

STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN INC., ET AL.,

Defendants.

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Case No 04 CV 1709

Unclassified - Civil: 30703

**DEFENDANT TAP PHARMACEUTICAL PRODUCTS, INC.'S
INDIVIDUAL REPLY IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS THE AMENDED COMPLAINT**

In its individual memorandum in support of defendants' motion to dismiss, Defendant TAP Pharmaceutical Products, Inc. ("TAP") established that: 1) the State failed to allege fraud against TAP with the specificity required by Section 802.03 of the Wisconsin Rules of Civil Procedure; 2) the State released any of its Medicaid claims insofar as they relate to Lupron[®], a product manufactured by TAP; and 3) the State has been enjoined from pursuing any remaining Lupron[®] related claims to the extent they are covered by a nationwide class settlement pending final approval before a federal judge in Boston. Below TAP replies to the State's response on these issues.¹

¹ TAP adopts and incorporates by reference the defendants' joint reply memorandum and, to the extent applicable, the arguments contained in the other defendants' individual reply memoranda in support of the motion to dismiss.

I. Rule 802.03 Applies to the State's Claims, and The State Cannot Point To Any Specific Allegations Against TAP.

The State contends that: 1) Rule 802.03 does not apply to its claims; and 2) even if it did, the complaint satisfies the rule's heightened pleading requirements. (*See* Pltf. Resp. to Defs. Jt. Mem. at 37-44). As explained in defendants' joint reply, both arguments lack merit. Rule 802.03 applies to more than merely claims of common law fraud, but to any averments of fraud. (*See* Defs. Jt. Reply, at 1-5.) Because plaintiff's claims are grounded in fraud, they must be pled with particularity. *Id.* The State's contention that its complaint in fact satisfies the specificity requirements of Rule 802.03 defies reality. The State does not dispute that its complaint fails to make any particularized allegations against TAP, including, for instance, which TAP products are at issue; the allegedly fraudulent prices that TAP submitted for the unidentified products; and what prices TAP should have submitted instead. Nor can the State point to any allegation in the complaint that it or any individual or entity actually paid for a specific TAP product based on AWP. These omissions require dismissal of the State's claims. (*See* Defs. Jt. Reply at 5-9.)

II. The State Admits That It Has Released All of Its Medicaid Claims Relating to Lupron®.

The State concedes that it has released all of its Medicaid claims against TAP insofar as they relate to Lupron®, a drug manufactured by TAP. (*See* Pltf. Resp. to Ind. Mem. at 13.) Thus, all of the State's Medicaid-based claims as to Lupron® should be dismissed.

III. The Federal Court Presiding over the Lupron® MDL Has Enjoined All Claims Covered by the Lupron® Settlement Agreement.

In its opening brief, TAP explained how the federal court presiding over the Lupron® MDL (Judge Stearns) entered an Order preliminarily approving a nationwide class settlement and certified for settlement purposes a nationwide class of “[a]ll individual persons or entities who, during the Class Period, made Lupron® Purchases” *See In re: Lupron® Marketing and*

Sales Pract. Litig., 345 F. Supp. 2d 135, 139 (D. Mass. 2004). TAP further explained how Judge Stearns, in order to preserve his jurisdiction and to oversee the orderly administration of the nationwide settlement, enjoined all members of the Lupron[®] Purchaser Class (including all Lupron[®] purchasers in Wisconsin) from commencing, continuing, or prosecuting any claims based on Lupron[®] pending final approval of the settlement. Thus, to the extent that the State is pursuing claims in this case on behalf of citizens or entities covered within the Lupron[®] Purchaser Class, the injunction operates to stay those claims pending final approval of the Lupron[®] MDL settlement. (*See* TAP's Ind. Mem. at 3.)

In response, the State asserts that: 1) the Lupron[®] MDL settlement has not been finally approved; 2) a “gigantic issue” exists as to whether a federal court can enjoin a State from pursuing claims²; 3) the State will “almost certainly” opt-out of the Lupron[®] MDL settlement, and its claims will proceed against TAP “no matter what”; and 4) Judge Stearns’ injunction merely stays these proceedings as to Lupron[®] and is not a basis to dismiss the lawsuit against TAP.³ (*See* Pltf. Resp. at 13-15.)

² The State does not take the position that Judge Stearns lacks the authority to enjoin the State from pursuing its representative Lupron[®] claims in this case. Nevertheless, any suggestion that Judge Stearns lacks such authority is contrary to the law. *See In re Baldwin-United Corp.*, 770 F.2d 328, 334, 342 (2d Cir. 1985) (affirming district court’s injunction against Attorneys General from prosecuting or commencing claims that could in any way affect the class members because “[i]f states or others could derivatively assert the same claims on behalf of the same class members . . . , there could be no certainty about the finality of any federal settlement”); *accord Pennsylvania v. BASF Corp.*, No. 3127, 2001 WL 1807788 (Pa. Com. Pl., March 15, 2001) (“to assure the finality of the Class Action settlement and to adhere to the District Court’s exclusive jurisdiction over the settlement, this court cannot now allow the Commonwealth to assert *parens patriae* claims on behalf of Pennsylvania citizens who released the defendants for the same conduct alleged in this action”).

³ The State also complains in its response that TAP did not attach to its individual memorandum the settlement agreement from the Lupron[®] MDL, or the November 24, 2004 order containing Judge Stearns’ injunction. TAP did not (and still does not) see a need at this point to attach the settlement agreement from the Lupron[®] MDL to its briefing on the motions to dismiss, and unnecessarily add to the substantial amount of paper already received by the Court in this case. As to Judge Stearns’ injunction, it is part of a published opinion, 345 F. Supp. 2d 135 (D. Mass. 2004), as cited in TAP’s opening brief. Nevertheless, to the extent the Court would like to see a copy of either document, TAP will submit them promptly.

TAP agrees with the State that the Lupron[®] MDL settlement has not yet received final approval. TAP further agrees that the Lupron[®] MDL settlement will not become a basis for dismissing any claims in this case unless and until it receives final approval by Judge Stearns. Because TAP is not seeking dismissal of any claims at this time based on the Lupron[®] MDL Settlement, there are no issues for the Court to decide with respect to the Lupron[®] MDL Settlement.

Nevertheless, by way of background for the Court, several filings and at least one preliminary ruling have been made in the Lupron[®] MDL relating to the State's ability to opt-out the claims of its citizens and other payors, after the State filed its response to defendants' motion to dismiss in this case on March 10, 2005. On March 15, 2005, the State (along with Kentucky and Illinois) filed an Objection to the Final Approval of the Class Settlement Agreement and a Notice of Intention To Appear at the April 13, 2005 Fairness Hearing. In its objection, the State indicated "it appears that the Class Settlement Agreement, if approved, would release the claims of the consumers and third-party payors brought by the Attorneys General [including Wisconsin]." On March 28, 2005, the State withdrew its objection and filed a Notice of Exclusion of the State of Wisconsin from the Class Settlement Agreement. In its Notice, the State purported to exclude from (or "opt-out of") the Class Settlement Agreement "all claims possessed by the State of Wisconsin on behalf of itself, its citizens, its residents, or its employees." On April 11, 2005, TAP and other defendants in the Lupron[®] MDL moved to strike the purported mass opt-outs filed by Wisconsin and other states.

On April 13, 2005, Judge Stearns held a fairness hearing on the Lupron[®] MDL settlement. No ruling as to final approval has been issued to date. On April 15, 2005, Judge

Stearns entered an Order regarding the Notices of Exclusion (or “opt-outs”) submitted by several states, including Wisconsin, on behalf of their citizens. The Order states in part:

The court has preliminarily concluded that State Attorneys General do not have the legal authority to exercise exclusion from the putative Lupron® Purchase Class of private citizens and entities (third-party payors). The Attorneys General of Illinois, Kentucky, and Wisconsin, who were previously invited to brief the issue, now acknowledge the correctness of the court’s preliminary conclusion.
...

The court is further of the preliminary view that should final approval be given to the proposed Settlement Agreement, all claims brought by State Attorneys General purporting to seek relief on behalf of class members, however cast, will be extinguished. All Attorneys General are invited to address this issue again within fourteen (14) days of the date of this Order.

Thus, although this issue has not yet been finally determined, it appears that the State's claims on behalf of its citizens and third-party payors could also be barred as a result of the Lupron® MDL settlement.

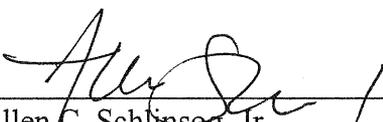
IV. CONCLUSION

For the foregoing reasons, and those identified in defendants' joint reply, TAP respectfully requests that this Court dismiss the State’s Amended Complaint with prejudice. If and when the Lupron® MDL settlement receives final approval, TAP reserves the right to seek dismissal of any of the State’s claims insofar as they are released by that settlement, to the extent that they have not already been dismissed on independent grounds.

Dated: April 19, 2005

Respectfully Submitted,

DEFENDANT TAP PHARMACEUTICAL
PRODUCTS, INC.



Allen C. Schlinseog, Jr.
Mark A. Cameli

Reinhart Boerner Van Deuren s.c.
1000 North Water Street
P.O. Box 2965
Milwaukee, WI 53201-2965
(414)298-1000
(414)298-8097 (fax)

Lynn M. Stathas
Reinhart Boerner Van Deuren s.c.
22 East Mifflin Street
P.O. Box 2018
Madison, WI 53701-2018
(608)229-2200
(608)229-2100 (fax)

Of Counsel

Daniel E. Reidy
Lee Ann Russo
Tina M. Tabacchi
JONES DAY
77 West Wacker
Chicago, IL 60601-1692
312.782.3939
312.782.8585 (fax)