2008-CA-01659 SCTE

CERTIFICATE OF INTERESTED PERSONS

Pursuant to Mississippi Rule of Appellate Procedure 28(a)(1), the undersigned counsel of record certifies that Bayer Corporation, Bayer Pharmaceuticals Corporation, and Bayer Healthcare, LLC[†] (collectively, "Bayer" or "Bayer Defendants") have an interest in the outcome of this case. In its appeal, the State of Mississippi challenges the Chancery Court's dismissal with prejudice of all of the State's claims against each of the Bayer Defendants. These representations are made in order that the justices of the Supreme Court may evaluate possible disqualification or recusal.

[†] In the caption of its brief, the State misidentified Appellee Bayer Healthcare, LLC as "Bayer Healthcare Corporation."

TABLE OF CONTENTS

TABLE OF CASES

Page(s)

CASES

OTHER AUTHORITIES

STATEMENT OF THE ISSUE

Whether, under Rule 9(b) of the Mississippi Rules of Civil Procedure, the Chancery Court correctly dismissed an action by the State against Bayer for alleged fraudulent reporting of "average wholesale prices," where: (1) a 2001 Settlement Agreement between the State and Bayer expressly released the State's claims as to certain Bayer products for the time period prior to the settlement; (2) once the Settlement Agreement was signed, Bayer was required to report "true pricing information" in the form of "average sales prices" to the State for all of Bayer's products, and the State made no allegation that Bayer failed to comply with this requirement; and (3) the State made no specific allegation of wrongdoing as to any non-released Bayer product for the pre-settlement time period.

STATEMENT OF THE CASE

I. COURSE OF PROCEEDINGS

The State filed its initial complaint on October 20, 2005, alleging that over eighty defendant pharmaceutical manufacturers, including Bayer, committed fraud and unfair trade practices by inflating the "average wholesale price" ("AWP") of their products. AWPs are benchmark prices published by third-party reporting services. The Mississippi Medicaid Program uses AWPs in some of its formulas for calculating reimbursement to pharmacies and physicians for Medicaid-covered drugs. The State alleged that, by inflating the AWPs of their products, the defendants caused Mississippi's Medicaid program to overpay pharmacies and providers for the drugs they dispensed to Medicaid recipients.

Bayer moved to dismiss the State's initial complaint based on its 2001 settlement agreement with the State (the "Settlement Agreement") and Rule 9(b) of the Mississippi Rules of Civil Procedure. On July 28, 2006, the Court-appointed Special Masters recommended in their

Report and Recommendation No. 2 ("R&R 2") that, as to pre-settlement claims involving the drugs covered by the release, the complaint should be dismissed with prejudice. (S.R.E. 5 at 001799.)[1] Likewise, the Special Masters recommended that post-settlement claims involving any Bayer product should be dismissed with prejudice since, during that time period, Bayer had reported the "average sales prices" ("ASPs") requested by the State as a measure of "true pricing" for all Bayer products. (S.R.E. 5 at 01800.) Finally, as to pre-settlement claims involving drugs other than those covered by the release, the Special Masters recommended that such claims be dismissed without prejudice based on Rule 9(b). "[A]bsent any specific allegation of wrongdoing as to [non-released drugs]," the Special Masters concluded, "we find no basis for the State's claims relating to the pre-settlement period to proceed at this point." (S.R.E. 5 at 001800.) R&R 2 continued: "If at a later date the State has evidence the comprehensive investigation previously made against Bayer that resulted in the settlement should have included other drugs for the time prior to 2001, the State may bring a new action at that time." *Id.* The Chancery Court adopted the Special Masters' R&R 2 by order dated October 10, 2006. (S.R.E. 3 at 001557; S.R.E. 8 at 001318 & Ex. C.)

Without filing any objection to R&R 2, the State filed its First Amended Complaint ("FAC") on October 5, 2006. Again, Bayer moved to dismiss based on the 2001 Settlement Agreement and Rule 9(b). On April 2, 2008, the Special Masters recommended that the Court grant Bayer's motion, this time with prejudice. In their Report and Recommendation No. 35 ("R&R 35"), the Special Masters noted that, with respect to the FAC's allegations with respect to "Bayer products other than the Qui Tam Drug [*i.e.*, the drugs released under the 2001 Settlement Agreement]," the State "failed ... to make any allegation or at the hearing to offer any

[1] References to the State's Record Excerpts will use the abbreviation "S.R.E." followed by the relevant tab and page numbers. References to Bayer's Record Excerpts will follow the same pattern but use the abbreviation "B.R.E."

evidence that the comprehensive investigation previously made against Bayer should have included these drugs." (S.R.E. 3 at 001558.) The State filed objections to R&R 35, and the Chancery Court heard oral argument on June 30, 2008. By order of August 29, 2008, the Chancery Court adopted R&R 35 "in its entirety as the order of the Court." (S.R.E. 2 at 002273.) At no time did the State seek leave to amend its FAC as to Bayer. The State filed notice of its appeal on September 30, 2008.

II. STATEMENT OF FACTS

A. The 2001 Settlement Agreement

Federal-State Investigation. Of the dozens of defendants in the case below, Bayer is unique in having entered into a prior settlement agreement with the State dating back to 2001.[2] The 2001 settlement was preceded by a joint federal and state investigation of Bayer's price reporting practices. Like this case, the investigation concerned allegations that Bayer had fraudulently inflated the AWPs of its products. Ultimately, the 2001 Settlement Agreement focused on six drugs (identified as the "Qui Tam Drugs").[3] *See* Settlement Agreement, Part II(C). (B.R.E. 1 at 000485–86.) Significantly, the State decided at the time of the 2001 settlement *not* to pursue any claims against Bayer with respect to any drugs other than the six Qui Tam Drugs.

Release. In consideration of Bayer's payment to the State of $48,608.09, the State agreed to a broad release. Specifically, the State released Bayer and its "subsidiaries and affiliates" from:

---

[2] The Chancery Court and Special Masters properly considered the impact of the 2001 Settlement Agreement on the State's subsequent claims against Bayer. *See* Part III(B), below.

[3] The six Qui Tam Drugs are Koate®, Kogenate®, Konyne®-80, Gamimune® N 5%, Gamimune® N 10%, and Thrombate® III. *See* Settlement Agreement, Part II(C). (B.R.E. 1 at 000485–88.)

> *any* civil or administrative monetary claim, action, suit or proceeding the State has or may have relating to claims submitted to the State Medicaid Program for the Covered Conduct.

See Settlement Agreement, Part III(2 & 3) (emphasis added). (B.R.E. 1 at 00490–91.) Further, the release "fully discharge[d] Bayer from any obligation to pay restitution, damages, and/or any fine or penalty to the State for the Covered Conduct." *Id.* In addition to Bayer Corporation, the Settlement Agreement releases "Bayer, its parent corporation(s), subsidiaries and affiliates." *Id.*, Part III(3). (B.R.E. 1 at 000491.)[4]

ASP Reporting. The 2001 Settlement Agreement required Bayer to comply with detailed price reporting obligations. Specifically, Bayer agreed to report the "average sales price" ("ASP") for *every* drug that it sells in the United States to Mississippi for a period of five years. *Id.*, Part III(8). (B.R.E. 1 at 000493–97.) The ASP reporting requirement applied not only to the six Qui Tam Drugs, but to *all* Bayer products. The stated purpose of the ASP reporting requirement was to provide the State "with **true pricing information** that accurately reflects the prices at which actual purchasers buy the drug and biological products sold by Bayer." *Id.* (emphasis added).

In accordance with the terms of the Settlement Agreement, Bayer faithfully reported ASPs to the State on a quarterly basis for a period of five years beginning with a report covering the second quarter of 2001.[5] *Id.*, Part III(8)(a). (B.R.E. 1 at 000493–94.) Each ASP report contained a statement of the methodology used in calculating the ASPs. As required, Bayer kept and made available to the State all of the workpapers that supported its ASP calculations. *Id.*, Part III(8)(g). (B.R.E. 1 at 000497.) The State never questioned the accuracy

---

[4] The Agreement thus covers Defendants Bayer Pharmaceuticals and Bayer Healthcare to the same extent as Bayer Corporation. *See* FAC ¶ 23 (identifying Bayer Pharmaceuticals and Bayer Healthcare as affiliates of Bayer Corp). (S.R.E. 7 at 001057.)

[5] Bayer continues voluntarily to provide quarterly ASP reports to the State.

of Bayer's ASPs or asked to review Bayer's workpapers, and it makes no allegation in this case of any flaws or shortcomings in Bayer's ASP reports.

B. The Initial Complaint and Motion to Dismiss

On October 20, 2005, over four years after entering into the Settlement Agreement, the State filed a complaint alleging that over eighty pharmaceutical manufacturers (including Bayer) committed Medicaid fraud, common law fraud, mail fraud, and other violations of Mississippi law, by improperly inflating the AWPs of their products. The conduct at issue in the 2001 Settlement Agreement and the conduct for which the State sought to recover in its initial complaint were identical. *See* Compl. ¶¶ 172, 178, 181, 184, 187, 189, 193, 197. (B.R.E. 2 at 000051–56.) The complaint made no attempt to plead around the settlement. Indeed, the only allegations specific to Bayer in the original complaint comprise two paragraphs. The first described the terms of the Settlement Agreement, while the second acknowledged that the State had received its portion of the settlement amount but indicated that the State believed "it ha[d] not been compensated fully for its losses from the wrongful conduct" underlying the settlement. *Id.* ¶¶ 157, 163. (B.R.E. 2 at 000047, 000049.)

Bayer filed a motion to dismiss the State's initial complaint based on the 2001 Settlement Agreement and the State's failure to plead fraud with the particularity required by Rule 9(b) of the Mississippi Rules of Civil Procedure. (B.R.E. 1 at 000465.) On July 28, 2006, the Special Masters issued R&R 2. In R&R 2, the Special Masters recommended that the Court (1) dismiss with prejudice pre-settlement claims involving the six Bayer drugs released under the Settlement Agreement; (2) dismiss with prejudice claims regarding any Bayer drug for the post-settlement time period in light of Bayer's quarterly ASP reports to the State; and (3) dismiss without prejudice claims involving non-released drugs for the pre-settlement time period. (S.R.E. 5 at 001800.) As to the latter category of claims, the Special Masters concluded that

"absent any specific allegation of wrongdoing as to non-Qui Tam Drugs, we find no basis for the State's claims relating to the pre-settlement time period to proceed at this point." *Id.* (citing *Harold's Auto Parts, Inc. v. Mangialardi*, 889 So. 2d 493, 495 (Miss. 2004)). But the Special Masters left the door open to the State for a corrected pleading: "If at a later date the State has evidence the comprehensive investigation previously made against Bayer that resulted in the settlement should have included other drugs for the time prior to 2001, the State may bring a new action at that time." *Id.*

On October 10, 2006, the Chancery Court adopted R&R 2 in its entirety without objection by the State. (S.R.E. 3 at 001557; S.R.E. 8 at 001318 & Ex. C.)

C. The First Amended Complaint

Rather than object to R&R 2, the State filed its First Amended Complaint ("FAC") on October 5, 2006. With respect to Bayer, the only difference between the initial Complaint and the FAC was the addition of an exhibit identifying specific Bayer drugs allegedly at issue and the inclusion of two new paragraphs. The first new paragraph merely applied to Bayer the same set of allegations that the FAC made against every defendant:

> Plaintiff's claims against Baxter [sic] pertain to the pharmaceuticals listed in the attached Exhibit A .... Baxter [sic] caused false Average Wholesale Prices for each of the listed pharmaceuticals to enter the stream of commerce knowing that they would be used by Mississippi as the principal means of estimating the acquisition cost of pharmaceuticals dispensed to beneficiaries of the Medicaid program, causing Mississippi to overpay Baxter's [sic] customers in violation of state law .... The difference between the Average Wholesale Price this defendant caused to enter or to be maintained in the stream of commerce and the true Average Wholesale Price in the marketplace at the time of each claim for reimbursement for each of its products listed in Exhibit A was at least 17%.

FAC ¶ 23 (S.R.E. 7 at 001058–59.) The second new paragraph represented the State's effort to come to grips with the 2001 Settlement Agreement, as required under R&R 2. There the State alleged as follows:

> Plaintiff acknowledges that the Special Masters have recommended the dismissal without prejudice of Bayer. Nevertheless, these allegations, which are limited to pharmaceutical products other than the *qui tam* drugs referred to in the 2001 settlement agreement and release, are different from the allegations which formed the basis of that settlement agreement and release to the extent that this lawsuit attacks the industry practice of introducing a [sic] an Average Wholesale Price into the stream of commerce which is at least 17% above the average wholesale price of its drugs to the retail classes of trade, knowing that it would be relied upon by Mississippi in establishing Estimated Acquisition Cost. To the extent that the investigation which led to the 2001 settlement and release focused upon products and practices where spread and spread marketing techniques were more extreme or flagrant, and in view of the allegations of this complaint, that these pharmaceuticals bore an AWP which was inflated by a minimum of 17%, Plaintiff reasserts her claims against Bayer as permitted by the Report and Recommendation of the Special Masters, No. 2.

Id. Other than the attempt made in this paragraph, the FAC nowhere sets forth "any specific allegation of wrongdoing as to non-Qui Tam Drugs," as required under R&R 2. (S.R.E. 5 at 001800.) Neither did it allege any basis for concluding that the "comprehensive investigation previously made against Bayer that resulted in the settlement should have included other drugs for the time prior to 2001." *Id.*

As with the initial complaint, Bayer moved to dismiss the FAC based on the Settlement Agreement and Rule 9(b). Following briefing, the Special Masters heard argument on March 12, 2008.[6]

[6] Following the filing of the FAC, the case was removed to federal court. Bayer's motion to dismiss the FAC was filed following remand.

pricing information" defeats any basis for the State to claim that it received false, fraudulent, or deceptive information from Bayer. In any event, the State waived any post-settlement claims when it failed to object to the Special Masters' recommendation in R&R 2 that these claims be dismissed with prejudice and again when it failed to raise any objection to the dismissal of post-settlement claims in its opening brief on appeal.

3. **Pre-Settlement Claims for Non-Qui Tam Drugs.** The State failed to plead the circumstances surrounding the State's fraud claims against Bayer concerning non-Qui Tam Drugs with the degree of particularity required by Rule 9(b). The FAC makes no real attempt to meet the Chancery Court's directive to explain why the "comprehensive investigation" that preceded the 2001 Settlement Agreement did not identify the claims the State now raises. Instead, the State impermissibly relies on the same one-size-fits-all allegations of an "industry practice" of AWP inflation that the FAC makes against every defendant. Such cookie-cutter pleading demonstrates that the State made no serious attempt to investigate the facts underlying its claims and is instead engaged in a strike suit or fishing expedition for unknown wrongs — tactics that Rule 9(b) was specifically adopted to prevent.

Neither of the State's arguments for overturning the Chancery Court's decision has any merit. First, the State is incorrect in concluding that the Chancery Court applied a heightened pleading standard to Bayer because the Court upheld the sufficiency of the FAC's identical allegations as to other defendants. Rule 9(b), of its own force, requires a court to take into account the particular known circumstances of the defendant. Second, the State is wrong in faulting the Chancery Court for considering the Settlement Agreement on Bayer's motion to dismiss. Where, as here, a complaint repeatedly refers to a document and uses it to frame its claims, the document is properly considered on a motion to dismiss. In any event, even if the

A. The State's Receipt of Average Sale Prices For All Bayer Products Throughout the Post-Settlement Period Bars the State's Claims

The State fails to mention in its opening brief that the Special Masters recommended in R&R 2 that all post-settlement claims against Bayer in the State's initial complaint be dismissed *with prejudice*. The Special Masters explained that, by its own terms, the 2001 Settlement Agreement required Bayer to give the State quarterly ASP reports in order to provide the State with "true pricing information that accurately reflects the prices at which purchasers buy the drug and biological products sold by Bayer." *See* Settlement Agreement, Part III(8). (B.R.E. 1 at 00493.) Consequently, the Special Masters explained, "[a]bsent any allegation that Bayer has not complied with this requirement," all post-settlement claims should be "dismissed with prejudice." R&R 2 at 4–5. (S.R.E. 5 at 001800–01).

For its part, the State has never contended that it failed to receive Bayer's ASP reports or that the reports did not contain the bargained-for "true pricing information" as to Bayer's products. Indeed, under the terms of the 2001 Settlement Agreement, the State was allowed to inspect the "workpapers and supporting documentation" relating to average sales price calculations as a way to verify the truth of its ASP reports. *See* Settlement Agreement, Part III(8)(g). (B.R.E. 1 at 000497.) The State has not sought to do so. Instead, it filed the same cookie-cutter allegations against Bayer that it filed against other, non-settling defendants.

In these circumstances, the State simply cannot prove its post-settlement claims. For example, to properly plead a claim for common law fraud, the State must allege:

> (1) a representation, (2) its falsity, (3) its materiality, (4) the speaker's knowledge of its falsity or ignorance of its truth, (5) his intent that it should be acted upon by the person and in the manner reasonably contemplated, (6) the hearer's ignorance of its falsity, (7) reliance upon its truth, (8) a right to rely on the representation, and (9) an injury proximately caused by the reliance on the representation.

Taylor v. Southern Farm Bureau Cas. Co., 954 So. 2d 1045, 1049 (Miss. Ct. App. 2007) (citing *Levens v. Campbell*, 733 So. 2d 753, 761–62 (Miss. 1999)).

The FAC fails to properly plead any of these elements. While ASP and AWP may have been calculated differently, neither can be considered "false" given that the State knew that ASP "accurately reflects the prices at which actual purchasers buy the drug and biological products sold by Bayer." *See* Settlement Agreement, Part III(8). (B.R.E. 1 at 000493–97.) Thus, Bayer could not knowingly have made a false or misleading representation as to a material fact concerning its AWPs. Nor could the State reasonably rely on any alleged misrepresentation by Bayer regarding what AWPs were. As a matter of law, "where a plaintiff has an opportunity to investigate the statements upon which she allegedly relied, the plaintiff cannot be said to have reasonably relied on those statements," and cannot prevail on a claim for common law fraud. *Taylor* 954 So. 2d at 1050 (citing *Martin v. Winfield*, 455 So. 2d 762, 765–66 (Miss. 1984)). In this case, Bayer's ASP reporting provided the State with more than ample information and opportunity to investigate Bayer's AWPs. Thus, as to Bayer, the complaint does not properly allege a common law fraud claim.

For the same reasons, the State has failed properly to allege its statutory claims. *See* FAC ¶¶ 49–51. (S.R.E. 7 at 001082–84.) To plead a violation of Mississippi's unfair or deceptive trade practices act, the State must allege that Bayer's AWPs were "deceptive" or "unfair." Miss. Code Ann. § 75-24-5(1). But the State cannot have been deceived by the allegedly false AWPs it received, nor can publication of those AWPs be considered unfair, given that the State had before it Bayer's ASP reports at the same time it received the allegedly false AWPs. Likewise, to prevail on its claims under the Mississippi Medicaid Fraud Control Act, the State must prove that Bayer caused the submission of claims that Bayer knew were "false,

fictitious or fraudulent," which the State contends Bayer did because it knew that its allegedly inflated AWPs caused the State to overpay for Bayer's products. *See id.* §§ 43-13-207, -211, -213; *see also* FAC ¶ 50. (S.R.E. 7 at 001082–83.) However, Bayer cannot be faulted for the State's decision to reimburse its Medicaid providers for Bayer drugs based on AWP when the State has at its disposal Bayer's ASPs, which "accurately reflect[] the prices at which purchasers buy the drug and biological products sold by Bayer." *See* Settlement Agreement, Part III(8). (B.R.E. 1 at 00493.)[8]

For these reasons, the State's post-settlement claims fail as a matter of law, and the Chancery Court correctly dismissed them with prejudice pursuant to Rule 12(b)(6). At the very least, by failing to address the significance of Bayer's ASP reporting in its FAC, the State has failed to plead the circumstances of its post-settlement fraud claims with the particularity required by Rule 9(b).

B. The State Has Voluntarily Abandoned or Waived Any Post-Settlement Claims

Even if the State's post-settlement claims were theoretically viable, the State has voluntarily abandoned or waived them as to *all* Bayer products. As noted above, the State has expressly abandoned any claims as to the Qui Tam Drugs without any limit as to time period. But the State omits from its opening brief the fact that the Special Masters recommended in R&R 2 that post-settlement claims as to *all Bayer products* be dismissed *with prejudice*. The State never objected to R&R 2. By failing to raise the issue of post-settlement claims below, the State has failed to preserve the issue for appeal. *See Germany v. Denbury Onshore, LLC*, 984 So. 2d 270, 275–76 (Miss. 2008); *Levens*, 733 So. 2d at 763.

[8] The State was entirely free to use ASP or any other pricing metric it found appropriate. States are given wide discretion to reimburse pharmacies and providers in a manner the State finds appropriate. 42 U.S.C. § 1396a(a)(30)(A); 42 C.F.R. 447.331(b) (2006).

Furthermore, by failing to address the issue in its opening brief, the State has waived any objection it might have to the Chancery Court's dismissal with prejudice of all claims against Bayer for the post-settlement period. *Bishop v. State*, 882 So. 2d 135, 154 (Miss. 2004) ("'We will not consider issues raised for the first time in an appellant's reply brief.'") (quoting *United States v. Anderson*, 5 F.3d 795 (5th Cir. 1993)); *Sanders v. State*, 678 So. 2d 663, 669–70 (Miss. 1996); *Dock v. State*, 802 So. 2d 1051, 1053 (Miss. 2001); *Moffett v. State*, 938 So. 2d 321, 330 (Miss. Ct. App. 2006).

III. THE FIRST AMENDED COMPLAINT ALLEGES NO VIABLE CLAIMS AS TO THE PRE-SETTLEMENT PERIOD FOR NON-QUI TAM DRUGS

A. The First Amended Complaint's Pre-Settlement Claims Concerning Non-Qui Tam Drugs Fail To Satisfy the Particularity Requirements of Rule 9(b)

For most claims, Mississippi courts require only notice pleading. M.R.C.P. 8. However, claims of fraud are held to a higher standard. Rule 9(b) of the Mississippi Rules of Civil Procedure requires that, "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." "Fraud will not be inferred or presumed and may not be charged in general terms." *Brabham v. Brabham*, 483 So. 2d 341, 342 (Miss. 1986).[9] Here, the State failed to plead with particularity any viable claim relating to the non-Qui Tam Drugs — *i.e.*, those drugs which the state and federal governments declined to proceed against at the time of the 2001 Settlement Agreement.

Rule 9(b) requires a plaintiff to allege with particularity "matters such as the time, place, and contents of the false representations, in addition to the identity of the person who

---

[9] Mississippi Rule of Civil Procedure 9(b) is identical to and construed consistently with Federal Rule of Civil Procedure 9(b). *Hignite v. Am. Gen. Life & Acc. Ins. Co.*, 142 F. Supp. 2d 785, 789 (N.D. Miss. 2001) (explaining that Mississippi Rule 9(b) and Federal Rule 9(b) are "phrased identically"); *Nichols v. Tubb*, 609 So. 2d 377, 383 (Miss. 1992) ("It is well known that our Mississippi Rules of Civil Procedure were copied from the Federal Rules of Civil Procedure, and we construe ours as the Federal courts construe the federal rules.").

made them and what he obtained as a result." M.R.C.P. 9(b) cmt.; *see Howard v. Estate of Harper ex rel. Harper*, 947 So. 2d 854, 861 (Miss. 2006). "At a minimum," as the Fifth Circuit explained, "Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud." *United States ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 328 (5th Cir. 2003) (internal quotation marks omitted). Significantly, the purpose of this particularity requirement is not simply to give the defendant notice of the claims against it, but also to ensure that the plaintiff has "conduct[ed] a precomplaint investigation in sufficient depth to assure that the charge of fraud is responsible and supported, rather than defamatory or extortionate." *Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999); *see Fidelity Nat'l Title Ins. Co. v. Intercounty Nat'l Title Ins. Co.*, 412 F.3d 745, 748–49 (7th Cir. 2005) (explaining that Rule 9(b) "forces the plaintiff to conduct a careful pretrial investigation and thus operates as a screen against spurious fraud claims"); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007) (stating that "notice is not the only reason for the requirement of Rule 9(b)").[10]

There is no one-size-fits-all set of allegations that will satisfy Rule 9(b) in every case. Rather, the degree of particularity required by Rule 9(b) "necessarily differs with the facts of each case." *Tuchman v. DSC Commc'ns Corp.*, 14 F.3d 1061, 1067–68 (5th Cir. 1994); *see also Guidry v. Bank of LaPlace*, 954 F.2d 278, 288 (5th Cir. 1993). In particular, courts look to the "relationship between the parties," including whether the plaintiff has previously had an opportunity to discover the facts underlying its fraud claims. *BJC Health Sys. v. Columbia Cas.*

[10] For other cases explaining the purposes behind Rule 9(b)'s particularity requirement in fraud cases beyond notice to the defendant, see *United States ex rel. Snapp Inc. v. Ford Motor Co.*, 532 F.3d 496, 504 (6th Cir. 2008); *Robert N. Clemens Trust v. Morgan Stanley DW, Inc.*, 485 F.3d 840, 847 (6th Cir. 2007); *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 549 (8th Cir. 1997); *Tuchman v. DSC Communications Corp.*, 14 F.3d 1061, 1067–68 (5th Cir. 1994); and *Billard v. Rockwell Int'l Corp.*, 683 F.2d 51, 57 (2d Cir. 1982).

Co., 478 F.3d 908, 917 (8th Cir. 2007); *see Billard v. Rockwell Int'l Corp.*, 683 F.3d 51, 57 (2d Cir. 1982); *M&I Heat Transfer Prods., Ltd. v. Willke*, 131 F. Supp. 2d 256, 261 (D. Mass. 2001).

In light of the unique circumstances of the case as to Bayer, the State's FAC falls far short of the requirements of Rule 9(b). First, the FAC never explains why the 2001 Settlement Agreement failed to deal with any price reporting problems relating to non-Qui Tam Drugs. As the Special Masters observed, the 2001 settlement was preceded by a "comprehensive" joint federal and state investigation. R&R 2 at 4 (citing Settlement Agreement, Part II(H)). (S.R.E. 5 at 001800.) Moreover, in the Settlement Agreement, the State expressly acknowledges Bayer's "cooperation in the State's investigation of drug pricing practices and agrees to communicate the nature and extent of this cooperation to other parties." *See* Settlement Agreement, Part III(12). (B.R.E. 1 at 000499.)

Presumably, had problems emerged with the price reporting for non-Qui Tam drugs, they would have been included in the settlement. But the FAC never comes to grips with this fact. Put simply, the State found no way to plead around the investigation and 2001 settlement. In the words of the Special Masters, the State had failed "to make any allegation [in the FAC] or at the hearing to offer any evidence that the comprehensive investigation previously made against Bayer should have included these [non-Qui Tam] drugs." R&R 35 at 3. (S.R.E. 3 at 001558.)

To be sure, the State pays lip service to the Special Masters' admonition to plead around the 2001 settlement and preceding investigation, but the FAC's allegations concerning these matters simply reinforce the conclusion that the State has not alleged fraud with adequate particularity against Bayer. For example, the State makes the bald assertion that the allegations in the FAC are different from those covered by the Settlement Agreement "to the extent that this

lawsuit attacks the industry practice of introducing a [sic] an Average Wholesale Price into the stream of commerce which is at least 17% above the average wholesale price of its drugs to the retail class of trade, knowing that it would be relied upon by Mississippi in establishing Estimated Acquisition Cost." FAC ¶ 23. (S.R.E. 7 at 001058.) Other than its assertion of an "industry practice" of AWP inflation, the State alleges no facts that would suggest that Bayer has engaged in such conduct.

Such undifferentiated allegations of an "industry practice," without any claim of conspiracy and no particulars that would distinguish Bayer from the non-settling defendants, do not comport with Rule 9(b). The State contends that Bayer, like all other defendants, "caused" AWPs for its products upon which the State relied to exceed a "true" AWP by more than 17%. Even if true as to the Qui Tam Drugs, Bayer has already settled and been released for these claims. As to the non-Qui Tam Drugs, the State offers no specifics to undergird the application of its industry-wide theory to Bayer. Indeed, the one-size-fits-all nature of the allegations is evident from the State's failure even to change the defendant's name from "Baxter" to "Bayer" in the allegations purportedly relating specifically to Bayer. But alleging fraud based on a so-called "industry practice" is just the kind of "lumping together" of defendants that that Rule 9(b) means to prevent. *Ambrosia Coal & Constr. Co. v. Pages Morales*, 482 F.3d 1309, 1317 (11th Cir. 2007); *see Estate of Harper*, 947 So. 2d at 861 (dismissing with prejudice a complaint that alleged fraud against "the collective defendants (not each defendant specifically).").

The State's only other attempt to address the Settlement Agreement in its allegations as to Bayer consists of the following passage: "To the extent that the investigation which lead [sic] to the AWP Settlement and release focused on products and practices where spread and spread marketing techniques were more extreme or flagrant, and in view of the

allegations of this complaint, that these pharmaceuticals bore an AWP which was inflated by a minimum of 17%, Plaintiff reasserts her claims against Bayer as permitted by the Report and Recommendation of the Special Masters, No. 2." FAC ¶ 23. (S.R.E. 7 at 001058–59.) It is difficult to understand what this passage means. If the State is suggesting that the claims raised in the FAC were not sufficiently meritorious to be addressed in the Settlement Agreement, this suggestion only underscores why the State must plead with sufficient particularity its claims against Bayer in the FAC in light of the investigation leading up to the 2001 AWP Settlement. Moreover, the allegation that Bayer's AWPs were inflated by more than 17% simply reiterates the State's allegations of an industry-wide practice.

In an attempt to justify its undifferentiated industry-wide pleading, the State alleges that defendants (again without any specific allegations as to Bayer) have prevented the State from discovering the "true average wholesale prices of [their] drugs" and therefore the State cannot allege its fraud claims "with greater particularity." FAC ¶ 5. (S.R.E. 7 at 001043–44.) Putting aside whether these factual allegations, if true, entitle the State to lump together an entire industry under one boilerplate allegation of fraud, they are simply untrue as to Bayer. Far from concealing its pricing information from the State, Bayer cooperated with the pricing investigation leading up to the 2001 Settlement (a fact that the State expressly acknowledged) and has provided ASP information to the Mississippi Medicaid program and kept it continually updated since the second quarter of 2001.[11]

The FAC simply does not link up the known facts regarding Bayer's settlement with the State's theory of an ongoing, industry-wide price reporting fraud. Indeed, the State's

[11] In addition, Mississippi has the right to inspect "all workpapers and supporting documentation relating to the average sale prices of [Bayer's] drugs." *See* Settlement Agreement, Part III(8)(g). (B.R.E. 1 at 000493.) The State has never requested to do so.

failure to allege the "what" and "how" of its fraud claims against Bayer demonstrates that the State's attorneys have not conducted an adequate investigation of the facts available to the State to ensure that the FAC's fraud claims against Bayer are "responsible and supported." *Ackerman*, 172 F.3d at 469. For example, the FAC does not allege any circumstances that would suggest that the State's attorneys made any inquiry concerning the investigation leading up to the 2001 Settlement Agreement to ascertain whether the claims in the FAC had been considered at that time or had any support in fact. Nor does the FAC allege any circumstances that would suggest that the State's counsel reviewed Bayer's ASPs in determining whether the State had viable claims against Bayer.[12]

In sum, the glaring omissions in the State's allegations as to Bayer demonstrate that the State made no serious attempt to investigate the facts "in sufficient depth to assure that the charge of fraud [as to Bayer] is responsible and supported."[13] *Ackerman*, 172 F.3d at 469. Rather, the holes in the FAC's allegations as to Bayer suggest that the State has used this industry-wide litigation as a strike suit or fishing expedition for unknown wrongs by Bayer — a tactic that Rule 9(b) was specifically adopted to prevent. *See, e.g., Tuchman*, 14 F.3d at 1067;

---

[12] The State's failure to conduct an adequate investigation is also apparent from the fact that, among the products the State identifies as at issue in the FAC, the State identified Qui Tam Drugs it expressly carved out of its claims (Gamimune, S.R.E. 7 at 01104), as well as Bayer products that were not marketed until well after the 2001 Settlement and thus outside the time period at issue in the FAC (Cipro XR, *id.* at 001103).

[13] The State makes a weak attempt to fill this gap in its opening brief by asserting that before filing its FAC it "went back and combed through its research of the Non-Qui Tam Drugs and reasserted claims against specific Bayer products with fraudulent AWPs." State's Br. at 5. However, even this tardy attempt to allege a "responsible and supported" predicate for the State's claims fails to provide any of the particulars required by Rule 9(b). Moreover, counsel's argument on appeal fails for the more fundamental reason that even these allegations are not contained in the FAC. *See In re Estate of Hudson*, 962 So. 2d at 93 (disregarding appellate argument concerning "evidence of fraud and the lack thereof," because the court must "look only to the particularity of the allegation in the pleadings"); *Shushany*, 992 F.2d at 523 (dismissing plaintiff's claim under Rule 9(b) despite the fact that counsel for plaintiff "demonstrated a greater knowledge of the factual basis for the fraud claims than appears in the complaint," noting that plaintiff made "no effort ... to amend [the complaint] to incorporate these details, in spite of the district court's prior admonition and [defendant's] repeated Rule 9(b) objections").

Fidelity Nat'l, 412 F.3d at 748–49; *United States ex rel. Snapp Inc. v. Ford Motor Co.*, 532 F.3d 496, 504 (6th Cir. 2008); *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 549 (8th Cir. 1997); *Billard*, 683 F.2d at 57.

B. The State's Purported Grounds for Reversal Have No Merit

Rather than address the application of Rule 9(b) to the specific circumstances as to Bayer, the State raises two challenges to the Chancery Court's consideration of those circumstances. First, the State argues that, by analyzing the specific circumstances of the State's relationship with Bayer, the Chancery Court imposed a "heightened pleading standard as regards Bayer." State's Br. at 14. Second, the State contends that the Chancery Court erred by considering the import of the State's 2001 Settlement Agreement on Bayer's motion to dismiss because doing so required the Court to impermissibly consider matters beyond the "face of the complaint." *Id.* at 15. Neither argument has merit.

1. The Chancery Court Did Not Apply A Heightened Pleading Standard as to Bayer

The State argues that once the Chancery Court concluded that the allegations in the FAC satisfied Rule 9(b)'s requirements as to defendants other than Bayer, "the court's analysis should have ended there." State's Br. at 15. However, the State's argument rests on a false premise that Rule 9(b) somehow mandates that the same boilerplate allegations that might arguably suffice as to some defendants must also suffice as to Bayer. To the contrary, as explained above, the particularity with which a plaintiff must allege the circumstances of fraud to satisfy Rule 9(b) "necessarily differs with the facts of each case." *Tuchman*, 14 F.3d at 1067–68; *Guidry*, 954 F.2d at 288. Among the facts relevant to the application of Rule 9(b) are the "relationship between the parties" and, importantly, the plaintiff's access to information underlying its fraud claims. *See, e.g.*, *BJC Health Sys.*, 478 F.3d at 917; *Billard*, 683 F.3d at 57.

Consistent with the flexibility with which Rule 9(b) must be applied, the Special Masters recognized that Bayer was uniquely situated among the defendants. For example, in their Report and Recommendation No. 33 ("R&R 33"), the Special Masters explained that in a prior report reviewing the initial complaint's claims against defendants other than Bayer they had ordered the State to amend its complaint to "set forth the allegedly fraudulent AWP for each drug and the basis for alleging that each such AWP was fraudulent." (S.R.E. 11 at 002248.) In reviewing the FAC, however, the Special Masters declined to dismiss the State's claims for failing to satisfy their earlier directive because the information necessary to do so was "'known only by the party or parties alleged to have committed the fraud.'" *Id.* (quoting *Crystal Springs Ins. Agency v. Commercial Ins. Co.*, 554 So. 2d 884, 885 (Miss. 1989).) The same is not true as to Bayer.

Where, as here, a plaintiff has greater access to information concerning a particular defendant, allegations of fraud that might be sufficiently particular as applied to other defendants nonetheless fail to satisfy Rule 9(b). *See Billard*, 683 F.3d at 57 ("The policies underlying Rule 9(b) require greater precision than is found in this complaint when full discovery has been had in a prior case."); *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003) (refusing to overlook the failure of the plaintiff to make particularized allegations where the necessary information was within knowledge of third parties because "courts have held that Rule 9(b) may be relaxed where information is *only* within the opposing party's knowledge" (emphasis original; alterations and quotation marks omitted)); *M&I Heat Transfer*, 131 F. Supp. 2d at 261 (holding that allegations "strikingly similar" to those previously held sufficient to permit a plaintiff to proceed to discovery were insufficient when "the information needed to properly plead fraud is not in the exclusive control of the defendant.").

In short, consistent with Rule 9(b), the Chancery Court correctly found that, although the State's boilerplate allegations might be sufficient as to other defendants, they did not satisfy Rule 9(b)'s particularity requirement as to Bayer because they failed to account for the specific known circumstances of the relationship between the State and Bayer.

2. The Chancery Court Properly Considered the State's 2001 Settlement Agreement with Bayer

In a second attempt to disregard its prior settlement with Bayer, the State contends that it was impermissible for the Chancery Court to consider the 2001 Settlement Agreement on Bayer's motion to dismiss because in doing so it inappropriately relied upon matters "extrinsic" to the complaint. State's Br. at 15. Alternatively, the State argues that, by considering "matters outside the pleadings," the Chancery Court transformed Bayer's motion to dismiss into one for summary judgment without giving the State adequate notice pursuant to Rule 12(b) of the Mississippi Rules of Civil Procedure. State's Br. at 17.

To the contrary, it was well within the Chancery Court's discretion to consider the 2001 Settlement Agreement. A court may properly consider documents not attached to the complaint "where [the] plaintiff has actual notice of all of the information in the movant's papers and has relied upon these documents in framing the complaint." *Sennett v. U.S. Fidelity & Guar. Co.*, 757 So. 2d 206, 209 (Miss. 2000) (quotation marks and alterations omitted); *Vinson v. Prather*, 879 So. 2d 1053, 1056 (Miss. App. 2004). Likewise, a court may consider documents outside the complaint on a motion to dismiss when neither party "questions the authenticity of [the] documents and [they] were sufficiently referenced in the complaint." *Walch v. Adjutant General's Dep't of Tex.*, 533 F.3d 289, 294 (5th Cir. 2008).

Each of these conditions is met here. The State uses the Settlement Agreement to frame its claims by relying upon it as the sole factual support for its allegation that Bayer

engaged in the AWP inflation for which the State seeks to recover. *See* Compl. ¶¶ 157, 163. (B.R.E. 2 at 000047, 000049.)[14] Specifically, the State describes the allegations at issue in the Settlement Agreement, namely, the allegation that "Bayer set and reported AWPs for the [Qui Tam] drugs at levels far higher than the actual acquisition costs of the products." *See id.* ¶ 157. (B.R.E. 2 at 000047.) Then, despite acknowledging that Bayer paid the State what the State bargained for, the State asserts that it "has not been compensated fully for its losses from the wrongful conduct that [the Settlement Agreement] evidence[s]." *Id.* ¶ 163. (B.R.E. 2 at 000049.)[15] The State also uses the Settlement Agreement to frame the products it alleges are at issue, *i.e.*, "pharmaceutical products other than the *qui tam* drugs referred to in the 2001 settlement agreement and release." FAC ¶ 23. (S.R.E. 7 at 001058.) Having thus attempted to use the Settlement Agreement as a sword in its complaint, the State may not deny Bayer the opportunity to use it as a shield.

Alternatively, even if the State is correct that consideration of the 2001 Settlement Agreement effectively converted Bayer's motion to dismiss into a motion for summary judgment, the Chancery Court gave the State more than adequate notice of its intent to do so. To be sure, this Court has ruled that the combination of Rules 12(b) and 56(c) entitle a plaintiff to 10 days' notice prior to the conversion of a motion to dismiss into a motion for summary judgment by consideration matters outside the complaint. *See, e.g., Jones v. Jackson Pub. Schs.*, 760 So. 2d 730, 731 (Miss. 2000). However, "no specific decree is required ... so long as an adequate opportunity to respond has been given to the party opposing the motion."

---

[14] The FAC expressly incorporates these paragraphs of the initial complaint by reference. FAC ¶ 3. (S.R.E. 7 at 001043.)

[15] By pointing to the Settlement Agreement as evidence of "wrongful conduct," the State overlooked the provisions of the Agreement which expressly provide that the "Agreement does not constitute ... evidence of any liability or wrongful conduct." *See* Settlement Agreement, Part II(G). (B.R.E. 1 at 000488.)

Id.; *see Walton v. Bourgeois*, 512 So. 2d 698 (Miss. 1987); *Sullivan v. Tulos*, No. 2007-00823, 2008 WL 4782540, at ¶¶ 9–11 (Miss. Ct. App. 2008) (en banc). Thus, where a party is actually aware that the court intends to rely on matter outside the pleadings sufficiently in advance of a ruling, the party's objection that the court erred by failing to provide formal notice of its intention "is without merit." *Jones*, 760 So. 2d at 731.

Here, the State has known for years that the Chancery Court would consider the 2001 Settlement Agreement on Bayer's motions to dismiss. Indeed, the State was well aware of this fact at the very latest by June 2006, when the Special Masters issued R&R 2 relying on the Settlement Agreement in recommending that the Chancery Court grant Bayer's motion to dismiss. *See, e.g.*, Bayer's Mot. to Dismiss (B.R.E. 1); R&R 2 (S.R.E. 5). Likewise, at the latest by the end of 2007, the State has known that the 2001 Settlement Agreement would be significant on Bayer's motion to dismiss the FAC. *See* Bayer's Mot. to Dismiss the Am. Compl. (S.R.E. 8 at 001317); *see also* R&R 35. (S.R.E. 3 at 001556). Furthermore, the State had over four months from the date the Special Masters issued R&R 35 until the Chancery Court approved R&R 35 to bring forward any matters they believed to be relevant. Because the State had well over two years' notice of the Chancery Court's consideration of the 2001 Settlement Agreement, the State's argument that the Court's decision should be overturned for failure to provide formal notice is wholly without merit. *Jones*, 760 So. 2d at 731.

These facts put the State on nearly identical footing as the plaintiff in *Jones*. There, the Hinds County Court, without giving formal notice of its intent to do so, dismissed the plaintiffs' tort suit with prejudice based on the court's review of a video tape of the incident underlying the plaintiffs' claims. *Id.* at 730. The plaintiff argued that the County Court had erred in failing to give her formal notice of its intent to convert the defendant's motion to dismiss

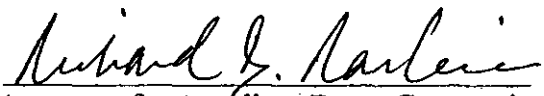
into one for summary judgment by taking into account the video. *Id.* This Court rejected the argument, explaining that no "specific decree" is required because "'[a]nyone who reads the Rule 12(b) motion is thereby on actual notice that a motion to dismiss has the potential to be treated as a motion for summary judgment'" if matters extrinsic to the complaint are considered. *Id.* (quoting *Walton*, 760 So. 2d at 700). The plaintiff in *Jones* was "aware" that the County Court "was considering matters outside of the pleadings by reviewing the video tape." *Id.* Moreover, the County Court had "postponed making [its] final ruling for over three months, granting ample time for the opposing party to respond and gather additional discovery." *Id.* The same is true here. The Chancery Court was therefore well within its discretion to make use the Settlement Agreement in its decision under appeal.

CONCLUSION

For the reasons stated above, the Chancery Court's decision dismissing all claims against Bayer should be affirmed.

Dated: June 23, 2009

Respectfully submitted,

By: 

Attorneys for Appellees Bayer Corporation, Bayer Pharmaceuticals Corporation, and Bayer Healthcare, LLC

William F. Goodman, III (# 4896)
Steven D. Orlansky (# 3940)
WATKINS & EAGER PLLC
P.O. Box 650
Jackson, MS 39205
Telephone: (601) 965-1913
Facsimile: (601) 354-3623

Richard D. Raskin
Michael P. Doss
Ben J. Keith
Sidley Austin LLP
One South Dearborn Street
Chicago, Illinois 60603
Telephone: (312) 853-7000
Facsimile: (312) 853-7036

CERTIFICATE OF FILING AND SERVICE

The undersigned counsel hereby attests that on June 23, 2009, he caused the foregoing Brief for Appellees to be filed with the clerk of the Supreme Court of Mississippi and served via United States first class mail (postage prepaid) on the persons listed below.

Jim Hood
Harold E. Pizetta III
Office of the Attorney General
Walter Sillers Building
550 High Street, Suite 1200
Jackson, Mississippi 39201

J. Leray McNamara
Ronnie Musgrove
Frank Kolb
Copeland, Cook, Taylor & Bush, P.A.
Post Office Box 6020
Ridgeland, Mississippi 39158

Clinton C. Carter
Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
Post Office Box 4160
Montgomery, Alabama 36103

The Honorable William Singletary
Hinds Chancery Court
Post Office Box 686
Jackson, Mississippi 39205-0686

Ben Keith

Ben J. Keith
Counsel for Appellees Bayer Corporation, Bayer Pharmaceutical Corporation and Bayer Healthcare, LLC