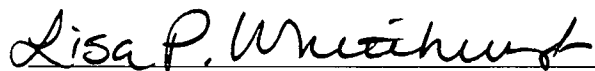
Pleadings: **Reply in Support of Motion for Leave to Supplement the Record on Appeal**

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A handwritten signature in black ink that reads "Lisa P. Whitehurst". The signature is written in a cursive style and is positioned above a horizontal line.

Lisa P. Whitehurst  
Administrative Assistant

April 23, 2013