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November 7, 2005

Judith A. Coleman
Clerk of Circuit Court
City County Building, Room GR10
210 Martin Luther King Jr. Blvd.
Madison WI 53703

Re: *State of Wisconsin v. Amgen Inc., et al.*
Case Number 04-CV-1709

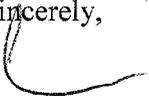
Dear Ms. Coleman:

Enclosed please find the State of Wisconsin's Motion To File Supplemental Authority, along with a certificate of service in the above-captioned matter.

By copy of this letter these documents are being served on Daniel W. Hildebrand via e-mail and to local Wisconsin counsel via U.S. Mail.

Thank you in advance for your assistance.

Sincerely,


Charles Barnhill

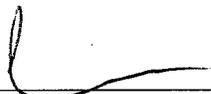
CB:jlz

Cc: Hon. Moria Krueger
Local Wisconsin Counsel
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Wisconsin's Memorandum In Opposition To Defendants' Joint Motion To Dismiss The Amended Complaint) to none upholding them.

Dated this _____ day of November, 2005.

Respectfully submitted,



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IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania :
by Gerald J. Pappert, in his capacity :
as Attorney General of the :
Commonwealth of Pennsylvania, :
Plaintiff :

v. :

TAP Pharmaceutical Products, Inc.; :
Abbott Laboratories; Takeda Chemical :
Industries, LTD.; AstraZeneca PLC; :
Zeneca, Inc.; AstraZeneca :
Pharmaceuticals LP; AstraZeneca :
LP; Bayer AG; Bayer Corporation; :
GlaxoSmithKline, P.L.C.; SmithKline :
Beecham Corporation; :
Glaxo Wellcome, Inc.; Pfizer, Inc.; :
Pharmacia Corporation; Johnson & :
Johnson; Amgen, Inc.; Bristol-Myers :
Squibb Company; Baxter International :
Inc.; Aventis Pharmaceuticals, Inc.; :
Boehringer Ingelheim Corporation; :
Schering-Plough Corporation; Dey, Inc., : No. 212 M.D. 2004
Defendants : Argued: June 8, 2005

BEFORE: HONORABLE JAMES GARDNER COLINS, President Judge
HONORABLE BERNARD L. McGINLEY, Judge
HONORABLE DORIS A. SMITH-RIBNER, Judge
HONORABLE ROCHELLE S. FRIEDMAN, Judge
HONORABLE BONNIE BRIGANCE LEADBETTER, Judge
HONORABLE RENÉE COHN JUBILIRER, Judge
HONORABLE MARY HANNAH LEAVITT, Judge

OPINION
BY PRESIDENT JUDGE COLINS

FILED: November 3, 2005

The Plaintiff, the Commonwealth of Pennsylvania, through its Attorney General, has filed a Corrected Amended Complaint¹ on behalf of the Commonwealth, and in its asserted status of *parens patriae*, on behalf of citizens of Pennsylvania, who, according to the Amended Complaint, the Defendants have injured through allegedly improper conduct that has caused entities of the Commonwealth and some of its citizens to pay inflated prices for certain pharmaceuticals the Defendants manufacture, market, and sell.

Before the Court are the Defendants' preliminary objections to the Amended Complaint. In their Joint Brief, the Defendants contend that this Complaint, like the original, fails to plead facts with sufficient detail under the Rules of Civil Procedure, Pa. R.C.P. No. 1019(a) and (b). The Defendants also contest the legal merits of the various causes of action the Plaintiff has brought against them, including claims of unjust enrichment, misrepresentation or fraud, violations of the Unfair Trade Practice and Consumer Protection Law (UTPCPL),² and civil conspiracy. The Defendants' objections also include challenges to the Commonwealth's standing under the UTPCPL and the Commonwealth's standing as *parens patriae*. Finally, the Defendants contend that the "filed rate" doctrine, the "state action" doctrine, and federal preemption bar the Commonwealth's action.³

¹ This court previously sustained the Defendants' preliminary objection to the original Complaint, after agreeing that the Plaintiff had failed to allege sufficient facts under Pa. R.C.P. No. 1019(b), *Commonwealth v. TAP Pharmaceutical Products, Inc.*, 868 A.2d 624 (Pa. Cmwlth. 2005) (*TAP I*). We will refer to this action hereafter as the Amended Complaint.

² Act of December 17, 1968, P.L. 1224, as amended, 73 P.S. §§201-1 --- 201-9.3.

³ Most of the individual Defendants have filed additional supplemental briefs raising issues particular to those individuals, which issues we address later in this opinion.

The Commonwealth brings this action in its sovereign capacity and its proprietary capacity⁴ as a purchaser and end-payor for certain drugs manufactured, marketed, and ultimately sold to persons covered by the state-related programs listed in footnote 4 and to Commonwealth citizens.

As noted in this Court's earlier decision in this matter, *TAP I*, the present controversy primarily arose around the use of a pricing standard known as the Average Wholesale Price (AWP). The Commonwealth's claims are based generally on its assertion that all the Defendants knowingly inflated this self-reported AWP for inclusion in a pharmaceutical publication upon which the Commonwealth relied. The Commonwealth alleges that the reason the Defendants inflated the AWP, which in some cases reflected a price hundreds of times higher than what would constitute an actual average wholesale price, is that the Defendants would generate revenue by virtue of direct purchasers paying more for their products and such systematic inflation would also result in increased market share.

As stated above, AWP's are used by the Commonwealth to establish a basis for reimbursement to the middleman --- such as physicians who administer drugs to patients directly (such as intravenous cancer drugs), and pharmacy benefit

⁴ The Commonwealth asserts these claims on behalf of departments, bureaus, and agencies for which it or they have been harmed by virtue of reimbursements to pharmacies, physicians, and pharmacy benefit managers for certain drugs provided under the following programs: Medicaid, the Pharmaceutical Assistance Contract for the Elderly (PACE), the Communicable Disease Program, the Bureau of Family Health programs (Renal, Spina Bifida, Cystic Fibrosis, Metabolic Conditions and Metabolic Formula programs), programs for people receiving workers' compensation benefits, and the Pennsylvania Employee Benefit Trust Fund (PEBTF), which provides a drug program for current and retired Commonwealth employees.

The Commonwealth acknowledges that it has settled some of its Medicaid-related claims regarding certain drugs, and accordingly is not seeking recovery for damages resulting to the Medicaid program as to those drugs. See Amended Complaint, paragraph 4 for those drugs.

managers who buy in quantity for resale to consumers. The AWP, according to the Amended Complaint, achieves the goal of increased market share by creating a monetary incentive to the middleman to choose a particular drug, based not on superior performance, but rather on the increased revenues to the middleman that result from the so-called spread, which is described as the difference between the actual cost to the middleman and the amount of reimbursement he or she receives, in this case from the Commonwealth programs. Because the reimbursement rate is based on the inflated AWP, the middleman receives a windfall of sorts, and the greater the windfall, the more likely the middleman is to choose such drugs.

In specifics, the Commonwealth avers that three of its largest drug purchasing or reimbursement programs are (1) Medicaid (run by the Department of Public Welfare (DPW)), (2) PACE (run by the Department of Aging), and (3) PEBTF (run for the benefit of state employees, retirees, and their dependents). All of these programs, the Commonwealth attests, pay for prescription drugs using a formula that includes AWP to determine reimbursement.

Thus, DPW, in accordance with 55 Pa. Code §1121.56, must use the lower of two formulas: (1) the "Estimated Acquisition Cost" (EAC), which under the regulations, 55 Pa. Code §1121.1, is the current AWP for the most common package size minus 10%, and (2) the state MAC, which the Commonwealth alleges "is similar to the federal upper limit price," (Amended Complaint, paragraph 55). The Commonwealth contends that the AWP for the drugs and time at issue was the starting point for determining reimbursement, and that for those drugs for the 2003-2004 fiscal year, the Commonwealth incurred approximately \$1.5 billion in reimbursement expenses.

With regard to the Department of Aging's PACE program, the Commonwealth avers that Aging uses a formula providing for reimbursement of 90% of the average wholesale cost (not specifically AWP) that exceeds the co-payment, plus a dispensing fee. The Commonwealth avers that, although the applicable statutory provision does not specify AWP, it references AWP by directing the formula to reflect drug prices published in whichever national drug pricing system the Department uses as the average wholesale price, 72 P.S. §3761-502.⁵ The Commonwealth avers that it incurred \$506 million in PACE reimbursement expenses during the 2003-2004 fiscal year.

PEBTF engages a pharmacy benefit manager, to which PEBTF pays a reimbursement based upon AWP minus a discount, plus a dispensing fee, minus a rebate. PEBTF obtains the AWP from one of two sources depending on particular contract obligations. PEBTF reimbursed its benefits manager approximately \$247 million for drugs prescribed for its beneficiaries for the 2003-2004 fiscal year.

As to the Bureau of Family Health Programs,⁶ which is run by the Department of Health, but which is administered under a memorandum of understanding by the Department of Aging, the Commonwealth avers that it reimburses using a formula that reflects 90% of the average wholesale cost that exceeds the co-payment, plus a dispensing fee.

The Commonwealth further points out that the AWP plays a significant role in budgeting strategies, and that it affects administrative decisions,

⁵ Section 502 of the State Lottery Law, Act of August 26, 1971, P.L. 351, *as amended*, added by Section 2 of the Act of November 21, 1996, P.L. 741.

⁶ This Bureau operates the following programs: Renal, Spina Bifida, Cystic Fibrosis, Metabolic Conditions, and Metabolic Formula Programs.

we presume such as eligibility standards based on income and the scope of coverage.

Much of the Commonwealth's claim for relief is based upon its averments that the AWP was intended as a device to ensure that doctors or pharmacies are recompensed, but not enriched, for services to end users encompassed under the various above-noted drug plans and programs; that the Defendants knew, or should have known, how inflated AWPs affect the Commonwealth's reimbursements to intermediaries, such as doctors and pharmacies, and cause the Commonwealth to pay higher reimbursement amounts and result in economic harm to the Commonwealth, its businesses, and its consumers. This imputed knowledge on the part of the Defendants of the Commonwealth's use of AWP and the results of its deviation from actual average wholesale, according to the Commonwealth, created an obligation on the part of the Defendants not to manipulate the AWP.

Further implicating the Defendants, the Commonwealth contends the Defendants had sole control over confidential data that would show the true acquisition costs of their drugs, thus leaving the Commonwealth in the dark as to how the Defendants established the AWP they reported to the publishers of AWPs. As noted above, by using inflated AWPs, the Commonwealth avers that the Defendants were able to generate greater revenue in two ways: first, direct purchasers paid more for their products, and second, the Defendants obtained an increased share of the market, because intermediate purchasers such as doctors and pharmacies would be more inclined to use their products if the benefit to themselves increased by the spread between actual acquisition costs and the reimbursement rate based on AWP.

The Commonwealth pleads that the Defendants used five distinct methods or incentives to encourage the use of their drugs: (1) creation of the spread; (2) providing free goods and drug products with the knowledge that the dispenser would charge the Commonwealth and its consumers for the free goods the dispensers received from the Defendants; (3) providing other financial incentives to induce sales; (4) in reporting the AWP, the Defendants failed to have these figures reflect the value of the free goods, rebates, discounts, and other incentives that would reduce the actual wholesale price of a drug; and (5) engaging in efforts to conceal and fraudulently suppress their wrongful conduct to maintain the alleged scheme and conspiracy.

The Commonwealth breaks down its claims against the Defendants into two primary groups. The first group involves drugs that generally require a physician to administer them in the office (prescriber-dispensed drugs), in which case, the prescriber (typically a physician) buys or obtains the drugs from the manufacturer or distributor and bills the Commonwealth at the AWP-based reimbursement rate. Because the prescriber reaps the benefit of the difference between his or her cost to buy and the reimbursement based on AWP, the greater this difference or spread, the more likely the dispenser is to select a particular drug. The second group involves pharmacies and drug benefit plans (pharmacy and non-prescriber dispensed drugs) in which similar spreads are created when the pharmacy pays a reduced price for drugs or obtains rebates for purchased drugs, and then seeks reimbursement from the Commonwealth based upon the inflated AWP. This practice, the Commonwealth contends, creates an incentive for the pharmacy to select certain drugs and thereby results in a greater market share for the Defendants' products.

While recognizing that federal criminal actions have resulted in certain sanctions against some of the Defendants and that federal litigation has produced some compensation, the Commonwealth contends that through this action it is pursuing claims for which it has not yet been fully compensated.

As noted above, the Commonwealth generally asserts four causes of action arising from its factual allegations: unjust enrichment, violations of the UTPCPL, fraud/misrepresentation, and civil conspiracy. However, because the Defendants' individual conduct varies to some extent, and because some drugs are prescriber dispensed and others are pharmacy dispensed, the claims against individual Defendants do differ slightly.

Consequently, while the Defendants' preliminary objections jointly challenge the Commonwealth's claims as to (1) the legal sufficiency of the Complaint under Pa. R.C.P. No. 1019(a) and (b) and as to each claim as a matter of law, (2) its standing in a *parens patriae* capacity and under the UTPCPL, and (3) whether the filed rate doctrine and the doctrines of state action and federal preemption bar the Commonwealth's claims. The individual Defendants have additional objections that the Court shall address as required.

Does the Commonwealth's Amended Complaint Satisfy Pa. R.C.P. No. 1019?

Pa. R.C.P. No. 1019(a) requires that "[t]he material facts upon which a cause of action or defense is based shall be stated in a concise and summary form." Pa. R.C.P. No. 1019(b) provides that "averments of fraud or mistake shall be averred with particularity. Malice, intent, knowledge, and other conditions of mind may be averred generally."

In *TAP I*, this Court, citing *Department of Transportation v. Shipley Humble Oil Co.*, 370 A.2d 438 (Pa. Cmwlth. 1977), dismissed the original Complaint after concluding that the Commonwealth had failed to plead facts that adequately apprised the Defendants of the Commonwealth's claims against them, and therefore failed to provide notice of such a nature as to enable the Defendants to defend themselves against the Commonwealth's claims. In response to the changes in the Amended Complaint, the Defendants join in arguing that the Court should also dismiss the present Complaint because it too fails to satisfy Pa. R.C.P. No. 1019(a) and (b). Defendants contend that, although the Amended Complaint is longer than the original, the Commonwealth has not improved upon it in substance.

Defendants argue that the Complaint fails to satisfy Pa. R.C.P. No. 1019(a) in four ways. Initially, they suggest that the Complaint does not adequately differentiate between companies in a given group of company Defendants. Thus, for example, Defendants in the AstraZeneca group, which is comprised of a parent company, AstraZeneca PLC, and three wholly owned subsidiaries, contend that the Complaint is insufficient because it groups them together as being "engaged in the business of manufacturing, distributing, marketing and selling" certain drugs (Amended Complaint, paragraphs 20-24), without specifying which aspect of the target conduct in which each engaged.

Although the Complaint does not specify how specific subsidiaries were involved in the development of AWP or its use as a means to garner increased market share, as the Commonwealth notes, when applicable, the Complaint, as in the case of the Johnson & Johnson Defendants does indicate which subsidiary was involved in the marketing and sale of particular drugs manufactured by Johnson & Johnson. By inference, at this pleading stage, we can

assume that in the case of the AstraZeneca Defendants, the parent company and the subsidiaries were all involved in the distribution, marketing and sale of all of the parent company's drugs.

The Defendants argue that the Amended Complaint is deficient because it does not specify "products, times, places, conduct, or anything else that would satisfy the Court's directives." (Joint Brief, p. 5.) We agree with the Commonwealth that specificity as to time and place is not required under Pa. R.C.P. No. 1019(a). The underpinning of the Amended Complaint relates to the development of AWP and the relationship of AWP to the spreads. The minutiae of how the Defendants developed the allegedly inflated AWP and the mechanics as to how they allegedly promoted their products through the creation of the spread incentives are matters that the Commonwealth will have to flesh out through discovery and future proceedings. However, we believe that the Amended Complaint fares better than the original in reaching the threshold requirements of the Rule set forth in subsection (a), and we overrule this preliminary objection.

Similarly, the Amended Complaint has adequately identified the injured parties. The new Complaint differentiates the programs it alleges were harmed by the Defendants' conduct, and how each program used AWP to determine reimbursement. The Amended Complaint specifically indicates those aspects of its Medicaid program for which it has already been compensated.

The Defendants contend that the Amended Complaint fails to describe how their published AWP's were misleading or legally impermissible. First, the Defendants assert that the Amended Complaint includes no factual averments that they represented to anyone that the reported AWP reflected fact-based average wholesale prices. However, the allegations in the Amended Complaint do indicate

that persons for whom this information is relevant would have a reasonable basis to rely on the reported AWP as being something more substantial than a number selected arbitrarily.

The Defendants attempt to discredit the adequacy of the Amended Complaint by asserting that the Commonwealth inconsistently pleads both that some Defendants provided AWP's to publishers and some "continued to transmit or allowed to be published inaccurate information about AWP's." However, at this point, we cannot conclude that the suggestion in the pleading, that some passive, rather than affirmative, conduct on the part of some of the Defendants led to inflated AWP's, necessarily limits the Commonwealth's causes of action.

The Defendants argue that the Amended Complaint fails to satisfy the requirement of Pa. R.C.P. No. 1019(b) to plead allegations of fraud with particularity. In *Martin v. Lancaster Battery Co., Inc.*, 530 Pa. 11, 19, 606 A.2d 444, 448 (1992), the Supreme Court noted:

This Court has stated that although it is impossible to establish precise standards as to the degree of particularity required under this rule, two conditions must be met to fulfill the requirement: (1) the pleadings must adequately explain the nature of the claim to the opposing party so as to permit the preparation of a defense, and (2) they must be sufficient to convince the court that the averments are not merely subterfuge.

More recently, the Superior Court in *Youndt v. First National Bank of Port Allegheny*, 868 A.2d 539 (Pa. Super. 2005), addressed preliminary objections arising under Rule 1019(b). The Court noted that the purpose of the Rule was to ensure that plaintiffs do not levy "generalized and unsupported fraud" claims upon defendants. *Id.* at 544 (quoting *Sevin v. Kelshaw*, 611 A.2d 1232, 1235 (Pa. Super.

1992)). In that case, the Superior Court concluded that the plaintiff's complaint failed to satisfy Rule 1019(b) because it failed to describe the method by which the defendant made an allegedly fraudulent misrepresentation. The Court concluded that the complaint failed to provide averments as to the precise actions or statements constituting the fraudulent misrepresentation. *Youndt*, 868 A.2d at 545.

In this case, perhaps minimally, the Commonwealth has recited sufficient averments to provide the Defendants with adequate notice of the Commonwealth's claims involving fraud. The Amended Complaint avers that the Defendants knowingly provided publishers with AWP's that in no way reflected an actual average wholesale price. Although the Defendants did not provide these inflated AWP's to the Commonwealth agencies involved, the Complaint alleges that the Defendants were aware, through statute and regulation, that the Commonwealth relied upon these publications as a basis for reimbursing the physician and pharmacy dispensers of their drugs.

Because the facts in the Amended Complaint apprise the Defendants of the nature of the Commonwealth's claims to an extent that will provide them with adequate information to defend against the claims, and because, in this Court's view, the claims do not appear to be mere subterfuge, *Martin*, we overrule the Defendants' preliminary objections under Pa. R.C.P. No. 1019(b).

Failure to State a Cause of Action

Unjust Enrichment

Unjust Enrichment is an equitable doctrine. *Styer v. Hugo*, 619 A.2d 347 (Pa. Super. 1993), *affirmed*, 535 Pa. 610, 637 A.2d 276 (1994). Under the doctrine, the law implies that a contract exists when a party is found to have been

unjustly enriched; the doctrine requires the offending party to pay the plaintiff the value of the benefit he has conferred on the defendant. *Mitchell v. Moore*, 729 A.2d 1200 (Pa. Super. 1999), *petition for allowance of appeal denied*, 561 Pa. 698, 751 A.2d 192 (2000). A party alleging that a defendant has been unjustly enriched must establish the following: (1) plaintiff conferred a benefit on the defendant; (2) the defendant appreciated the benefit; and (3) acceptance and retention by the defendant of the benefits, under the circumstances, would make it inequitable for the defendant to retain the benefit without paying for the value of the benefit. *Styler*, 619 A.2d at 350. Further, a defendant need not have accepted and appreciated the benefit intentionally; instead, the focus remains on the question of whether the defendant has been unjustly enriched. *Torchia v. Torchia*, 499 A.2d 581 (Pa. Super. 1985). Additionally, the plaintiff bears the burden of establishing either that the defendant wrongfully secured the benefit or passively received a benefit that it would be unconscionable to retain. *Id.*

The Defendants assert that the Commonwealth has failed to state a cause of action for unjust enrichment because they have not pleaded facts showing that the Commonwealth conferred any **direct** benefit on the Defendants. However, the Commonwealth is contending that its reimbursement did confer a benefit on the Defendants --- an increase in market share. The Defendants argue that the Amended Complaint does not aver that the Defendants actually obtained an increase in the market share as a result of the alleged AWP scheme. However, we agree with the Commonwealth that we can infer that fact from the pleading. Certainly, in order to obtain some of its requested relief, the Commonwealth will have to establish not only liability but also damages. Accordingly, the Commonwealth will have to offer some proof that the scheme-induced, inflated

reimbursements did lead dispensers to select the drugs at issue. Assuming the Commonwealth can establish such an effect, and assuming the Court were to conclude that the Defendants' retention of such a benefit without paying for its value is inequitable, under the doctrine of unjust enrichment, whether the retention of the benefit was intentional or not, the Commonwealth would be entitled to relief. Accordingly, we overrule this preliminary objection.

Misrepresentation/Fraud

The elements of misrepresentation or fraud are: (1) a misrepresentation; (2) that is made knowingly, or if innocently made relates to a matter material to the transaction; (3) where the maker of the misrepresentation intended that the recipient will be induced to act by virtue of the misrepresentation; (4) the recipient justifiably relied upon the misrepresentation; and (5) damage to the recipient is the proximate result. *Gibbs v. Ernst*, 538 Pa. 193, 207-8, 647 A.2d 882, 889 (1994) (citing W. Page Keating, *Prosser and Deaton on the Law of Torts* §105 (5th ed. 1984)).

The Defendants argue that the Commonwealth has failed to allege that the Defendants made a false representation or had a duty to disclose the misrepresentation. The Defendants initiate this discussion by noting that plaintiffs who base a claim of fraud on a **non-disclosure** must plead facts showing that the defendant had a duty to disclose. See *GMH Associates, Inc. v. Prudential Realty Group*, 752 A.2d 889, 902 (Pa. Super.), *petition for allowance of appeal denied*, 568 Pa. 663, 795 A.2d 926 (2000). The Defendants take a decidedly semantic approach to the Commonwealth's pleadings, suggesting that because the Defendants never affirmatively stated that AWP's bear "any particular relationship

to prices actually paid in the Commonwealth by medical providers or other purchasers,” (Defendants’ Joint Brief, p.18), any fraud could constitute only a type of non-disclosure for which the Commonwealth needed to plead a duty to disclose. Therefore, the question posed by this reasoning is whether the simple submission for publication of figures as average wholesale prices can be regarded as a disclosure of the thing it purports to be, an average wholesale price.

As noted by the Commonwealth, the Amended Complaint does aver that, in reporting the AWP’s to the publishing compendia, the Defendants were making representations that these figures reflected real, fact-based average wholesale prices. (Amended Complaint, paragraph 181.) Further evidentiary exploration may show that the medical community and others who rely upon the published AWP have a reasonable expectation that the AWP represents a figure close to a real average wholesale price that the publisher prints with only the expectation of such being the case. Accordingly, contrary to the Defendants’ characterization of the AWP being a case of non-disclosure, we believe the Amended Complaint could very well establish this as a case of disclosure rather than non-disclosure, with the former not requiring the Commonwealth to establish that the Defendants had a duty to disclose the true nature of the published AWP. Accordingly, we need not address the Defendants’ arguments that the Commonwealth failed to aver necessary facts showing a duty to disclose.

The Defendants make numerous arguments attacking the Commonwealth’s averment that it justifiably relied upon the published AWP. The Defendants point to various sources suggesting that the Commonwealth should have known that the AWP was not reliable. While these sources do suggest that information available to the Commonwealth might have provided the

Commonwealth with some notice as to problems with reported AWP's, we believe that the Defendants will have to develop this defense at a later stage. Although some of the sources may be ones of which this Court could take judicial notice, the question of whether the Commonwealth justifiably relied upon the information requires further factual exploration.

Thus, we overrule the Defendants' preliminary objection as to the Commonwealth's misrepresentation/fraud claim.

Violation of the Unfair Trade Practices and Consumer Protection Law

The Defendants assert that the Amended Complaint fails to state a cause of action under the UTPCPL. The Amended Complaint includes charges that the Defendants engaged in unfair methods of competition and unfair or deceptive acts or practices as those terms are defined in Section 2(4) of the Law, UTPCPL, 73 P.S. §201-2(4), specifically the following subsections:

....
(ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;

....
(v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or qualities that they do not have or that a person has sponsorship, approval, status, affiliation or connection that he does not have;

....
(ix) Advertising goods or services with intent not to sell them as advertised;

....
(xi) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;

....
(xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

The first aspect of the Defendants' objection as to the UTPCPL claim is that the Commonwealth has failed to state a claim for monetary relief. The Defendants, pointing to the language in Section 4.1, 73 P.S. §201-4.1,⁷ contend that, because the Commonwealth never directly paid the Defendants, the Court cannot "direct that the defendant restore any money[]" to the Commonwealth. Also, the Defendants, recognizing that Section 9.2 of the UTPCPL, 73 P.S. §201-9.2, provides for a cause of action to private parties to obtain actual damages for a violation of the Law, argue that the Commonwealth is not a private party within the meaning of the Law, and that, even if the Commonwealth has standing as *parens patriae*, such status does not provide an avenue for monetary relief under this section because the Commonwealth has not pleaded that the injured Commonwealth consumers ever paid money directly to the Defendants, but only to the intermediaries. However, as the Commonwealth argues, the UTPCPL, while providing for recovery of damages, does not specifically require that the damages sought arise from payments made directly to a defendant. Section 201-4.1 provides that a court may order a defendant to restore any money lost as a result of a violation. 73 P.S. §201-4.1. Hence, if the Court were to conclude that the Defendants' conduct constitutes a violation of the Law, and the Commonwealth establishes the loss of money as a result of the conduct, the Commonwealth may prevail in its claims.

The Defendants also argue that the Commonwealth's UTPCPL claim fails because the pleaded facts do not establish that any Defendant engaged in an

⁷ Sections 4.1 and 9.2 were added by Section 1 of the Act of November 24, 1976, P.L. 1166.

unfair or deceptive act or practice within the meaning of the five subsections of the Law quoted above. For example, Subsection 2(4)(ii) applies only to conduct “causing likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or services.” 73 P.S. §201-2(4)(ii). The Defendants assert that there is no conduct at issue involving source, sponsorship, approval or certification. The Commonwealth apparently concedes that the conduct at issue does not implicate issues as to sponsorship, approval, or certification, but does contend that the Defendants conduct created confusion or misunderstanding as to the source of the drugs, such as when a doctor uses a sample drug he received at no cost to himself and administers the drug to a patient who assumes that “the source of the drug is Defendants’ commercial sales channels.” (Commonwealth’s Brief, p. 39.) This averment does assert a claim as to a source of drugs in the alleged scheme. Given the remedial nature of the UTPCPL legislation, we will deny this preliminary objection.

The Defendants also challenge the Commonwealth’s claims under Subsections 201-2(4)(v),(ix), and (xi), which generally encompass false advertising elements. The Commonwealth relies for these claims on the allegedly false representations made by virtue of the published, inflated AWP. At this juncture, we will permit the Commonwealth’s claims under these provisions to continue and await further evidentiary foundation as to the nature and manner of publishing AWP before dismissing the Commonwealth’s claims.

We further overrule the Defendants’ objection under Subsection 2(4)(xxi), in which they assert that the Commonwealth cannot establish that it believed that the AWP represented actual selling prices. This is a factual issue

that we cannot address in considering preliminary objections. Accordingly, we overrule all of the Defendants' preliminary objections under the UTPCPL.

Civil Conspiracy

Defendants assert that the Commonwealth's claim fails to state a cause of action for civil conspiracy. "Civil conspiracy occurs when two or more persons combine or agree intending to commit an unlawful act or do an otherwise lawful act by unlawful means." *Brown v. Blaine*, 833 A.2d 1166, 1173, n.16 (Pa. Cmwlth. 2003). A party asserting such a claim is required to aver "material facts which will either directly or inferentially establish elements of conspiracy." 833 A.2d at 1173. The Court in *Brown* noted that, in addition to alleging the combination above, a plaintiff must allege facts supporting a claim for conspiracy, namely that (1) the persons combine with a common purpose to do an unlawful act or to do a lawful act by unlawful means or unlawful purpose, (2) that an overt act in furtherance of the common purpose has occurred, and (3) the plaintiff has incurred actual legal damage. 833 A.2d at 1173, n.16 (citing *McKeeman v. Corestates Bank, N.A.*, 751 A.2d 655 (Pa. Super. 2000)).

The Defendants contend that the Amended Complaint fails to allege facts suggesting that two or more of the Defendants conspired or had the intent to conspire. Citing several cases, including *Brown*, the Defendants argue that facts from which a court could minimally infer interaction between the Defendants, such as telephone calls or meetings, are necessary in order to state a conspiracy claim. The Defendants contend that the Amended Complaint fails in this regard by averring facts that simply show that the Defendants marketed their products in a similar fashion, and none that would suggest even inferential conspiratorial

conduct. However, as noted by the Commonwealth, at paragraphs 951 and 952, the Amended Complaint avers as follows:

951. TAP and Abbott engaged in conspiratorial meetings with the AstraZeneca Defendants, the Amgen Defendants, the Bristol-Myers Defendants and the J & J Defendants, among the purposes of which meetings were to discuss the importance of controlling AWP, maintaining inflated AWP for their drugs and blocking efforts by Medicare/Medicaid to eliminate AWP as the reimbursement benchmark, all in an effort to increase their individual profits and market share at the expense of reimbursers and end payors for their drugs, including the Commonwealth and Pennsylvania Consumers.

952. Additional conspiratorial meetings, conferences, telephone and other communications were held between and among the defendants for the purpose of discussing the improper sales and marketing practices set forth above and throughout the Complaint.

Although these averments do not specify the dates and times of the alleged meetings, as the Commonwealth argues, a plaintiff is not required to plead the specifics of such contact, only that such contact occurred. Facts averring that two or more Defendants met to discuss taking action to ensure the continued use of inflated AWP by reimbursers tend to establish the existence of a combination in an alleged conspiracy. However, as the Commonwealth notes, citing *Baker v. Rangos*, 324 A.2d 498, 507 (Pa. Super. 1974), courts do not require minute detail in the pleading of such contact, but rather only allegation of facts that, if proven, would support an inference that defendants are acting together for an unlawful purpose. We believe the Amended Complaint satisfies this requirement.

The Defendants also argue that the Amended Complaint fails to allege facts showing that they acted with malice. However, the Complaint at paragraphs 953 and 954 avers that the Defendants acted with the intent "to injure reimbursers

and end payors of their drugs ... by causing them to pay artificially inflated prices ... ,” and that they acted “with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences.” These allegations are sufficient to satisfy the Commonwealth’s pleading requirements.⁸ Accordingly, we overrule this preliminary objection.

Standing

a. Can the Commonwealth bring a private action under the UTPCPL?

Section 9.2 of the UTPCPL, 73 P.S. §201.9.2, provides:

(a) Any **person** who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by any person of a method, act or practice declared unlawful by section 3 of this act, may bring a private action to recover actual damages or one hundred dollars (\$100), whichever is greater. The court may, in its discretion, award up to three times the actual damages sustained, but not less than one hundred dollars (\$100), and may provide such additional relief as it deems necessary or proper. The court may award to the plaintiff, in addition to other relief provided in this section, costs and reasonable attorney fees.

(Emphasis added.)

The Defendants contend that the Commonwealth’s statement in the Amended Complaint that it is seeking damages under this section “on behalf of ‘persons’ who have purchased” the drugs at issue, does not provide the

⁸ The Defendants also argue that the civil conspiracy counts fail because the Amended Complaint fails to state a cause of action for a common law tort. However, as we concluded above, the Amended Complaint does state a fraud/misrepresentation cause of action.

Commonwealth with the status of a “person” under Section 9.2 of the Law. Rather, the Defendants argue, the Commonwealth is acting as an employer or administrator with regard to the acquisition or reimbursement for the Defendants’ drugs, and cannot be said to have purchased the products for personal, family, or household purposes. The Commonwealth replies to this argument by noting that, unlike the case upon which the Defendants rely, *Balderston v. Medtronic Danek, Inc.*, 285 F.3d 238 (3^d Cir. 2002), its status arises not from its position as a business enterprise, but rather in its capacity as a representative of its constituents. Unlike the orthopedic surgeon in *Balderston*, who sought damages arising from his purchase of pedicle screws for his patients, the Commonwealth argues that its purchases of the Defendants’ products, in the case of PEBTF’s drug program, on behalf of current and retired employees, satisfy the statutory requirement that purchases be primarily for personal use.

While it is easy to agree that the Commonwealth’s ultimate purpose of buying the Defendants’ drugs is for the personal benefit of the end user, it is also easy to see that PEBTF’s drug program’s immediate purpose is not to acquire drugs for the personal use of its members, but rather the indirect benefit of purchasing in quantity in order to obtain a lower price on the Defendants’ drugs.

Nevertheless, the Superior Court’s reasoning in *Valley Forge Towers South Condominium v. Ron-Ike Foam Insulators, Inc.*, 574 A.2d 641 (Pa. Super. 1990), *affirmed*, 529 Pa. 512, 605 A.2d 798 (1992), persuades the Court that the Commonwealth’s representative capacity renders it a person under Section 9.2. That Court, in discussing the meaning of the word “person,” looked to the definition found in Section 2 of the Law, 73 P.S. §201-2, which describes a “person” to “mean[] natural persons, corporations, trusts, partnerships,

incorporated or unincorporated associations, and any other legal entities.” That definition is broad enough to encompass the entities involved here.

Second, in *Valley Forge Towers*, the Court rejected the defendant’s focus on the type of product involved. The Court reflected that the UTPCPL restricts suits not on the basis of the type of product, but rather the purpose of the purchase. Here, as in that case, the drugs are ultimately used for a personal, family or household purpose. The Court further rejected the defendant’s argument that the Law restricted business purchasers, such as the condominium manager in that case, from asserting claims under Section 9.2. The fact that the condominium manager acted in a representative capacity on behalf of the condominium owners when contracting and bringing suit persuaded the Court that the purchases at issue were nevertheless for one of those purposes listed in Section 9.2: “When a condominium association acts in its representative capacity on behalf of unit owners, it is the purpose of the unit owners’ purchases which controls for the purposes of the primary purpose restrictions of 73 P.S. §201-9.2.” 574 A.2d at 648. Based upon the foregoing, that the Commonwealth’s programs do qualify as “persons” under the UTPCPL, and that the purchases the programs made were for personal, family, or household use under *Valley Forge Towers*, we overrule the Defendants’ preliminary objection.

b. Does the Commonwealth have parens patriae standing?

The Defendants argue that the Commonwealth lacks *parens patriae* standing to pursue the alleged damages of individual consumers in Pennsylvania. The key to resolving this question is determining whether the Commonwealth has pleaded a quasi-sovereign interest rather than simply representing the interests of

individuals who could have pursued their own claims. A “state must assert an injury to what has been characterized as a ‘quasi-sovereign’ interest, which is a judicial construct that does not lend itself to a simple or exact definition.” *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982). In *Alfred L. Snapp & Son, Inc.*, the Supreme Court noted that states may have three types of interests: those purely sovereign, those non-sovereign, and those that are quasi-sovereign. The first type consists of the state’s power to develop and enforce civil and criminal codes, and the right to demand recognition from other sovereigns, such as might occur in a border dispute. The second type encompasses a state’s proprietary interests and its pursuit of the interests of private parties, in which case the state is only a nominal party. The third category, quasi-sovereign interests, “consist of a set of interests that the State has in the well-being of its populace.” 458 U.S. at 601-602.

As noted by the Court in that opinion, within the spectrum of interests that the Court has regarded as quasi-sovereign is included a state’s interest in the economic well-being of its people. 458 U.S. at 606 (quoting *Georgia v. Pennsylvania R. Co.*, 324 U.S. 439 (1945) (in which the state of Georgia had asserted that a large number of railroad companies had conspired to fix rates in a discriminatory way that violated federal antitrust laws)). The Court, while pointing out that a state claiming such standing must allege more “than injury to an identifiable group of individual residents[,]” also stated that “the indirect effects of the injury must be considered as well in determining whether the State has alleged injury to a sufficiently substantial segment of its population.” 458 U.S. at 607.

Even after recognizing this quantitative element in evaluating *parens patriae* standing, the Court in that case looked to Puerto Rico’s broader interest in

preventing residents from having to suffer the consequences of discrimination, and concluded that, even though there were only 787 job opportunities at issue (a number which could not have a substantial direct or indirect impact on the economy of Puerto Rico), Puerto Rico's significant interest provided it with *parens patriae* standing.

The Defendants do not suggest that the Commonwealth lacks *parens patriae* standing with regard to its claims for damages for Commonwealth drug programs, but only that it lacks such standing to pursue damage claims of individuals. With regard to these claims, the Defendants assert that the Commonwealth has nothing more than a nominal interest, and no interest rising to the level of one that is quasi-sovereign in character.⁹

Here, the Commonwealth contends that the Amended Complaint pleads its interest in the economic well-being of its populace as its source for its claim of *parens patriae* standing. According to the Commonwealth's reasoning, the fact that individuals could have pursued their own actions is not determinative of the question. Even in such cases, the Commonwealth may assert such claims if it has stated facts supporting its own interest in the economic well-being of the Commonwealth and its citizens.

⁹ As noted by the Commonwealth, one of the reasons an inflated AWP has a negative effect on people in the state is that the Commonwealth uses the AWP as a budgeting tool. Thus, had the Defendants not inflated the AWP the Commonwealth may have been better able to provide needed medications to more citizens than it has. Even if the inflated AWP did not affect the number of beneficiaries of the Commonwealth's programs could assist, the Amended Complaint makes clear the Commonwealth's position that the Defendants' inflated AWP affected the extent of benefits to which those covered under the Commonwealth's programs could claim entitlement.

However, as noted above, even if an individual could assert his or her own claim, thus rendering the Commonwealth in one sense a nominal party, if the Commonwealth has asserted its own quasi-sovereign interest, then the fact that individuals could pursue their own claims is irrelevant. The Amended Complaint does allege facts supporting the Commonwealth's position. The Complaint contends that the use of AWP's has affected the economic health and well-being of its citizens by requiring those purchasers and reimbursers of the Defendants' drugs to pay inflated amounts for the Defendants' drugs. Accordingly, we conclude that the Commonwealth has pleaded facts supporting its position that it has a quasi-sovereign interest in seeking damages under the UTPCPL.

Do the Doctrines of Filed Rate, State Action, or Federal Preemption Bar the Commonwealth's Claims?

a. Filed Rate Doctrine

The Defendants argue that the filed rate doctrine, common to practice in the public utility sector, also applies to the formulas used for reimbursement and co-payments under the Medicaid Part B and PACE programs. As the Defendants point out, the reasoning underlying the doctrine is that courts have less competence to address certain rate-making issues and should not undermine the rate-making process by interfering with administrative determinations. See *American Telephone & Telegraph Co. v. Central Office Telephone Inc.*, 524 U.S. 214 (1998).

Both parties refer to this Court's decision in *Ciamaichelo v. Independence Blue Cross*, 814 A.2d 800 (Pa. Cmwlth. 2002), *petition for allowance of appeal granted*, 574 Pa. 749, 829 A.2d 1158 (2003), in which the Court recognized the defending party, Independence Blue Cross, "[a]s a special

class of insurer ... subject to regulation by the Insurance Department, which must approve its rates, reserves, and surplus, as well as the investment of its reserves and surplus." 814 A.2d at 802. This simple sentence illustrates the distinction between the formula used in the case we are considering and those upon which the Defendants rely, including *Independence Blue Cross*. The extensive administrative framework involved in regulating the operation of rate-making for the utility and insurance sector is different from the administrative scheme developed for the social and governmental insurance programs at issue in this case. Unlike the insurance industry, no administrative agency can dictate to the Defendants the amount they may charge for their drugs. In contrast to the extensive hearings involving insurers and utilities in determining what formula will ensure that the providers of such services obtain a fair rate or return, none of the formulas at issue are devised to balance the needs of end users against the manufacturers' right to a fair rate of return. The function and effect of the rates developed for consideration of the filed-rate doctrine is for the protection of both the producer and end user. In this case, the formula adopted is for the purpose of reimbursement to providers. The formulas were adopted in part to encourage participation by intermediary purchasers, not to protect the interests of the drug manufacturers.

While we recognize the distinction the Defendants assert in their argument --- that the filed rate doctrine is implicated as a barrier to collateral attack on rate-making, rather than a means to bar an action against an individual defendant --- we can find no cases that have applied the doctrine to the type of reimbursement formulas at issue here. Accordingly, we reject this objection.

b. State Action

The Defendants argue that the doctrine of state action bars this litigation. As they note, the doctrine precludes litigation when a governmental action, however prompted by private parties' influence, is the direct cause of the harm a plaintiff alleges to have occurred. The Defendants quote a passage from 32 Pa. Bulletin 4864 (October 5, 2001), suggesting that the Commonwealth knew that AWP's were unreliable. The Defendants then assert that "[i]t was the Commonwealth and federal governments that affirmatively decided (with full knowledge of the public record) to make those AWP's the basis for government reimbursement and any co-payments." (Joint Brief, p. 52.) However, the issue of whether some Commonwealth entities affirmatively knew or merely suspected that the Defendants were submitting grossly inflated AWP's is essentially a question of fact, and we cannot at this juncture assume that the Commonwealth had a concrete grasp of the Defendants' conduct. The standard for the application of the doctrine recited by the Defendants above --- namely that the harm must be the direct result of the government's action --- cannot be addressed without reference to the question of the Defendants' alleged misrepresentation of the AWP. If the Commonwealth had a reasonable basis to rely on the AWP information the Defendants submitted, then we cannot say that the harm the Commonwealth alleges to have sustained was caused directly by its own action. Accordingly, we overrule this preliminary objection.

c. Federal Preemption

The Defendants contend that federal conflict preemption applies here to preclude the Commonwealth's claims arising under Medicaid. The Defendants

reason that federal law requires states joining in the Medicaid program to set reimbursements rates at a level high enough that a sufficient number of providers will participate in order to ensure coverage throughout the state to the target beneficiaries. The Defendants assert that, by virtue of the Amended Complaint, “the Commonwealth wishes to challenge the rates paid to Medicaid providers for drugs without any provision for examining how that challenge will affect the federal mandate for equal access to care and services.” (Joint Brief, p. 54.) Further, the Defendants assert that, because federal law requires drug manufacturers to pay rebates as a condition of having their drugs prescribed for Medicaid beneficiaries, the ultimate price states pay for the drugs is much lower than the prices states pay to providers based on AWP.

We note that, following argument in this case, the Defendants sought to remove this matter to the federal district court. The Commonwealth followed that action by filing a motion for remand with the federal court. On September 9, 2005, Judge Juan R. Sanchez of the federal District Court for the Eastern District of Pennsylvania, issued an order and opinion granting the Commonwealth’s motion, concluding that the federal court lacked jurisdiction over this case. *Commonwealth v. TAP Pharmaceutical Products, Inc.*, No. 2:05-cv-03604 (E.D. Pa. filed September 9, 2005). Based upon the federal court’s opinion, we reject the Defendant’s preemption argument. Further, even if the federal court had not had to address the issue, we agree with the Commonwealth that this issue is not one that we could have determined on the basis of preliminary objections. The issues require investigation into matters that warrant a greater evidentiary foundation. For these reasons we overrule this objection.

Additional Objections of Individual Defendants

a. Immunex

Defendant Immunex raises an objection under Pa. R.C.P. No. 1019(b) and demurrers to the Commonwealth's unjust enrichment, misrepresentation/fraud, and UTPCPL claims. The Amended Complaint groups Immunex with its parent corporation, Amgen, which the Commonwealth alleges owns a majority of Immunex stock and a controlling interest, and indicates that Immunex produces four specific subject drugs: Leukine, Leucovorin Calcium, Prokine, and Enbrel. The Commonwealth avers that Immunex, by virtue of its production of these drugs, engaged in the same conduct addressed above in our discussion of the arguments raised in the Joint Brief. We believe that that discussion adequately addresses the issues Immunex raised in its individual brief, and accordingly we overrule Immunex's preliminary objections.

b. Amgen

Amgen contends that the Amended Complaint fails under Rule 1019(b) and that, with regard to its drug Epogen, the factual averments fail to state a cause of action because they do not create any inference of fraud on the part of Amgen. Initially, for the reasons above, we reject Amgen's general argument that the Amended Complaint fails under Rule 1019(b). Further, the Amended Complaint avers sufficient facts with regard to the Commonwealth's misrepresentation claim. Amgen argues that a report upon which the Commonwealth relies is outdated and pertains to its drug Epogen in relation to Medicaid Part B reimbursements. That report, Amgen contends, had nothing to do with AWP-based reimbursement. The Commonwealth does not concede that AWP

plays no role in reimbursements for Epogen. Factual issues obviously exist, and we cannot as a matter of law conclude that the Commonwealth will not be able to establish its case. We will overrule Amgen's objections at this point of the proceedings.

c. Dey, Inc.

Dey, Inc.'s arguments have been primarily addressed in our discussion of the issues raised in the joint brief. Dey also relies upon orders of the district court in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp. 172 (D. Mass. 2003), granting a motion seeking dismissal under the federal rules for failure of the plaintiff there, the Commonwealth of Massachusetts, to list the AWP's for each drug at issue. However, the trial judge in that order apparently based her decision in part on the fact that Massachusetts's pleadings did not aver whether the Defendants communicated AWP or WAC, and to whom they communicated such information. Clearly the Commonwealth's Amended Complaint specifically refers to inflated AWP's that the Defendants allegedly communicated to the publishing compendia. Again, for the reasons stated earlier, we overrule Dey Inc.'s objections.

d. Schering-Plough

Schering-Plough argues that the Amended Complaint fails to plead sufficient factual averments, and that the Commonwealth failed to have the proper representative verify the Complaint in violation of Pa. R.C.P. Nos. 1024(c), (e) and 1002. The Court's docket reveals that the Commonwealth has corrected the verification defect, and our discussion above addresses the specificity argument. Accordingly, we overrule Schering-Plough's preliminary objections.

e. Bristol-Myers Squibb

Bristol-Myers Squibb, relying on an affidavit it submitted to a state court in Arizona, asserts that the Commonwealth wrongly avers that it submitted inflated AWP's to the pricing compendia. Rather, Bristol-Myers Squibb states that it reported wholesale list prices from which the compendia develop AWP's. However, whether another entity is ultimately responsible for the allegedly inflated AWP's reported in the compendia is a question of fact that we cannot address at this stage of the proceedings. Further, the Commonwealth claims that Bristol-Myers Squibb unlawfully gained from not only the use of spreads but other means as well. Bristol-Myers Squibb also asserts that the Amended Complaint fails to aver sufficient facts in support of the Commonwealth's misrepresentation/fraud claim, relying upon the same order of the federal district court to which Defendant Dey referred. For the reasons stated above in relation to that Defendant, we overrule Bristol-Myers Squibb's preliminary objections.

f. Johnson & Johnson

The Johnson & Johnson-related Defendants argue that the Court should sustain their preliminary objections because the Amended Complaint lacks sufficient specific averments regarding the individual Johnson & Johnson companies named as defendants and the drugs they manufacture, distribute, market, and sell. Johnson & Johnson contends, as did all the Defendants in the Joint Brief, that the Commonwealth fails to aver facts regarding the conduct of each company within the group. However, the Amended Complaint does connect each drug with the particular company within the sub-groups responsible for the

drug. Where the averments pertain to Johnson & Johnson as a whole, the Complaint indicates that all of the companies within the group engaged in the same conduct. As we discussed above, while the Rules of Civil Procedure do require specificity, the averments, taken as a whole, minimally satisfy the Rules. While the Johnson & Johnson Defendants argue, for example, that the Amended Complaint fails to state a cause of action for fraud with regard to epoetin alfa, because the paragraphs in the Complaint that refer specifically to this drug do not include any averment of fraud as to this drug, a later paragraph does allege that Johnson & Johnson “created promotional materials and worksheets to allow them to market the spread” Based on the foregoing and our discussion above of the arguments made in the Joint Brief, we overrule the objections.

g. Pharmacia

At the outset, for the reasons provided in our discussion of the arguments Defendants made in their Joint Brief, we reject Pharmacia’s objections under Pa. R.C.P. No. 1019. Pharmacia further argues that we should sustain its objection to the inclusion in the Amended Complaint of Pharmacia physician-administered drugs, asserting that the claims in paragraphs 472-474 do not allege specific misconduct on the part of Pharmacia (or Pfizer, Pharmacia’s parent company). However, a review of the averments in the sub-parts of the Amended Complaint setting forth the Commonwealth’s unjust enrichment, fraud/misrepresentation, and UTPCPL claims include additional averments that, as discussed above, state causes of action against Pharmacia. Accordingly, we overrule Pharmacia’s preliminary objections.¹⁰

¹⁰ We overrule Pfizer’s preliminary objections on the same grounds.

h. SmithKline Beecham (d/b/a GlaxoSmithKline or GSK)

GSK argues that the Amended Complaint lacks specificity as to certain of its drugs. We agree with the Commonwealth's response that the averments are sufficient to provide GSK with notice of the Commonwealth's claims to enable GSK to prepare a defense as to all of the drugs the Commonwealth alleges GSK unlawfully sought to market and sell.

GSK also seeks an order of the Court striking material in the Amended Complaint it claims is scandalous or impertinent. In *TAP I* we cautioned the Commonwealth not to include such material in an amended complaint. GSK provides examples of material it believes is impertinent or scandalous: (1) reference to a federal civil settlement involving GSK in the "best price" case; (2) the use of words such as "implicate," "admitted," "evidence," and "demonstrate" in a context that GSK essentially asserts creates a negative connotation; and (3) a reference to a civil settlement which the Commonwealth averred included an agreement to resolve a federal criminal investigation. While we can understand GSK's concern that reference to such matters could influence this Court's perception of the matters presented, we do not believe they constitute impertinent and scandalous materials under the Rules. Further, as we said in the first opinion, the members of the Court are quite able to sort through pleadings, including those that lack relevance to the pleadings and are hyperbolic in nature. We do not believe the measure of striking the materials cited is necessary. Accordingly, we overrule GSK's objections.

i. Aventis

Aventis raises issues similar to those GSK has raised, particularly concerning allegedly scandalous or impertinent material. We believe our discussion in response to GSK's objections answers the objections Aventis has raised, and accordingly, we overrule its objections.

j. Bayer and Bayer AG¹¹

Bayer, relying upon a 2001 AWP settlement agreement¹² between itself and the Commonwealth, argues that the agreement bars all of the Commonwealth's claims against Bayer, at least with regard to the drugs that were the subject of the agreement.¹³ Bayer relies upon the following language of the release the Commonwealth signed in the agreement which covered "any civil or administrative monetary claim, action, suit or proceeding the [Commonwealth] has or may have under any source of law for the Covered Conduct." (State Settlement Agreement, Part III(2)). The Amended Complaint names all of the six drugs noted above that the Settlement Agreement covers. The Agreement covered conduct predating the Agreement, and the Agreement required Bayer to submit to the Commonwealth average sales prices, or ASPs, following the effective date of the Agreement. Thus, Bayer asserts that its release of the ASPs during the post-settlement period vitiates any claim the Commonwealth might otherwise have

¹¹ By order this Court earlier deferred consideration of Bayer AG's preliminary objection as to personal jurisdiction.

¹² Bayer AG, in a separate brief, joins in its parent company's arguments regarding the Settlement Agreement. Although Bayer AG is not listed as a party signing that Agreement, the Agreement includes Bayer and its subsidiaries.

¹³ Those drugs are: Koatec, Kogonate, Konyne-80, Gamimune N 5%, Gamimune N 10%, and Thrombate III.

concerning alleged deception caused by published AWP's for the same post-Settlement period. The Commonwealth responds to this argument by asserting that the Settlement Agreement does not release the Commonwealth's *parens patriae* or non-Medicaid claims. The Commonwealth also cites Part III(2) of the Agreement, which provides that, in return for payment under the Agreement, the [Commonwealth] **(on behalf of itself, its officers, agents, agencies and departments)** agrees to release Bayer" Further, the Commonwealth argues that the phrase "Covered Conduct," as used in the Agreement includes only claims involving Medicaid fraud.

Initially, of course, our consideration of this objection is limited to the six drugs the Agreement encompasses. Second, the Commonwealth does not apparently dispute that the Agreement does resolve its claims arising from these particular drugs with regard to the period covered by the Settlement Agreement, namely January 1993 through August 1999. (Settlement Agreement, Part II (C).) Hence, the questions remaining concern whether the Agreement forecloses (1) any claims other than Medicaid, (2) any claims arising after that latter date of August 1999, considering that Bayer asserts that it began to forward ASP information to the Commonwealth in 2001 (thus placing in question the claims arising between August 1999 and 2001 and onward), and (3) any claims in the state's capacity as *parens patriae*.

Defendants point to a decision of a Nevada state court wherein the state of Nevada sought to bring an action against Bayer following the signing of the Settlement Agreement. The Nevada court decision does conclude that that the "Covered Conduct" encompasses the *parens patriae* claims and also includes all

claims in addition to the Medicaid claim. *State of Nevada v. Abbott Laboratories, Inc.*, No. CV02-00260 (Washoe County Ct., December 13, 2004).

However, we are inclined to overrule part of Bayer's objection. We note initially that Part II (B) of the Settlement Agreement states, "[the Commonwealth] contends that Bayer caused to be submitted claims for payment to the state's Medicaid Program, established by Title XIX of the Social Security Act." Part II(D) of the Agreement states, "[the Commonwealth contends that it has certain administrative claims against Bayer for administrative and monetary penalties under state and federal law for the Covered Conduct." Bayer argues that this language does not encompass the claims the Commonwealth brings in its Amended Complaint. The record before us does not really flesh out what the term "administrative claims" means. That expression could mean something related to administrative claims arising from the Medicaid program, the "Covered Conduct" defined in Part II(C)(i-iv). All of those subparagraphs specifically refer to conduct relating to the Medicaid program. Contrary to the conclusion of the Nevada court, we conclude that, because the term "Covered Conduct" pertains solely to Medicaid claims, the reference in Part II(D) to administrative claims "for the "Covered Conduct" must limit the terms of the Commonwealth's release to claims solely arising under the Medicaid program. As to the terms of Part III(3), pertaining to the Commonwealth's release of claims, again, that paragraph releases all claims concerning the "Covered Conduct," (which as noted above is limited to Medicaid claims), except those claims encompassed by the "Covered Conduct" specifically listed in Part III(6). Accordingly, we agree with the Commonwealth that the Commonwealth's claims arising from other programs are not barred.

As to the question of whether the Agreement bars the Commonwealth's parens patriae claim as to Medicaid, as discussed above, the Commonwealth in acting in a parens patriae capacity is acting in a quasi-sovereign capacity. We conclude that, although the Commonwealth, as parens patriae, is acting for the benefit of the citizens of the Commonwealth, the claim nevertheless belongs to the Commonwealth alone. Therefore, the exceptions to the release of the Medicaid "Covered Conduct" do not include the Commonwealth's parens patriae claims. Accordingly, we sustain that part of Bayer and Bayer AG's preliminary objection as to the Commonwealth's Medicaid claims, including that asserted in its capacity as parens patriae, and as indicated above, only as to the six drugs encompassed in the Settlement Agreement.

We overrule Bayer's preliminary objection to the Complaint under Paragraphs 10 and 11 of the Settlement Agreement, R.C.P. No. 1019.

k. AstraZeneca

Two of the AstraZeneca Defendants, AstraZeneca PLC and Zeneca Holdings, preliminarily object, contending that the Court lacks both general and specific jurisdiction over them. The Commonwealth suggests that, in light of our order deferring consideration of the question of whether the Court has personal jurisdiction over Bayer AG until after the resolution of the other preliminary objections, we should also defer consideration of these Defendants' personal jurisdiction arguments. The Commonwealth asserts that it has not yet engaged in discovery for jurisdictional purposes with regard to these Defendants because the Commonwealth only recently named one, Zeneca Holdings, as a Defendant, and the other, AstraZeneca PLC, is a foreign corporation that was not served until after

briefing on the objections to the Original Complaint. Further, the Commonwealth argues that the Court should permit it to conduct discovery limited to the issue of personal jurisdiction over these Defendants. Under the circumstances, the Court shall defer consideration of these AstraZeneca Defendants' preliminary objections on the basis of personal jurisdiction, to provide the Commonwealth an opportunity to engage in discovery on this issue. As with Bayer AG, the Court will issue a briefing and argument schedule on the issue following the issuance of the order in this case. We reject the objections to the Amended Complaint alleging failure of pleading under Pa. R.C.P. No. 1019, for the reasons related above.

l. TAP¹⁴

Relying upon a federal court injunction, TAP argues that the pending multi-district federal Lupron litigation bars consideration of the claims the Commonwealth brings on behalf of other programs and its parens patriae claim. The injunction appears to bar any class member from initiating, continuing in, or prosecuting any Lupron-related claim in another court. However, the Commonwealth asserts it has opted out of the Lupron federal class action lawsuit. Further, as noted above, the federal district court rejected the Defendants' attempt to remove this case to federal court by granting the Commonwealth's motion for remand to this Court. *Commonwealth v. TAP Pharmaceutical Products, Inc.*, No. 2:05-cv-03604 (E.D. Pa. filed September 9, 2005). Finally, for the reasons stated above, we reject the objection TAP raises under Pa. R.C.P. No. 1019.

¹⁴ We note that the Commonwealth settled all Medicaid-related Lupron claims in a Settlement Agreement signed in 2001. Accordingly, the Commonwealth is not asserting such claims in this action.

m. Abbott

Abbott first argues that we should dismiss the Commonwealth's Amended Complaint because it fails to satisfy Pa. R.C.P. No. 1019. In arguing the failings of the Amended Complaint, Abbott stresses that one of the components of the Commonwealth's claims is that the purpose of the Defendants' conduct was to increase market share, and hence the Commonwealth needed to plead specific facts regarding drugs that allegedly competed with Abbott's drugs. While the Commonwealth will have a burden to establish how competition was the underpinning of the conduct at issue, we do not believe that the Commonwealth was required to plead facts regarding Abbott's drugs' competition. The absence of such information will not hamper Abbott's defense against the Commonwealth's claims. Nor has Abbott persuaded the Court that the absence of specifics regarding actual spreads for particular drugs and free goods and drug products will impair its ability to defend against the claims in the Commonwealth's Amended Complaint. Accordingly, the objection as to specificity is overruled.

Abbott also objects to the Commonwealth's claims under Medicare Part B for multiple source drugs.¹⁵ Abbott claims that the Commonwealth's theory for recovery under Medicare Part B is economically unfeasible. Abbott describes the reimbursement formula (which apparently reflects the fact that prescribers and consumers may in some circumstances elect a more expensive, though identical drug) as follows:

For multiple source drugs the Medicare allowable amount is 95% of the lesser of: (1) the median AWP for all sources of the

¹⁵ Although not defined in the pleadings, we infer multi-source drugs are identical drugs available through name brand or generic sources.

generic forms of the drug; and (ii) the lowest AWP of the brand name form of the drug. 42 C.F.R. §405.517. Medicare pays 80% of the allowable amount, i.e., either 80% of the provider's actual charges or 80% of 95% of the median AWP or lowest AWP of the "brand-name" multiple-source drug. The Medicare beneficiary then pays the remaining 20% as a co-payment.

(Abbott Brief, p. 6.)

Abbott provides a helpful illustration at page 6 of its Brief:

If, for example, five companies manufacture the drug, then the Medicare reimbursement will be based on the median AWP of that drug. Therefore, if the AWPs of the five manufacturers' formulations of the drug are \$3, \$5, \$7, \$8, and \$50, then the reimbursement will be based on an AWP of \$7. Regardless of how much any company increases the AWP for its own product, all five products will be reimbursed under Medicare Part B on the *same* AWP, either the lesser of the median AWP for the five products (in this case \$7) or the lowest AWP of the "brand-name" drug. Thus, no manufacturer could gain a competitive advantage by raising the AWP of a multi-source drug, as all forms of the drug are always reimbursed at the same rate.

This example does suggest that Abbott would have no incentive to inflate the AWP with regard to this program. However, because we are at the pleading stage, we must conclude that the example, while persuasive, is not conclusive at this point in the proceedings. Accordingly, we reject this objection.

Abbott's last individual objection pertains to the interrelationship between TAP and Abbott.¹⁶ Abbott contends that the Amended Complaint fails to plead facts sufficient to establish liability of Abbott for TAP's conduct. Abbott contends that if the Commonwealth is seeking to recover from Abbott for the

¹⁶ TAP is a subsidiary of Abbott.

conduct of a subsidiary company, it must allege facts sufficient to pierce the corporate veil. However, the Commonwealth responds by saying, “[t]he Amended Complaint alleges that Abbott participated with TAP in marketing Lupron and Prevacid, not that Abbott is liable by virtue of its ownership of TAP. Therefore, the Amended Complaint need not allege facts sufficient to prove veil piercing.” (Commonwealth’s Brief, p. 22.) Because the Commonwealth is apparently not seeking to recover in this regard, we also overrule this preliminary objection.

Summary of Disposition

Based on the foregoing, we overrule the Defendants’ preliminary objections, with the exceptions noted as follows: (1) deferral of Bayer AG’s, AstraZeneca PLC’s, and AstraZeneca Holdings’ preliminary objection as to personal jurisdiction, and (2) sustaining the preliminary objection of Bayer and Bayer AG as to the Commonwealth’s *parens patriae* claims involving the specific drugs listed in footnote 13.

JAMES GARDNER COLINS, President Judge

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania :
by Gerald J. Pappert, in his capacity :
as Attorney General of the :
Commonwealth of Pennsylvania, :
Plaintiff :

v. :

TAP Pharmaceutical Products, Inc.; :
Abbott Laboratories; Takeda Chemical :
Industries, LTD.; AstraZeneca PLC; :
Zeneca, Inc.; AstraZeneca :
Pharmaceuticals LP; AstraZeneca :
LP; Bayer AG; Bayer Corporation; :
GlaxoSmithKline, P.L.C.; SmithKline :
Beecham Corporation; :
Glaxo Wellcome, Inc.; Pfizer, Inc.; :
Pharmacia Corporation; Johnson & :
Johnson; Amgen, Inc.; Bristol-Myers :
Squibb Company; Baxter International :
Inc.; Aventis Pharmaceuticals, Inc.; :
Boehringer Ingelheim Corporation; :
Schering-Plough Corporation; Dey, Inc., : No. 212 M.D. 2004

Defendants: :

ORDER

AND NOW, this 3rd day of November 2005, upon consideration of
the Defendants' preliminary objections to the Amended Complaint we hereby:

(1) Sustain the preliminary objection of Bayer and Bayer AG as to the
Commonwealth's *parens patriae* claims involving the drugs Koatec, Kogenate,
Konyne-80, Gamimune N 5%, Gamimune N 10%, and Thrombate III;

(2) Defer consideration of the personal jurisdiction objections of Bayer AG, AstraZeneca PLC and AstraZeneca Holdings;

(3) Overrule the Defendants' remaining preliminary objections;

(4) With the exception of those Defendants for which the Court must still resolve the question of personal jurisdiction, direct the Defendants to file an answer to the Complaint within thirty days of this order; and

(5) Direct the Chief Clerk to establish a briefing schedule for the remaining Defendants who have filed preliminary objections raising lack of personal jurisdiction as a defense.

JAMES GARDNER COLINS, President Judge

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