Decision

Matter of: Boehringer Ingelheim Pharmaceuticals, Inc.

File: B-294944.3; B-295430

Date: February 2, 2005

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DIGEST

Protests arguing that solicitations for formulary drugs are unduly restrictive because the solicitations limit competition to those drugs within the class that treat certain conditions is denied where the limits on competition reasonably reflect the agency's needs.

DECISION

Boehringer Ingelheim Pharmaceuticals, Inc. (BI) protests the terms of two solicitations issued by the Department of Veterans Affairs (VA) for Angiotensin II Receptor Antagonists, also known as Angiotensin II Receptor Blockers (or ARBs), for inclusion on the VA's National Formulary.[1] One solicitation (request for

[1] A formulary is a list of prescription drugs, grouped by therapeutic class, which a health care organization prefers that its physicians prescribe. Drugs are chosen for a formulary on the basis of their medical value and price. The formulary system seeks to standardize drug use, ensure availability and consistency of the product for nationwide usage, increase the continuity of care, standardize the process for evaluating the safety and efficacy of drugs, and manage cost growth. Schering Corp., B-286329.3, B-286329.4, Feb. 2, 2001, 2001 CPD ¶ 19 at 2 n.2; VA Health Care: VA's

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proposals (RFP) No. RFP-797-NC-04-0016) seeks one of two identified ARBs for the treatment of patients with both hypertension and type 2 diabetes mellitus with nephropathy;[2] the other (RFP No. RFP-797-NC-05-0003) seeks one of two identified ARBs for the treatment of patients with heart failure. BI, the manufacturer of an ARB not identified under either solicitation, argues that these solicitations are unduly restrictive because they exclude ARBs that treat simple hypertension, but do not treat the other conditions identified.[3]

We deny the protests.

BACKGROUND

BI manufactures one of seven ARBs available in the U.S., all of which are approved by the Food and Drug Administration (FDA) for the treatment of hypertension. Drug Class Review at 1-2. BI's ARB is referred to as Telmisartan, and is marketed as Micardis®. All seven FDA-approved ARBs are viewed as equally effective in treating hypertension. Id. at 6.

The RFP seeking an ARB for the treatment of both hypertension and diabetic nephropathy (RFP 0016) was issued on August 23, 2004, and is the subject of a recent decision by our Office (Bristol-Myers Squibb Co., B-294944.2, Jan. 18, 2005, 2005 CPD ¶ ___). On its face, the RFP limited this competition to two ARBs--Irbesartan (manufactured by BMS and Sanofi, marketed as Avapro®) and Losartan (manufactured by Merck, marketed as Cozaar®).

The RFP seeking an ARB for the treatment of heart failure (RFP 0003) was issued on October 14, 2004. It limits competition to two other ARBs--Candesartan Cilexetil (manufactured by AstraZeneca, marketed as Atacand®) and Valsartan (manufactured by Novartis, marketed as Diovan®). Both RFPs anticipated award of

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Management of Drugs on its National Formulary, (GAO/HEHS-00-34, Dec. 14, 1999) at 4.

[2] For ease of reference, the remainder of this decision will refer to the medical condition of type 2 diabetes mellitus with nephropathy as "diabetic nephropathy."

[3] BI also contends that these solicitations are violating terms of the company's Federal Supply Schedule (FSS) contract with the General Services Administration. In our view, BI's complaint that the solicitation here is usurping requirements that BI contends should be placed against its FSS contract is a matter of contract administration beyond the scope of our bid protest jurisdiction. See Bid Protest Regulations, 4 C.F.R. § 21.5(a) (2004).

a fixed-price, indefinite-quantity contract for a base period of 1 year, with up to four 1-year options.

Prior to releasing these solicitations, the VA made several decisions that are reflected in these two limited competitions. In summary--but discussed in greater detail below--these decisions were: (1) to not add an ARB to the VA's National Formulary for the treatment of hypertension; (2) to select for the formulary one of the two ARBs shown to be effective in treating diabetic nephropathy; and (3) to select for the formulary one of two other ARBs shown to be effective in treating heart failure.

These decisions were made by doctors from the VA's Pharmacy Benefits Management (PBM) Section, together with the VA's Medical Advisory Panel (MAP)--a panel of 13 physicians throughout the VA and the Department of Defense. The process began with a Drug Class Review of all available ARBs, which is appended to both RFPs. Using the findings of the Drug Class Review, the VA's PBM and MAP doctors prepared a second document explaining the VA's approach to purchasing ARBs. This document--also appended to both RFPs--is entitled "Medical Determination of Minimum Needs for VA National Formulary Selection of an [ARB]," hereinafter the "Medical Needs Determination."

The VA decided not to add an ARB to its National Formulary for the treatment of simple hypertension because ARBs are not the VA's preferred method of treating simple hypertension. Medical Needs Determination at 3; Declaration of the MAP Chairperson, Dec. 13, 2004, at 3-4. In fact, the VA noted that there are four different classes of antihypertensive medications, several of which should be tried prior to prescribing an ARB for simple hypertension. Medical Needs Determination at 3-4. As a result of the VA's guidelines establishing a hierarchy of preferred drug classes for the treatment of simple hypertension--which places ARBs as a third or fourth line of defense--the VA expects the use of ARBs to treat simple hypertension to be rare. Declaration of the MAP Chairperson, Dec. 13, 2004, at 4.

The second and third decisions described above--i.e., to select an ARB for the formulary shown to be effective in treating diabetic nephropathy, and to select a second ARB shown to be effective in treating heart failure--are also set forth in the VA's Medical Needs Determination. Specifically, the VA took notice of medical literature describing research showing that two of the seven ARBs available in the U.S. had been shown to be effective in the treatment of diabetic nephropathy, and two others had been shown to be effective in the treatment of heart failure. Drug Class Review at 1; Medical Needs Determination at 2-3. The VA decided it could enhance the care of its patients by holding a limited competition to select one ARB from each of these two groups for the treatment of these conditions. Medical Needs Determination at 1.

As indicated above, BI's ARB, Telmisartan, is not one of the four ARBs selected for these two limited competitions, as it was not one of the four ARBs identified by the

Drug Class Review as effective in the treatment of diabetic nephropathy or heart failure. This protest followed.

DISCUSSION

BI argues that these solicitations are unduly restrictive of competition. In BI's view, the two medical conditions for which the VA is limiting its procurement of ARBs--i.e., diabetic nephropathy and heart failure--reflect only a small percentage of the likely use of ARBs by VA patients for simple hypertension. Since BI contends that its drug could be used to treat simple hypertension as well as the four drugs identified in these solicitations--but effectively will not be available for this use because it will not be on the formulary--BI argues that the agency is restricting competition improperly.

As a preliminary matter, we recognize that this protest reflects a larger disagreement between VA officials and certain pharmaceutical manufacturers, like BI, about the role of ARBs in the treatment of VA patients with simple hypertension. We also recognize that once a drug within a class is placed on the VA's National Formulary, access to the VA market, as a practical matter, is largely unavailable to other drugs within that class. See, e.g., Protester's Comments (B-294944.3), Jan. 10, 2005, at 4. As a result, our discussion of these challenges necessarily begins with the fact that the VA has decided that it does not need an ARB on its National Formulary for the treatment of simple hypertension. Instead, the VA has recommended several other classes of antihypertensive medications for the treatment of simple hypertension, before the use of an ARB to treat this condition. Medical Needs Determination at 3-4.

First and foremost, BI argues that the VA's conclusion that its need for ARBs is limited to those that will treat the two conditions reflected in these solicitations is flawed, and results in an unduly restrictive competition. Specifically, BI argues that there is no basis in fact for the VA's conclusion that "there is presently no significant medical need in VA for a national procurement of an ARB to treat simple hypertension." Declaration of the MAP Chairperson, Dec. 13, 2004, at 4. In support of its position, BI points out that ARBs are already being prescribed to treat VA patients with simple hypertension, and that the need for ARBs to treat hypertension is greater than the need for ARBs to treat either of the two conditions the VA has used to limit the competition here.

While a contracting agency has the discretion to determine its needs and the best method to accommodate them, Mark Dunning Indus., Inc., B-289378, Feb. 27, 2002, 2002 CPD ¶ 46 at 3-4; Parcel 47C LLC, B-286324; B-286324.2, Dec. 26, 2000, 2001 CPD ¶ 44 at 7, those needs must be specified in a manner designed to achieve full and open competition; solicitations may include restrictive requirements only to the extent they are necessary to satisfy the agency's legitimate needs. 41 U.S.C. §§ 253a(a)(1)(A), (2)(B) (2000). Where a protester challenges a specification as unduly restrictive, the procuring agency has the responsibility of establishing that the specification is reasonably necessary to meet its needs. The adequacy of the

agency's justification is ascertained through examining whether the agency's explanation is reasonable, that is, whether the explanation can withstand logical scrutiny. Chadwick-Helmuth Co., Inc., B-279621.2, Aug. 17, 1998, 98-2 CPD ¶ 44 at 3. A protester's mere disagreement with the agency's judgment concerning the agency's needs and how to accommodate them does not show that the agency's judgment is unreasonable. See AT&T Corp., B-270841 et al., May 1, 1996, 96-1 CPD ¶ 237 at 7-8. Specifically here, while we will review the reasonableness of the agency's determination of its needs, we defer to the judgment of agency medical officials on matters of medicine. See GlaxoSmithKline, B-291822, Apr. 7, 2003, 2003 CPD ¶ 77 at 5.

We note first that there is no dispute in the record about BI's claim that ARBs are already being prescribed for hypertension. In fact, the VA itself acknowledges that ARBs are appropriate for the treatment of hypertension, after other antihypertensive medications have been used. Medical Needs Determination at 3-4. In addition, there seems to be little doubt that the incidence of simple hypertension in the VA patient population is probably greater than the incidence of the two conditions used to limit the competition here; for the sake of argument, we will assume that this is true.

That said, neither of these matters renders the VA's medical judgment about its preferred prescribing practices, or its decision not to list an ARB on the formulary for the treatment of simple hypertension, unreasonable. As we indicated in our decision in Bristol-Myers Squibb, supra, at 6, the VA prefers that its doctors first prescribe diuretics and beta blockers, then ACE inhibitors,[4] and then ARBs for the treatment of simple hypertension. Given these guidelines--which are clearly matters of medical judgment entitled to deference here--the VA concludes that there will not be any significant use of ARBs to treat simple hypertension. Based on our review, and with little evidence from BI to support a different conclusion, we find reasonable the VA's estimate about the extent to which ARBs will be used to treat VA patients with hypertension.[5] See Lederle-Praxis Biologicals Div., Am. Cyanamid Corp., B-257104 et al., Aug. 22, 1994, 94-2 CPD ¶ 205 at 5.

With respect to any specific challenges to these solicitations--separate and apart from its complaint that the VA should instead be purchasing an ARB for the

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[4] "ACE inhibitors" is a short-hand reference to angiotensin-converting enzyme inhibitors. Id. at 3 n.4.

[5] As also indicated in our decision in Bristol-Myers Squibb, supra, at 8, we recognize that these procurements will result in the first listing by the VA of ARBs on its National Formulary. To the extent that dosing data is developed over the life of the contract that suggests heavier than expected use of ARBs to treat simple hypertension, the VA may want to reconsider whether it should procure an ARB for the treatment of simple hypertension.

treatment of simple hypertension--BI lacks the direct economic interest necessary to be considered an interested party in this protest. 4 C.F.R. § 21.0(a). This is because BI's ARB has not been shown to be effective in the treatment of either of the two medical conditions identified in these solicitations, and thus does not qualify for inclusion in the competition. At best, BI complains that it should not be excluded from the competition for an ARB to be used to treat heart failure (RFP 0003) because studies are underway that "might prove Micardis to be more effective than either of the two selected drugs." Protester's Comments (B-295430), Dec. 23, 2004, at 8. This argument, on its face, admits that BI's drug has not yet been shown effective in this regard, and supports our conclusion that BI is not an interested party here.[6] In addition, the VA suggests that if BI's ARB is later shown effective in the treatment of heart failure, the agency may elect not to exercise its option to continue this contract, and may instead hold a new competition. Agency Report (AR) (B-295430) at 11.

In fact, it does not appear that BI is raising any challenge to these solicitations that is separate from its complaint that the VA should be placing an ARB on the formulary for the treatment of simple hypertension. For example, BI complains that the VA's decision to procure an ARB for the treatment of heart failure is flawed because ACE inhibitors are the primary therapeutic choice for patients with heart failure, and ARBs are only a secondary choice for heart failure patients who cannot tolerate ACE inhibitors. In fact, the VA concurs with BI's description of the primary and secondary therapeutic choices for patients with heart failure. Declaration of the MAP Chairperson, Dec. 13, 2004, at 4. Nonetheless, BI asks our Office to conclude that it is unreasonable for the VA to procure an ARB for the second-line treatment of heart failure because of the relatively small number of patients who will need the drug for this purpose. Tellingly, BI argues that by purchasing an ARB for the treatment of heart failure, "the VA is eliminating competitive sources and decreasing the likelihood of getting a lower price for the *primary* treatment of hypertension." Protester's Comments (B-295430), Dec. 23, 2004, at 7 (italics in original).

While this argument is framed as an attack on the solicitation for an ARB to treat heart failure, we think it remains, essentially, an attack on the decision not to select

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[6] For the record, we also do not think BI can reasonably claim that the VA engaged in unequal treatment by including AstraZeneca's ARB, Candesartan Cilexetil, in this solicitation because that drug is not FDA-approved for the treatment of heart failure. The VA cited several medical studies which determined that AstraZeneca's ARB is effective in the treatment of heart failure. Supp. Declaration of MAP Chairperson, Jan. 14, 2005, at 3. In addition, AstraZeneca points out that there is no requirement that the VA limit its use of drugs to the indication for which the drug was approved by the FDA. Based on our review, there is nothing in this record to indicate that the VA cannot reasonably rely upon the studies it cites to include AstraZeneca's ARB in this procurement.

an ARB for the treatment of simple hypertension--a decision we find reasonable, as explained above. More importantly, we do not think it falls to our bid protest forum to tell the VA that not enough patients will need the second-line treatment for heart failure to justify the agency's selection of those drugs for its formulary. This is again a matter of medical judgment within the agency's discretion. See GlaxoSmithKline, supra.

With respect to BI's contention that the solicitations here include an impermissible bundling of agency requirements--i.e., bundling the requirement for a drug to treat simple hypertension with the requirement for a drug to treat either diabetic nephropathy or heart failure--we disagree. As shown above, the VA has not identified any significant requirement to use an ARB for the treatment of simple hypertension. Nor does the agency have an estimate, at this juncture, of how frequently ARBs will be used for the treatment of simple hypertension, given the agency's stated hierarchy of preference in the treatment of this condition. Accordingly, the facts do not support a conclusion that this procurement is combining two concrete requirements--a necessary ingredient of bundling. See EDP Enters., Inc., B-284533.6, May 19, 2003, 2003 CPD ¶ 93 at 4; Phoenix Scientific Corp., B-286817, Feb. 22, 2001, 2001 CPD ¶ 24 at 5.

As a final matter, we feel compelled to address the undercurrent of arguments throughout these pleadings implying that VA personnel are acting in bad faith--e.g., BI's assertions that the VA doctors are "hiding the ball," or have "a real objective" different from the objectives the agency claims. Protester's Comments (B-294944.3), Jan. 10, 2005, at 3; Protester's Comments (B-295430), Dec. 23, 2004, at 3. Based on our review of these protests--as well as our review of two other protests filed against these procurements--we have seen nothing in the record to support such a conclusion. Specifically, our review does not indicate that VA officials are hiding information about their decisions, or that they have an objective other than those claimed.

The protests are denied.

Anthony H. Gamboa
General Counsel