

STATE OF SOUTH CAROLINA)
)
 COUNTY OF SPARTANBURG)
)
 Ex. Rel. Alan Wilson in his capacity)
 as Attorney General of the State of)
 South Carolina,)
)
 Plaintiff)
)
 v.)
)
 Ortho-McNeil-Janssen)
 Pharmaceuticals, Inc., f/k/a Janssen)
 Pharmaceutica, Inc., And/or Janssen,)
 L.P., And Johnson & Johnson, Inc.,)
 Defendants.)
 _____)

IN THE COURT OF COMMON PLEAS

C.A.No.: 07-CP-42-1438

PENALTY ORDER

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The Jury has determined that Ortho-McNeil-Janssen Pharmaceutica, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen L.P. (hereinafter referred to as simply Janssen) have violated the South Carolina Unfair Trade Practices Act (SCUTPA) by willfully engaging in unfair or deceptive practices in the manner in which they conducted their trade or commerce and in the marketing and labeling of Risperdal in the State of South Carolina. The question now before this Court is: What are the appropriate penalties to be levied against those companies for their actions?

The statutes involved in this action are:

South Carolina Code Section 39-5-20: Unfair methods of competition and unfair or deceptive acts or practices unlawful; application of interpretations of Federal act.

(a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

South Carolina Code Section 39-5-110: Civil penalties for willful violation or violations of injunction.

(a) If a court finds that any person is willfully using or has willfully used a method, act or practice declared unlawful by Section 39-5-20, the Attorney General, upon petition to the court, may recover on behalf of the State a civil penalty of not exceeding five thousand dollars per violation.

(c) For the purposes of this section, a willful violation occurs when the party committing the violation knew or should have known that his conduct was a violation of Section 39-5-20.

The South Carolina Unfair Trade Practices Act provides that when it has been determined that willful violations of the Act have occurred, the State may recover a civil penalty that may not exceed five thousand dollars per violation. Id. It is within the judge's discretion to determine the total amount of the penalty, so long as it does not exceed the statutory limitation. There can be no error of law in imposing a fine within the limits authorized by the Act. Within those limits, the amount of the fine is a matter within the judge's discretion. State ex rel. McLeod v. C & L Corp., Inc., 280 S.C. 519, 313 S.E.2d 334, (S.C. App. 1984).

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During the trial of this matter, certain information and testimony presented to this Court was placed on a list of contested evidence. I have reviewed the proffer of this evidence and make the following rulings:

- Evidence of the Louisiana legal action was excluded and not considered by this Court.
- Evidence concerning the Topomax criminal settlement was excluded and not considered by this Court
- Testimony of Dr. William Wecker, I find, did not meet the tests of reliability for expert witnesses established by our courts, and therefore, the testimony should not be entered into the record. Further, I find some of the conclusions reached by him are not supportable. This conclusion is based on other scientifically reliable evidence already

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entered into the record of this case. Therefore, even if his testimony had been admissible, I would have found his testimony to be totally unreliable, and it would have been given no weight by this Court.

Both the Plaintiff and the Defendants agree that the Court, when exercising its discretion in determining the measure of penalties to be assessed, should consider factors similar to those articulated in United States v. Reader's Digest Ass'n, 662 F.2d 955, 967 (3rd Cir. 1981).

- The good faith or bad faith of the Defendant;
- The injury to the public;
- The desire to eliminate the benefits derived by a violation;
- The necessity of vindicating the authority of the agency involved; and;
- The Defendant's ability to pay.

I will begin my discussion of these factors by pointing out the Credo of the Defendants' parent company which expresses the standard of conduct to which the Defendants purport to hold themselves.

The Credo of Johnson & Johnson, as published on its website and referred to in its annual reports begins, "We believe our first responsibility is to the doctor, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality."

This Court is aware that the Defendants are for-profit corporations which are in the business of developing new and better medicines for a whole host of human ailments. In many ways, the competitive environment in which they operate is the engine that drives the research and development of new and evermore effective medicines from which all of mankind benefits.

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In this case in particular, it is acknowledged by all concerned that Risperdal is an excellent drug for the treatment of mental illnesses. It has been a quality of life saver for millions of patients. It allows those who are treated with it to escape many of the effects of their mental illnesses and live a more open and productive life.

Also, this Court is not so naive so as to not understand that these companies are in this business to generate a profit for their shareholders and investors. Pharmaceutical companies, such as the Defendants, must generate returns on their investments in order to assure their survival and continued vitality. However, as Janssen's parent company points out in its own credo, the first obligation which it owes is to the persons who prescribe, use and consume their products. It is the collision of these competing interests that has created the issues that we consider here. Additionally, it is the loss of the Company's focus, upon the primary objective of its credo, which brings us to this discussion.

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A. The good faith or bad faith of the Defendant:

In discussing this factor, I am mindful of the position taken by the Defendants throughout this trial. That position is that what Defendants said about Risperdal was true or was later proven to be true. Therefore, they could not have been unfair or deceptive in their actions.

The statutes provide for punishment for "unfair" or "deceptive" methods, acts or practices in the conduct of trade or commerce. S.C. Code Ann. § 39-5-20 & 39-5-110. This Court has consistently ruled that those issues concerning fairness or deceptiveness must be weighed using the information that was available and existed when the statements were made. The actions must be weighed in light of the intentions that existed when they were made. In considering the issues presented by this defense, I came upon an article by Joel Marks, in a

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magazine entitled *Philosophy Now*, issue 27;

(http://philosophynow.org/issue27/The_Truth_About_Lying) in which he discussed the nuances of deception, lies and the truth. I found the following excerpts from that article to be very helpful in my analysis of this case.

“Lying has nothing to do with truth and falsity. It is simply not true that the definition of lying is stating a falsehood. Lying seems instead to be a relation between a belief and an intention. If you utter what you believe to be false (regardless of whether it is false) for the purpose of inducing another to believe that it is true, **you have lied.**” *Id.*

“But deceiving is a broader category than lying.” Mark goes on to explain, “This is important to recognize because it implies that any comparable act of deception, lie or not, is just as wrong.” *Id.* It has become clear to me that the act of deception involves engaging in disingenuous actions by which one attempts to manipulate the intended audience into acting upon the deception in a certain desired fashion. Deceiving statements may involve issuing statements which are true but which are issued for the purpose of manipulation. In this Case, the manipulation was to get prescribers and patients to make treatment decisions based upon misleading or incomplete data or concealing data which would have impacted those decisions. Cases in our State have indicated that even true statements may serve as the basis for an action under the SCUTPA if they have the capacity or tendency to deceive. *Wright v. Craft*, 372 S.C. 1, 372 S.E. 2d 486 (2006 S.C. App.).

Here, in this case, the Jury has found the methods, actions and practices of the Defendants to be unfair and deceptive.

i. **Label**

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I will begin this discussion of the good or bad faith of the Defendant as it relates to the labeling of the drug Risperdal. The drug was approved by the FDA in 1994. The FDA approved the initial label for the drug and all subsequent labels. The law allowed the Defendant to unilaterally strengthen Risperdal's warning section of the label as soon as there was reasonable evidence of an association of a serious hazard with the drug. There was no requirement that this should be delayed until a causal relationship was proved. 21 C.F.R. §201.57(e) (2006).

Both Dr. Plunkett and Wirshing testified that the early evidence concerning the adverse events involving this drug, as well as its chemical makeup, should have given Janssen reason to strengthen the warnings in its label concerning diabetes, hyperglycemia and weight gain. During the early years (1994-1998) of marketing, evidence of adverse events began to appear indicating that there may be an increased risk of hyperprolactinemia, diabetes, hyperglycemia and weight gain. Also, during this time there was growing evidence of cardio vascular problems associated with the use of the drug in the elderly. The Defendants conducted and participated in studies specifically designed to shed light on the possible side effects of the drug. Specifically, these studies included RIS USA-113 & 275 and ERI. In the case of ERI and Study 113, the results indicated a substantial relationship between the use of this drug and weight gain and diabetes. Rather than making the information gathered in these studies available to the medical, regulatory and scientific communities, the Defendants chose to use pretenses to keep them hidden. It is apparent to this Court that this information was not disclosed because it did not fit the marketing department's vision for the promotion and marketing of the drug, and ultimately the content of the label. The top line results of Study 113 became available to the Defendants in September of 1999. It is clear to this Court, particularly after the top line results of study 113 became available, that the Company systematically set about in a concerted effort to conceal that

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information and to manipulate the information available to the public for the purpose of protecting or improving its market share. They characterized the results of the study as “flawed” and hid the results until 2009. When the results were released, they were not termed as a “flawed study,” but were characterized as one that had some problems with its methodology, which problems did not affect the overall results. These reports were only released after the patent on Risperdal had expired.

From 1999 to 2003, the Defendants continued to take actions to avoid the disclosure of information which was in its possession and failed to take action to strengthen the warnings in its label. In 2003, the FDA required a class change in the label, which resulted in the issuance of the Dear Doctor Letter discussed below. Throughout this period of time, the Plaintiffs showed during the trial that up through 2007 there was never a warning for weight gain or hyperprolactinmia. The Plaintiffs showed by ample evidence that labeling issues followed the distribution of this drug throughout the period of its distribution. This Court is keenly aware that the issues involving the label vary throughout the period of time from the drugs launch in 1994 through 2007. I have made a conscious effort to average the penalty awarded for the labeling issue and have not awarded a penalty that is close to the maximum penalty available for those violations.

I do note that courts in this State have consistently upheld that medical patients have the right to make informed decisions concerning their treatment. It is elementary that the right to make informed treatment decisions would extend to, and include, the right of a patient to have made available to them, full and complete disclosures of the critical information in the package insert, in the label published on the Physician’s Desk Reference or on the company’s website. This need for full and complete disclosure of all available information is especially critical when

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the majority of the patients treated with this drug suffer from conditions which diminish their ability to make such critical decisions to the point that they may rely more heavily on the advice of their physicians or guardians. Because of the diminished mental capacity of the patients being treated, this Court finds the actions of the Defendants, upon this audience, to be detestable.

Based on the reasons stated above, and the considerable volume of evidence presented during the trial, this Court finds that the Defendants exhibited a callous disregard to a patient's right to have all possible information available, and in the hands of their physician, before deciding to use or continue to use the drug. Further, I find that the Defendants allowed the "profit at all costs" mentality to cloud the vision of their own responsibilities as acknowledged in their credo.

Therefore, I find the bad faith of the Defendant to be considerable during the period September 1999 until 2007 as it relates to labeling questions. There is absolutely no doubt in my mind that the desire to protect market share overshadowed the good judgment of those in control at Janssen.

I note that the evidence supplied to this Court concerning the number of Risperdal prescriptions filled in South Carolina, during the applicable time periods, involved those which were filled under State sponsored programs, and it did not contain reliable information as to the total number of prescriptions filled in the State from all sources. Therefore, it would require too much speculation on the part of the Court to attempt to tie the penalties to the total number of prescriptions filled in the State.

ii. Dear Doctor Letter



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The Dear Doctor Letter, issued in November of 2003, was clearly an effort by the Company to manipulate the message about Risperdal. Specifically, the letter was sent during the same time period that the FDA was requiring a class label change, which required that all atypical anti-psychotics include in their labels a warning concerning the dangers of these drugs and their increased risk of diabetes. A careful review of the e-mail threads, both before and after the publication of that letter (which are replete in the record), indicate a conscious effort by the company to "spin" the message, driven by marketing considerations, about Risperdal.

The manner in which the letter was written indicates to this Court evidence of a clever effort to deliver a deceptive message to prescribing physicians. Specifically, I am referring to the use of eight studies listed, by themselves, on the final page of the letter, some of which do not support the premise of the letter itself. Examples of the clever deception included in the letter include the effort to contrast itself with Zyprexa. This was done after the FDA had directed the Defendants not to do so, and there was no mention of ERI or Study 113. This is true particularly in light of the information which the Defendants were concealing from public disclosure or consideration. The continued reference by the Defendants to Study 113 as a "failed study" during the ten years that it was concealed; then, after the patent for Risperdal was lost in 2009, to release this as a properly conducted study, illustrated the level of deception to which the Defendants stooped. I note no mention, to the public or the FDA, of the Study 113 during the years that it was concealed. The effort to hide these studies (113,275 & ERI) even continued despite a request from the FDA, in May 2000, for the Defendants to make available all information that they had in possession concerning hyperglycemia and diabetes risks to Risperdal users. The Defendants submitted voluminous responses to that request, but did not disclose the top line results of study 113 or ERI; apparently, because those results were

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unfavorable to their marketing message. While this is not a “fraud on the FDA” case, this concealment shows that the Company employed procedures and methods which almost guarantee repetition and further endangerment of the public.

I could not agree more with the Janssen executive, Scott Reines, who characterized the Dear Doctor Letter in an unfavorable light and railed against those in the Company who wrote, approved and distributed the Letter. He said in his e-mail of April 28, 2004, referring to the Dear Doctor Letter, “But no competent person would have let it go out.” He then went on to say, “It’s really a black mark for J&J.”

This Court finds that the actions of the Company in regards to this Letter exhibited extreme bad faith. It was a conscious effort to deceive and was unfair in the manner in which it was composed and delivered. Additionally, it was done in such a fashion so as to directly influence the prescribing decisions of doctors. Who knows how many of those mothers, fathers and patients referenced in their Credo, to be owed their best, were influenced into making incorrect decisions concerning their drug therapy?

An example of the subtle manner in which the Letter was used to deliver only a “certain” message to physicians is evident in the fact that the November Letter was placed in the folios of the detail persons who visited the doctors, so that it could be shown and emphasized to each doctor on every visit. However, later, when the FDA required that a corrective letter be mailed, the corrective letter was not placed in the detail person’s folios to be shown to the doctors on every visit.

B. Injury to the public

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It is noted that the issues involved in this Case do not require direct proof of any specific injury to the public. Rather, the SCUTPA requires a showing that the unfair or deceptive act is capable of repetition, which shows that the violation would have an effect on the public's interest. I quote from my charge on the subject:

“IN ADDITION, THE PLAINTIFF MUST PROVE THAT THE UNFAIR TRADE PRACTICE OR ACT AFFECTED PERSONS OTHER THAN THE PARTIES TO THE TRANSACTION IN WHICH THE ACT COMPLAINED OF OCCURRED. EXPRESSED DIFFERENTLY, THE PLAINTIFF MUST PROVE THAT THE UNFAIR TRADE PRACTICE OR ACT HAS AN IMPACT ON THE PUBLIC'S INTEREST. THE PLAINTIFF MUST PROVE THE ADVERSE EFFECT OR IMPACT ON THE PUBLIC INTEREST BY SPECIFIC FACTS.

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AN ACTION HAS AN IMPACT ON THE PUBLIC INTEREST IF IT IS SHOWN BY THE PREPONDERANCE OF THE EVIDENCE THAT THE UNFAIR TRADE PRACTICE OR ACT IS CAPABLE OF REPETITION.¹

SHOWING THAT AN ACT IS CAPABLE OF REPETITION CAN BE SHOWN IN SEVERAL WAYS, BUT IT CAN BE SHOWN IN TWO SPECIFIC WAYS:

- (1) BY SHOWING THE SAME KIND OF ACTION HAS OCCURRED IN THE PAST, THUS MAKING IT LIKELY THEY WILL CONTINUE TO OCCUR ABSENT DETERRENCE; OR
 - (2) THE COMPANY'S PROCEDURES CREATE A POTENTIAL FOR REPETITION.
- THESE ARE WAYS TO SHOW THE POTENTIAL FOR REPETITION, BUT NOT THE

¹ Burbach v. Investors Mgmt. Corp., 326 S.C. 492, 484 S.E.2d 119 (Ct. App. 1997).

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ONLY WAYS, THAT THE POTENTIAL FOR REPETITION MAY BE SHOWN. IT MAY BE SHOWN BY OTHER MEANS.”

My charge went on to say, “Since these two ways are not the only means for showing the potential for repetition or public impact, each case must be evaluated on its own merits to determine what a plaintiff must show to satisfy the potential for the repetition/public impact prong of the SCUTPA. Daisy Outdoor Advertising, Inc. v. Abbott, 322 S.C. 489, 497, 473 S.E.2d 47, 51 (1996). Nevertheless, a plaintiff has proven an adverse effect on public interests if he proves, by the preponderance of the evidence, and by specific facts, the potential for repetition exists”. Id. at 493, 473 S.E.2d at 49.

In this Case, the Jury found that the actions of the Defendants did affect the public interest and were capable of repetition. Such a finding was necessary in order for the Jury to reach the verdict that they did. In considering the principles that are at issue in this Case, this Court finds that these issues involved are of critical importance to the public, which use and consume prescription drugs in general. Additionally, it is the belief of this Court that this group constitutes a large percentage of the total population. The public’s interest in requiring that drug manufacturers fully disclose all information available to them concerning the effects of their drugs in a fair and non-deceptive manner is of paramount importance to the health and safety of those using the drugs. Only when full honest and fair disclosure is done, can doctors and patients make fully informed decisions concerning possible side effects that may be suffered as a result of the drug therapy to be used by the patient. Therefore, the public interest affected by the actions of these Defendants is enormous.

C. Desire to eliminate the benefits derived from a violation

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Quite frankly, in this Case, it would be virtually impossible to accurately determine the degree to which the Defendants benefitted from their actions. It is clear to this Court, that if the aim of these actions by the Defendants was to protect the market share of Risperdal; then it succeeded, in that the share did not suffer as a result of the ever expanding warnings. The purpose of this Court is to penalize the actions of the Defendants and is not intended to award damages based upon any measure of damages or ill-gotten gain. It is clear from the information stated below that the profits from this drug, to the Defendants, were enormous, and the penalties set by this Court represent a relatively small percentage of the overall profits generated by the companies. In determining this percentage, I note the relatively small percentage of the Defendant's business conducted in South Carolina in comparison to the overall worldwide scope of that business.

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D. The necessity of vindicating the authority of the agency involved

The SCUTPA was enacted by the legislature as a consumer protection measure. The Attorney General has been granted broad powers to enforce that Act, particularly when a willful violation of the Act has occurred. Here, the Jury determined that a willful violation of the Act occurred. In doing so, the Jury has determined that the public interest was affected by those wrongful actions and that those actions by the Defendants were willful and intentional.

It is clear, that when a company comes into this State and conducts its business in such an unfair manner, so as to deceive the public in the conduct of its trade or commerce, that there is a need for a central authority to challenge those actions and protect the public's interest. This protection of the public's interest should be done in such a manner so as to deter future violations of the Act, and to protect the public's interest to the extent necessary. The Legislature has

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clearly placed this burden and duty upon the Attorney General and it is the responsibility of that office to vindicate the public's interest in this Case.

E. The Defendant's ability to pay

In setting a penalty, it is necessary to consider what level of penalty is necessary to make the wrongdoer take notice of the problem and correct its future actions. Obviously, the level of the penalty will vary depending upon the financial ability of the wrongdoer to pay. This Court is aware that this is not a case involving the award of punitive damages, where the amount of punitive damages must bear some relationship to the amount of actual damages suffered. In those cases, the financial ability of the defendant alone will not support an award that far exceeds the actual damages suffered.

In this Case, however, the issue is the level of penalties that is appropriate to punish the wrong. I am limited by the statute as to the amount of penalties that can be assessed per occurrence. Where the number of wrongs is extremely large and the profits derived enormous, the penalties must have a direct relationship to those numbers. Where deterrence and punishment is the aim, the financial ability of the wrongdoer is clearly a factor to be considered

The Defendant's, which were found to have been responsible for the unfair or deceptive acts or practices in the conduct of the defendant's trade or business, are wholly owned subsidiaries of the Johnson & Johnson Corporation. Janssen, itself, reports no separate financial information of which this Court was made aware. Therefore, the publically disclosed financial information, which was made available to this Court, is in the form of the annual report to shareholders of the parent corporation. It does not contain any separate financial information for the Defendants. It does contain information that was specific to Risperdal and some information

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specific to pharmaceutical operations. Profits for the Corporation and net cash and cash equivalents are reported for Johnson & Johnson and not its individual subsidiaries. The information considered by this Court in making a determination of the ability of the Defendants to pay includes:

Annual Sales of Risperdal worldwide per annual reports of Johnson & Johnson, Inc.:

- 1994 \$ 0.172 Billion
- 1995 \$ 0.343 Billion
- 1996 \$ 0.502 Billion
- 1998 \$ 0.588 Billion
- 1999 \$ 0.892 Billion
- 2000 \$ 1.083 Billion
- 2001 \$ 1.845 Billion
- 2002 \$ 2.146 Billion
- 2003 \$ 2.512 Billion
- 2004 3.05 Billion
- 2005 3.552 Billion
- 2006 4.180 Billion
- 2007* 4.697 Billion
- 2008 1.309 Billion
- 2009 1.425 Billion
- 2010 1.50 Billion

Total for the period.....29.796 Billion.

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*Patent for Risperdal expired in 2007.

Testimony at trial indicated that the profit margin for sales of Risperdal was 97% or \$28.90 Billion for the period of 1994-2010.

Earnings: The 2010 Annual report for Johnson & Johnson, the parent corporation, indicates worldwide sales of \$61.6 billion which generated a free cash flow of \$14 billion. Johnson and Johnson, Inc. Annual Report 2010, p. 1.

The Pharmaceutical Division reported sales and operating profits of \$7.086 billion for the year 2010. Form 10-K for 2010, Filed with the Securities and Exchange Commission

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Number of Violations:

A. Label

It is clear that the label was published with each sample distributed to the public. Clearly, there were other occasions when the label would have been published, such as through the Physician's Desk Reference or on the Defendants website; however, to find violations from those sources would require this Court to speculate as to the number of violations. Each distributed sample clearly contains a copy of the label and would be the most likely source of information for patients who are considering entering into an ongoing therapy with the drug. For purposes of this discussion, the Court considers each publication of the Risperdal label (package insert), by way of sample, to prescribers in the State of South Carolina until April 23, 2007, to be a separate violation.

- Sample Boxes Distributed509,499

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This court finds the appropriate average penalty to be \$300.00 per violation:
\$152,849,700.00.

B. Dear Doctor Letter:


- Letters mailed7,184
 - Sales calls where letter published.....36,372
- Total publications of letter.....43,556.

The Court finds the appropriate penalty to be \$4,000.00 per violation: \$174,224,000.00.

Based on the record of the Case, and the above, it is hereby, **ORDERED**, that the Defendants shall pay, to the State of South Carolina, through its Attorney General, Alan Wilson, penalties in the sum of Three hundred twenty-seven million, seventy-three thousand, seven hundred and 00/100 dollars. (\$327,073,700.00)

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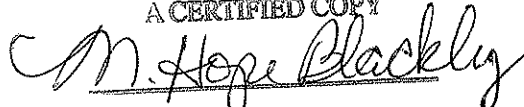
IT IS SO ORDERED.




(SEAL)
Roger L. Couch, Circuit Court Judge

Spartanburg, S.C.

June 3, 2011

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BY: 
DATED: 6/3/11