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April 13, 2006

Judith A. Coleman
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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 Reply Brief In Support Of Its Motion To Compel Novartis Pharmaceuticals Corporation To Answer One Interrogatory and Produce Certain Documents.

This document is filed under seal.

By copy of this letter this document is being served on local Wisconsin counsel via U.S. Mail, and on the Honorable William F. Eich via e-mail and U.S. Mail..

Thank you in advance for your assistance.

Sincerely,

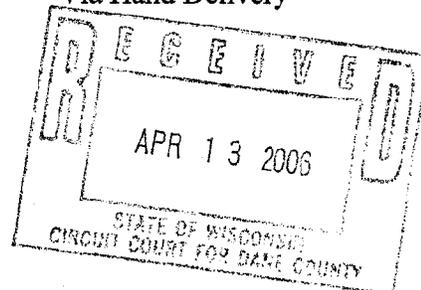
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Cc: Hon. William F. Eich
Local Wisconsin Counsel

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Novartis's knowledge that its reported prices were higher than the true prices. The documents at issue are therefore highly relevant to the central allegations in the State's First Amended Complaint.

The State may make many different uses of Novartis's internal calculations and reports while preparing this case for trial including: (1) using them as exhibits at depositions; (2) providing them to the State's expert witnesses for review and consideration in formulating their opinions, including a determination of the true prices of Novartis's drugs and the State's damages; or (3) formulating additional written discovery requests. Ultimately, the State may move to admit some or all of the documents into evidence. But the admissibility of the documents is not the issue in this discovery dispute. Rather, the issue is whether, under Wisconsin's principle of liberal and open pretrial discovery, these calculations and reports are reasonably calculated to lead to the discovery of admissible evidence. Plainly they are.

In Part I of this brief, the State summarizes the pricing terminology, the role played by wholesalers in the distribution channel for the pharmaceutical industry, and the State's allegations in this case. In Part II, the State describes the legal standard applicable to this motion, demonstrating that Novartis bears the burden of establishing that the State is not entitled to the documents at issue. In Part III, the State refutes Novartis's argument that the documents are not responsive to the State's discovery requests. Finally, in Part IV, the State demonstrates that Novartis's documents are reasonably calculated to lead to the discovery of admissible evidence. The State further demonstrates that even if the Court were to conclude that there is a good faith dispute about the relevance of these documents (which there is not), because Novartis has made no argument, much less showing, that production of the documents would be burdensome (nor that the documents are privileged), the documents should be produced.

Novartis should not be permitted to impose its own, narrower definition of relevance on the State.

I. Background

Novartis, like other defendants, sells its drugs to a variety of purchasers. Among these purchasers are wholesalers. Wholesale acquisition cost (“WAC”) is the price paid *by* wholesalers to Novartis for its drugs, net of all discounts, rebates and other price adjustments or incentives. Wholesalers in turn sell Novartis’s drugs to a variety of purchasers, including Medicaid and Medicare providers (pharmacies, doctors, etc...). Average wholesale price (“AWP”) is the average price paid *to* wholesalers inclusive of all discounts, rebates and similar price adjustments or incentives. In some instances, the sales by wholesalers are made at a price set by contract between Novartis and the providers. In other instances, the wholesaler sells the drug at a price equal to its acquisition cost plus a markup.

The State alleges that Novartis knows the true WACs and AWP for its drugs but reports false and inflated ones. Amended Complaint, ¶ 44. The State further alleges that Novartis provides a variety of off-invoice price reductions such as rebates, discounts, and chargebacks which reduce the real net price of its drugs. *Id.* At ¶ 48. Accordingly, although an invoice that Novartis sends to a wholesaler may reflect a price that Novartis calls “WAC,” the true price paid by the wholesaler is in fact less. As demonstrated below, Novartis admits that its internal calculations and reports contain and are based on: (1) total sales (which Novartis prefers to call “revenue”) which is the product of price times units; (2) various deductions that lower the true prices (which Novartis prefers to call “net revenue”); and (3) total units. The calculations and reports therefore bear on the true prices of Novartis’s drugs and Novartis’s knowledge that the prices it reported to the pricing compendia were false and inflated.

II. Novartis Bears the Burden of Demonstrating That Its Internal Calculations and Reports Are Not Likely to Lead to the Discovery of Admissible Evidence

Wisconsin law reflects a principle of liberal and open pretrial discovery. *Ambrose v. General Cas. Co. of Wisconsin*, 156 Wis.2d 306, 314-15, 456 N.W.2d 642, 645 (Wis. App. 1990) (citing *State ex rel. Dudek v. Circuit Court*, 34 Wis.2d 559, 585-86, 456 N.W.2d 642, 645 (1967)); see also *Ranft v. Lyons*, 163 Wis.2d 282, 290, 471 N.W.2d 254, 257 (Wis. App. 1991) (referring to the scope of permissible discovery under Wisconsin law as “expansive”). Pursuant to Wis. Stat. § 804.01(2)(a):

Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action, whether it relates to the claim or defense of the party seeking discovery or to the claim or defense of any other party, including the existence, description, nature, custody, condition and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. . . .

Wis. Stat. § 904.01 defines “relevant evidence” as “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” However, “what is relevant in discovery is different from what is relevant at trial, in that the concept at the discovery stage is much broader.” *Flora v. Hamilton*, 81 F.R.D 576, 578 (M.D.N.C. 1978). As Wis. Stat. § 804.01(2)(a) provides:

It is not ground for objection that the information sought will be inadmissible at the trial if the information sought appears *reasonably calculated to lead to the discovery of admissible evidence*. (Emphasis added)

Accordingly, even if Novartis’s internal calculations are not admissible evidence (an issue the court need not resolve unless and until a party moves for their admission), they must nevertheless be produced if they are likely to lead to the discovery of admissible evidence.

Faced with the State's assertion that the internal calculations and reports are responsive to the State's discovery requests and reasonably calculated to lead to the discovery of admissible evidence, Novartis should have moved for a protective order pursuant to Wis. State 804.01(3)(a), which provides:

Upon motion by a party or by the person from whom discovery is sought, and for good cause shown, the court may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . .

Had Novartis done so, it would have had the burden of demonstrating "good cause." Rather than moving for a protective order, Novartis engaged in self-help – it simply refused to produce the documents. The State was therefore forced to file a motion to compel. This does not, as Novartis argues, shift the burden to the State. Novartis's burden is no less than if it had moved for a protective order. It must overcome the presumption in favor of broad discovery and demonstrate that the documents are not reasonably calculated to lead to the discovery of admissible evidence. *See Gober v. City of Leesburg*, 197 F.R.D. 519, 521 (M.D.Fla. 2000) (finding, in the context of a motion to compel where the opposing party did not move for a protective order, that the party resisting production bears the burden of establishing lack of relevancy); *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc.*, 132 F.R.D. 204, 212 (N.D.Ind. 1990) (where party moved to compel production of documents, the party opposing discovery has the burden of showing that lack of relevance); *Josephs v. Harris Corp.*, 677 F.2d 985, 992 (3d Cir. 1982) (where party moved to compel answers to interrogatories, "the party resisting discovery must show specifically how . . . each interrogatory is not relevant"); *Burke v. New York City Police Dept.*, 115 F.R.D. 220, 224 (S.D.N.Y. 1987) (the party resisting production must demonstrate that the requested documents or information do not come within the broad

scope of relevance under the Federal Rules of Civil Procedure);¹ *Flor*, 81 F.R.D at 578 (“the burden of showing that the requested discovery is not relevant to the issues in the case is on the party resisting discovery.”).

Before showing that Novartis has failed to meet this burden, the State first addresses Novartis’s argument that the documents are not responsive to the State’s discovery requests.

III. Novartis’s Internal Calculations Are Responsive to the State’s Discovery Requests

There can be no serious dispute that the reports and internal calculations about which Mr. Rosenthal testified are responsive to the State’s discovery requests. Interrogatory No. 1 asks whether Novartis has ever calculated a “unit price, average sales price, aggregate sales figure, or other numerical price or sales figure . . . net of any or all Incentives.” Document Request 4 requests production of any such calculations. Mr. Rosenthal, Novartis’s Vice President for Finance and Administration, testified that although there is not a defined name for the internal calculations, they are referred to as “net sales, per unit,” “net price,” and “net revenue per unit.” Rosenthal Deposition Tr. at 140, 144-45 (attached as Exhibit 7 to the Memorandum in Support of the State’s Motion to Compel).

Although Novartis argues that the State is “cherry-picking” from Mr. Rosenthal’s testimony but avoiding the substance of it, it is Novartis that seeks to obfuscate the record. First, Novartis spins the facts, ignoring the data components that go into these calculations and focusing solely on the final figure. Because, according to Novartis, the final figure is not an “average price,” but rather profit per unit, the reports and calculations are not responsive. Initially, as the State demonstrated in its opening brief, whether these or any other calculations

¹ Like Wis. Stat. § 804.01(2)(a), the Federal Rules of Civil Procedure similarly provide that “[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party” and that “[r]elevant evidence need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26(b)(1).

are responsive to the interrogatory does not depend on the internal name assigned by Novartis, even if that name were accurate. Moreover, Mr. Rosenthal's deposition testimony and recent affidavit confirm, rather than refute, that among the data components that are used in these calculations are gross sales (which Novartis and Mr. Rosenthal prefer to refer to as "revenue"), "price deductions," Opposition,² at 6 (emphasis added),³ which include many of the items falling within the State's discovery request's definition of "Incentives," (e.g., rebates, discounts, chargebacks, allowances), and total units sold. Clearly, these calculations are "numerical price or sales figure[s] . . . net of any or all Incentives."

Next, Novartis argues that these calculations do not reflect the actual price paid by any single purchaser, and therefore are not responsive to the State's discovery requests. Opposition, at 14. This argument is at best misguided and at worst intentionally misleading and should be rejected. Novartis certainly knows that the discovery requests at issue do not ask for the actual price paid by an individual purchaser; rather, they seek information and documents regarding averages, *i.e.*, total sales, net of Incentives, per unit. The internal calculations described by Mr. Rosenthal comprise or contain this information.

Finally, Novartis argues that these internal calculations are not responsive to the State's discovery requests based on the subparts of Interrogatory Number 1. This argument is disingenuous. First, Novartis cites to subpart (b), which asks Novartis to identify "the applicable class(es) of trade for which each determination was made." Because, according to Novartis, the calculations are not performed for any specific class of trade but for *all* classes of trade, the calculations are not responsive. Opposition, at 10-11. Second, Novartis cites to subpart (g),

² "Opposition" refers to Novartis's "Memorandum in Opposition to Plaintiff's Motion to Compel Novartis Pharmaceuticals Corporation to Answer One Interrogatory and Produce Documents."

³ See also, Rosenthal Affidavit (attached to Novartis's Opposition), ¶¶ 7-8 (referring to "price reductions") (emphasis added).

which asks whether Novartis disclosed any of the calculations described in the interrogatory to any publisher, customer, or governmental agency. Novartis contends that because the internal calculations contain “highly sensitive and competitive information,” and therefore would not be disclosed to such entities, they are not within the scope of the State’s discovery requests. *Id.* at 11. Novartis’s argument is non-sensical. If Novartis performs the calculations for all classes of trade, or if it does not disclose such calculations, it should simply so state in its answers to subparts (b) and (g). But its answers to these subparts have no bearing on whether the calculations themselves are responsive to the main portion of the interrogatory that precedes the subparts.⁴

IV. Novartis’s Internal Calculations Are Likely to Lead to the Discovery of Admissible Evidence Relating to the Central Issues in This Litigation

Novartis’s internal calculations and reports are reasonably calculated to lead to the discovery of admissible evidence relating to the two central issues in this litigation: (1) the true prices, net of Incentives, of Novartis’s drugs; and (2) Novartis’s knowledge that the WACs and AWP’s it reported to the pricing compendia were false and inflated.

Novartis’s central argument in opposition to the State’s motion to compel is that its internal calculations of net revenue “bear[] no relation to the price that any purchaser of Novartis’ products pays to any seller.” Opposition, at 7. But of course they do. The starting point for these calculations is what Novartis has been paid for its drugs. This is the product of quantity times price. Novartis does not dispute, indeed Mr. Rosenthal’s recent affidavit confirms, that Novartis sells its drugs to a variety of purchasers, including wholesalers and retail chain warehouses at a price designated as wholesale acquisition cost (“WAC”). Rosenthal

⁴ Moreover, it is precisely because these reports and calculations are not disclosed to publishers, customers, or governmental agencies that they *are* relevant to the State’s claims, as the State alleges that Novartis knew (and knows) the true average prices of its drugs but reported (and continues to report) WACs and AWP’s that are false and inflated.

Affidavit, ¶ 6 (“Novartis sells its drugs to wholesalers at a price called the Wholesale Acquisition Cost (the ‘WAC’), which Novartis internally refers to as ‘ex-factory cost.’”). Nor does Novartis dispute that the next step in the calculations is to subtract various “*price* reductions.” Among these deductions are “allowances,” “rebates,” “discounts,” and “chargebacks.” *Id.* ¶ 7 (“all discounts, chargebacks, rebates, allowances, and other forms of *price* reductions are subtracted from the WAC for a specific drug when Novartis calculates the ‘net revenue.’”) (emphasis added). Plaintiff’s complaint specifically alleges that Novartis has reported false WACs because, among other things, the reported WACs do not take into account off-invoice reductions for “rebates,” “discounts,” and “chargebacks” (*see* Amended Complaint, ¶ 48), terms which are specifically identified in the State’s definition of “Incentives” in its discovery requests. Finally, it is undisputed that these calculations identify the quantity or units of product sold. Rosenthal Deposition Tr., at 140, lines 5-8.

Novartis nevertheless contends that “neither the price wholesalers pay nor the price they charge is changed by many of the deductions Novartis accounts for . . . in determining how much revenue is left for *it*.” Opposition at 3, n.3 (emphasis in original). Notably, Novartis chooses its words carefully, asserting only that the prices wholesalers pay and the prices they charge are unaffected by “many” rather than “all” of the deductions that Novartis takes into account.⁵ Novartis is therefore conceding, as it must, that at least some of the deductions do change the net price paid or charged by wholesalers. And in any event, the State may ultimately disagree with Novartis about the affect of the other deductions on the prices that wholesalers pay or charge for Novartis’s drugs. The State is therefore entitled to review the calculations and reports themselves. Indeed, the various deductions from gross sales are likely broken out by category,

⁵ Novartis is apparently referring to deductions such as returned product and subsidies to senior citizens and uninsured patients.

rather than lumped together. This would make economic and business sense – as Novartis, like any prudent company, surely wants to know how each deduction affects its bottom line so that it may make rational business decisions about how to become more profitable.⁶ Furthermore, to the extent that Novartis believes that some of the deductions it takes into account in this context do not affect the final price or cost of its products to its customers, these will be identified and quantified in further discovery, and offered by Novartis as part of its defense, if appropriate, to the State’s calculation of the true prices. But it is premature at this stage of the litigation, and particularly before the State has even seen these reports, for the court to decide which of the deductions are properly included or excluded in the determination of the true prices paid or charged by wholesalers.

Novartis’s final argument is that it does not “control” the prices charged by wholesalers. Opposition at 6, n.7. Initially, to the extent that Novartis has contracts with purchasers that set the price and require the purchasers to buy the drugs through a wholesaler, which Novartis concedes (Rosenthal Affidavit, ¶ 7), Novartis does in fact control the price. And to the extent that Novartis has no such contracts or otherwise is not directly involved in the sale from a wholesaler to a purchaser and ultimately proves that it does not “control” the price, this is beside the point. As Novartis well knows, regardless of whether Novartis directly “controls” the prices charged by wholesalers, the core of the State’s complaint is that Novartis *knows* the prices charged by wholesalers and yet reports AWP’s that are higher. At this stage of the proceedings,

⁶ That such deductions are likely broken out by category is supported by the format in which the reports and calculations are contained – Microsoft Excel spreadsheets. These spreadsheets should be produced in their original form, with all internal formulae and references and values, and with such information as is required to overcome any security measure which may have been applied to them. Plaintiff is also entitled to any documents utilized by Novartis in preparing the reports and making the calculations, and whatever variables to which those spreadsheets may refer in the ordinary course of business.

the State is not required to prove these allegations, nor refute Novartis's assertions to the contrary, in order to obtain relevant information and documents through discovery.

For these reasons, it is clear that these internal calculations and reports are reasonably calculated to lead to the discovery of admissible evidence. They should therefore be produced. However, even if the Court were to conclude that there is a good faith dispute about this issue (which there is not), because Novartis makes no argument, nor showing, that production of the documents would be burdensome (nor that the documents are privileged), the documents should still be produced. The State and Novartis may, indeed likely do, disagree about the relevance of the information contained in these reports to the State's claims. But at this stage of the proceedings, the appropriate way to resolve this dispute is to require production of the documents, and allow the parties to argue about admissibility if and when it arises.⁷ To do otherwise would deprive the State of its right to prepare for trial using its own theory of the case and allow Novartis to dictate which theories the State may pursue.

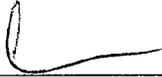
Conclusion

The purpose of the broad discovery rules is to allow a party to obtain information and documents that relate to the claims and defenses in the case. Discovery is also designed to enable a party to evaluate the arguments made by its opponent by looking at actual documents, rather than accepting the opponent's interpretation of their content or narrow construction of their relevance. Novartis's attempt to deprive the State of this opportunity should be rejected and

⁷ That the documents contain "highly sensitive and competitive information," as Novartis asserts (Opposition at 11), is of no moment, because of the protective order entered in this case.

the State's motion to compel should be granted.

Dated this 13th day of April, 2006.



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Dane County Case Number 04-CV-1709

Dear Counsel:

Enclosed is the State of Wisconsin's Reply Brief in Support of its Motion to Compel Novartis Pharmaceuticals Corporation to Answer One Interrogatory and Produce Certain Documents, which is being filed under seal today. Pursuant to the Case Management Order regarding electronic service, the pleading is not being served through LexisNexis File & Serve ("LNFS"). Rather, it is being served by hard copy on local counsel only.

Sincerely,

/s/

Robert S. Libman

RSL:jlz

Enclosure

cc: All Counsel (via LNFS w/o enclosure)