United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 11, 2003 Decided July 23, 2004

No. 02-1211

NORAMCO OF DELAWARE, INC.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

JOHNSON MATTHEY, INC.,
INTERVENOR

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

No. 03–1060

NORAMCO OF DELAWARE, INC.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

PENICK CORPORATION, INC. AND MALLINCKRODT, INC.,
INTERVENORS

On Petitions for Review of Orders of the
United States Drug Enforcement Agency

Thomas C. Morrison argued the cause for the petitioners. *John A. Gilbert, Jr.* and *Douglas B. Farquhar* were on brief.

Harry J. Matz, Attorney, United States Department of Justice, argued the cause for the respondents. Joseph S. Uberman, Attorney, United States Department of Justice, was on brief. *Rose A. Briceno*, Attorney, United States Department of Justice, entered an appearance.

James Dabney Miller argued the cause for intervenor Johnson Matthey, Inc.

Steven J. Poplawski and *Scott M. Badami* were on brief for intervenor Mallinckrodt, Inc.

Wayne H. Matelski and *Deborah M. Shelton* were on brief for intervenor Penick Corporation, Inc.

Before: GINSBURG, *Chief Judge*, and HENDERSON and ROGERS, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* HENDERSON.

KAREN LECRAFT HENDERSON, *Circuit Judge*: Noramco of Delaware, Inc. (Noramco) has filed two petitions for review of

final orders of the Drug Enforcement Agency (DEA, Agency) which grant applications by Johnson Matthey, Inc. (Johnson Matthey) and by Penick Corporation, Inc. (Penick) to register as importers of narcotic raw materials (NRMs) pursuant to the Controlled Substances Import and Export Act, 21 U.S.C. §§ 952 and 958, and the Controlled Substances Act, 21 U.S.C. §§ 823 *et seq.*, (collectively referred to as CSA). For the reasons set out below, we deny both of Noramco's petitions.

I. Background

The CSA establishes a comprehensive regulatory system that controls the manufacture, distribution and use of hazardous drugs. *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 10 (D.C. Cir. 1998). The DEA Administrator, by delegation of the United States Attorney General, 28 C.F.R. § 0.100(b), classifies each drug into one of five schedules according to such factors as its potential for abuse and its risk to the public health *Id.* (citing 21 U.S.C. § 811).[1] In order to import or

[1] The dangerousness and abuse potential of the drugs decrease with each schedule. Section 812 directs that drugs be assigned to the five schedules according to the following criteria:

(1) Schedule I.—
(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has no currently accepted medical use in treatment in the United States.
(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II.—
(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III.—
(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

export a controlled substance, a company must apply for and obtain registration with the DEA, 21 U.S.C. § 957, which is required to register an application for Schedule I or II substances if it "determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971," 21 U.S.C. § 958(a). Section 823(a) of title 21 sets out the factors to be considered in determining the public interest: (1) "maintenance of effective controls against diversion of [controlled substances and their compounds] into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research,

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(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

21 U.S.C. § 812(b).

and industrial purposes"; (2) "compliance with applicable State and local law"; (3) "promotion of technical advances in the art of manufacturing these substances and the development of new substances"; (4) the "prior conviction record of [the] applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances"; (5) "past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion"; and (6) "such other factors as may be relevant to and consistent with the public health and safety." Pursuant to these provisions, both Johnson Matthey and Penick filed applications with the DEA for registration.

Before filing its registration application, Johnson Matthey was already registered as an importer of phenyl acetone, a Schedule II controlled substance, and as a bulk manufacturer of Schedule I and II substances, including oxycodone and hydrocodone, which are active pharmaceutical ingredients (APIs) that it sells in bulk to manufacturers of narcotic-based prescription drugs. Because Johnson Matthey was not registered to import opium or poppy straw concentrate, the NRMs from which the narcotic alkaloids morphine, codeine and thebaine are extracted to produce oxycodone and hydrocodone, it had to rely on supplies from Noramco and Mallinckrodt, Inc. (Mallinckrodt), the two companies then registered to import the NRMs. Dissatisfied with this arrangement, on December 23, 1998 it filed an application to modify its registration to include importation of opium and poppy straw concentrate. At the same time it applied to renew its registration to manufacture Schedule I and II controlled substances in bulk. On May 10, 1999 Noramco and Mallinckrodt filed separate objections to and requests for hearing on Johnson Matthey's registration application.

An administrative law judge (ALJ) conducted a hearing in January 2000. In a decision filed September 21, 2000 the ALJ recommended that Johnson Matthey's application be granted, subject to the conditions that Johnson Matthey (1) demonstrate to the DEA's satisfaction, before receipt of its first NRM shipment, "the manner in which the NRMs will be imported, transferred to the processing facility, and pro-

cessed," (2) provide the DEA with a timetable for its proposed "ramp-up activities" and (3) inform the DEA of "any changes to these procedures and/or any changes made to the physical plant" and obtain approval thereof before making any shipment under the "changed circumstances." Johnson Matthey, Inc., Docket No. 99–27 (September 21, 2000) ("Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision") (ALJ Op. I), slip op. at 57.

In a decision dated May 22, 2002 the DEA Deputy Administrator adopted and incorporated the ALJ's findings and conclusions "in their entirety" and granted Johnson Matthey "a conditional registration until such time as Johnson Matthey's facilities are complete and DEA can complete its requisite physical security and record keeping evaluation to ensure Johnson Matthey's continued protection of NRMs against diversion." Johnson Matthey, Inc., 67 Fed. Reg. 39,041, 39,045 (June 6, 2002) (conditional grant of registration to import Schedule II substances). The decision further directed that "Johnson Matthey should provide DEA with a timetable of its proposed activities and submissions so that DEA may plan for the prompt scheduling of its inspection and review activities." *Id.* at 39,045–46.

Penick filed its application on April 11, 2000 for registration to import the Schedule II NRMs coca leaves, raw opium, poppy straw and poppy straw concentrate and to manufacture Schedule II APIs, including oxycodone, hydrocodone, morphine, hydromorphone and codeine, from the imported NRMs. On September 15, 2000 Noramco and Mallinckrodt each filed objections to and requests for hearing on Penick's registration application.

An ALJ conducted a hearing on Penick's application in July and August 2001. In a decision filed May 29, 2002 the ALJ recommended that Penick's application be granted. Penick Corp., Docket No. 01–3 (May 29, 2002) ("Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge") (ALJ Op. II). On February 11, 2003, the DEA Deputy Administrator issued a final order adopting the ALJ's findings and conclusions "in

their entirety." Penick Corp., Inc., 68 Fed. Reg. 6947, 6948 (Feb. 11, 2003) (grant of registration to import Schedule II substances).

Noramco filed a timely petition for review of each registration approval. Malinckrodt intervened in the challenge to Penick's registration. We address each registration separately.

II. Johnson Matthey's Registration

Noramco challenges the DEA's conditional grant of Johnson Matthey's registration application on two grounds: (1) the DEA misconstrued its obligation to ensure effective diversion control under section 823(a) and (2) the DEA acted arbitrarily and capriciously in failing to require Johnson Matthey to submit detailed plans for importing NRMs and processing them into APIs. We find neither ground meritorious.

First, Noramco contends the DEA's approval of Johnson Matthey's registration contravenes the plain language of section 823(a)(1). We review the DEA's interpretation of section 823 under the familiar two-step *Chevron* framework:

> We first ask "whether Congress has directly spoken to the precise question at issue," in which case we "must give effect to the unambiguously expressed intent of Congress." If the "statute is silent or ambiguous with respect to the specific issue," however, we move to the second step and defer to the agency's interpretation as long as it is "based on a permissible construction of the statute."

Bluewater Network v. EPA, No. 03–1120, slip op. at 10 (D.C. Cir. June 22, 2004) (quoting *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842–43 (1984)). Noramco contends that under *Chevron* step one, the unambiguous language of section 823(a)(1) requires that, before the DEA approves an application for registration to import a Schedule I or II controlled substance, the agency is required to balance the risk of unlawful diversion of the substance against the need for competition by ensuring both (1) that effective

controls will be maintained against diversion and (2) that approval will not increase the number of importers beyond that which can "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate . . . purposes," 21 U.S.C. § 823(a)(1). We disagree.

Section 823(a)(1) does not expressly speak to whether the DEA must consider the number of importers necessary to provide an adequate supply if it determines diversion will be effectively controlled regardless. The stated purpose of section 823(a)(1) is to effectively control against diversion and it expressly directs the DEA to limit competition only as a means to achieve "maintenance" of such control. In the absence of an express contrary statutory directive, the DEA reasonably concluded under *Chevron* step 2 that "if DEA determines that there would be no increased difficulty in controlling diversion, the requirements of [section 823(a)(1)] are satisfied, and an analysis of adequate competition is not required." 67 Fed. Reg. at 39,044; *see also id.* at 39,043–44 ("Furthermore, DEA has written that, stated conversely, DEA is 'required to register an applicant who meets all the other statutory requirements, without regard to the adequacy of competition, if the Administration determines that registering another manufacturer will not increase the difficulty of maintaining effective controls against diversion.' ") (quoting Bulk Manufacture of Schedule I and II Substance, 39 Fed. Reg. 12,138 (DEA April 13, 1974)).[2] The DEA determined,

[2] Noramco objects to the DEA's citation to this 1974 policy statement because the two rules proposed therein were not subsequently adopted. In this case, however, the DEA treated the policy statement merely as instructive and supportive of its independent construction of the statutory language. *See* ALJ Op. I at 43–44 & n.37 (finding policy statement to be "instructive but not determinative of the proper interpretation of the statute"). As the ALJ noted, the policy statement is also "consistent with the relevant regulatory language currently controlling in the importer application process" ALJ Op I. at 43–44 & n.38 (noting that "[t]he current regulation concerning the registration of a manufacturer of Schedule I and II substances states: '(b) In order to provide adequate

based on substantial expert testimony, that Johnson Matthey's registration is consistent with section 823(a)(1) because it found that "Johnson Matthey is in compliance with DEA regulations" and "maintain[s] effective controls against diversion of controlled substances," 67 Fed. Reg. at 39,044–45—findings that Noramco does not dispute, *see* Pet'r Br. (02–1211) at 24. After analyzing the other five statutory factors, the DEA concluded that registration is in the public interest based on findings that Johnson Matthey's registration (1) "promote[s] technical advances in the manufacturing of oxycodone and hydrocodone" because Johnson Matthey had obtained or applied for 6 patents to more efficiently produce APIs and (2) helps ensure a steady supply of APIs and pharmaceuticals. 67 Fed. Reg. at 39,045, ALJ Op. I at 16–17. Thus, under the DEA's permissible interpretation of section 823(a), it was required to approve Johnson Matthey's registration

Noramco challenges the DEA's reading of section 823(a)(1) on two grounds. First, Noramco charges that the DEA's interpretation ignores the distinction between the statutory regulation of Schedule I and II substances, at issue here, and of Schedule III and IV substances. Noramco points out that section 823(d), which governs Schedule III and IV substances, lists the same six public interest factors as section 823(a)—except that the first factor in 823(d)(1) lacks the limiting prepositional phrase addressing supply and competition contained in section 823(a)(1) ("by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes"). The DEA's interpretation, Noramco argues, "eviscerates" this distinction by eliminating the

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competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less [than] that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.' " (quoting 21 C.F.R. § 1301.33(b) (1999))).

competition factor from the public interest calculus. Not so. Under the DEA's interpretation, it must still ensure that the number of importers and manufacturers is limited where such limitation is necessary to maintain effective diversion controls; it is only where, as here, the DEA affirmatively finds that diversion will be effectively controlled without regard to limiting competition that it is not required to inquire into market competitiveness.

Second, Noramco contends the DEA's interpretation is inconsistent with the CSA's legislative history and with the testimony before the ALJ by a former DEA administrator. The statements Noramco cites, however, simply reflect a concern that the marketing of Schedule I and II controlled substances not be so broadened as to enhance the risk of diversion. *See* Pet'r Br. (02–1211) at 42–44 (quoting S. Rep. No. 91–613 at 7 (1969) (explaining that section 823(a)(1) addresses "concern ... that parts of [the CSA] ... may tend to expand the commerce in controlled dangerous substances, particularly narcotics, possibly adding to the danger of diversion and leading to unfavorable changes in the price structures of these substances") (first ellipsis added); *CSA, Hearings before the Subcomm. to Investigate Juvenile Delinquency of Sen. Comm. on the Judiciary*, 91st Cong. 261–62 (1969) (Statement of Attorney Gen. Mitchell) ("[T]here is no intention on the part of the Justice Department nor the Bureau of Narcotics and Dangerous Drugs by this provision to expand beyond necessity ... any manufacturers in this particular area"); *id.* at 371 (Statement of Dep't of Justice) ("If evidence indicates that additional licensing will result in more reasonable prices with no significant diminution in the effectiveness of drug control, the Attorney General should be able to license the additional manufacturers.")); Pet'r Br. (02–1211) at 40 (quoting testimony of former DEA Administrator Peter Bensinger) ("Given the intent of the law and regulations to limit the number of registrants, in administering the law one must accept that not all qualified persons who seek to register are entitled to be registered.... The public interest is served by limiting the access to NRMS to a much smaller number of companies than would be appropri-

ate in a free market."). That concern is not in play where, as here, the DEA affirmatively finds that diversion is effectively controlled.

Noramco next contends that the DEA acted arbitrarily and capriciously in not requiring that Johnson Matthey submit "concrete" plans for how it will import and process NRMs (specifically regarding the technology it will use, the amount and identity of NRMs imported, the kind of plant it will construct, the technical expertise of its employees and its commitment to spend sufficient funds). Noramco asserts that by failing to do so the DEA held Johnson Matthey to a "lower standard of proof" than it imposed when it granted the registration application of McNeilab, Inc. in 1981. Pet'r Br. (02–1211) 57. We see no material difference in the DEA's treatment of the two applicants. McNeilab's application was approved "contingent upon the successful completion of all necessary and pertinent actions outlined in the applications, such as the construction of a secure manufacturing facility, and upon the ultimate approval of those actions by the Drug Enforcement Administration." McNeilab, Inc., 46 Fed. Reg. 22,089 (DEA Apr. 15, 1981) (grant of registration; adopting findings of fact and conclusions of law from NcNeilab, Inc, Docket No. 78–12 (Aug. 20, 1980)). This is substantially what the DEA did in approving Johnson Matthey's application "upon Johnson Matthey's providing to DEA, prior to the receipt of the first shipment of NRMs, sufficient information concerning its facilities and procedures contingent upon the successful completion of all necessary and pertinent actions outlined in the applications, such as the construction of a secure manufacturing facility, and upon the ultimate approval of those actions by the Drug Enforcement Administration." 67 Fed. Reg. at 39,045. In each case, the DEA withheld final approval pending the applicant's completion of its facilities and the DEA's ultimate approval thereof. Noramco complains in particular that the DEA did not require that Johnson Matthey, as McNeilab was required to do, provide a "concrete business plan calling for the importation of opium and the construction of a plant capable of converting opium into APIs." Pet'r Br. (02–1211) at 58. Unlike McNeilab,

however, Johnson Matthey was already in the business of importing and manufacturing controlled substances and had facilities in place for doing so. Given Johnson Matthey's experience and its pre-existing facilities, the DEA reasonably required less detailed specifications in advance of Jackson Matthey's proposed expansion.[4]

III. Penick's Registration

Noramco and intervenor Mallinckrodt raise both statutory and evidentiary challenges to the DEA's approval of Penick's registration. We address, and reject, each of their arguments in turn.

First, Noramco and Mallinckrodt assert the DEA misinterpreted section 823(a)(1) as not requiring it to consider the effect of Penick's registration on diversion overseas, specifically potential diversion in India, a primary source of imported NRMs.[5] This argument fails for two reasons. First, the DEA in fact considered and rejected the contention that Penick's registration would increase diversion in India. Noramco argued before the agency that Penick's use of morphine-based technology was less efficient than Noramco's use of a high-thebaine-content poppy to produce oxycodone and would therefore increase demand, cultivation and production of opium in India and, in turn, the likelihood of diversion there. *See* JA 145–49 (Decl. of Noramco Vice President Michael Kindergan) (citing Decl. of Michael Wilson, Ph.D.). The ALJ found that "Noramco's and Mallinckrodt's claims that registering Penick would increase diversion in India are speculative at best, particularly in light of the as-yet-unknown impact of the expanded use of high-thebaine-content poppy

[4] We have no basis to speculate, as Noramco asserts, that the DEA's review of Johnson Matthey's final submissions will be less than "rigorous." *See* Pet'r Br. (02–1211) at 58.

[5] The "80/20 Rule," adopted by the DEA in 1981, requires that "[a]t least eighty (80) percent of the narcotic raw material imported into the United States shall have as its original source Turkey and India." 21 C.F.R. § 1312.13(g).

straw as a narcotic raw material." ALJ Op. II at 94.[6] We agree with the ALJ's assessment, especially in light of the testimony by Penick's research and development director that Penick could also manufacture oxycodone from high-thebaine poppy straw. *See* JA 997, 1004 (testimony of Bao–Shan Huang, Ph.D.) In any event, the DEA's alternate determination that it is not required to consider possible diversion overseas reflects a reasonable construction of section 823(a)(1) and we therefore uphold it under step two of *Chevron*.

As both the ALJ and the DEA noted, section 823(a)(1) is silent on whether the "diversion" the DEA must consider is limited to the United States or includes unlawful diversion overseas as well.[7] Nonetheless, the language of the statute itself, in its focus on importation and domestic manufacturing, suggests, reasonably enough, that the Congress was concerned with preventing diversion in this country rather than abroad. The legislative history similarly suggests an intent to prevent diversion through control of commercial activities that occur in this country, rather than in the countries of origin. *See Comprehensive Drug Abuse Prevention and Control Act of 1970*, H. Rep. No. 91–1444 (Sept. 10, 1970),

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[6] It is questionable whether Noramco has preserved a challenge to this finding, which it only barely disputes in a single paragraph of the factual portion of its opening brief, Pet'r Br. (03–1060) at 43. *See United States v. Hall*, 370 F.3d 1204, 1209 n.4 (D.C. Cir. 2004) ("[O]ne sentence, unaccompanied by argument or any citation to authority, does not preserve the issue for decision." (citing *United States v. Mathis,* 216 F.3d 18, 27 n.4 (D.C. Cir. 2000); *SEC v. Banner Fund Int'l*, 211 F.3d 602, 613–14 (D.C. Cir. 2000))).

[7] Noramco's brief repeatedly cites and quotes the Single Convention on Narcotic Drugs, a multinational treaty under which the United States "is obligated to take all necessary measures to ensure that the international movement of narcotics is limited to legitimate medical and scientific needs," 68 Fed. Reg. at 6949. Nonetheless, Noramco makes clear that "the command that DEA must take account of 'diversion' comes from the text of the CSA itself," specifically from section 823(a)(1), and not from the treaty. Pet'r Br. (03–1060) at 48.

reprinted in 1970 U.S.C.C.A.N. 4566, 4571–72 ("The Bill is designed to improve the administration and regulation of *the manufacturing, distribution, and dispensing* of controlled substances by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market. . . ."). On the flip side, we find unpersuasive the authorities Noramco cites to support its assertion that "diversion," within the meaning of section 823(a)(1), is intended to include pre-importation diversion overseas. Neither the CSA's restrictions on limiting the United States' *export* of narcotics nor policies, unrelated to the CSA, that reflect concern over overseas diversion nor the testimony of a former DEA Administrator (cautioning against registering importers whose activities might adversely affect " 'the worldwide control, stability and supply of NRMs' " or " 'the international drug control effort,' "Pet'r Br. at (03–1060) at 53 (quoting testimony of former Administrator Peter Bensinger)), negate the reasonableness of the DEA's construction of section 326(a)(1).[8]

Next, Noramco and Mallinckrodt challenge the DEA's decision on a sufficiency of evidence ground. Under the CSA, the

[8] Noramco and Mallinckrodt also argue that the DEA's position here is inconsistent with that expressed by DEA staff members in two other proceedings pending before the DEA (Chattem Chems., Inc., DEA Docket No. 01–45, and Houba, Inc., DEA Docket No. 02–6), in support of which Noramco has filed a supplemental appendix of materials from those proceedings in No. 03–1060 and moved to file a similar supplemental appendix in 02–1211. Challenging the DEA's decision here based on the agency's *subsequent* position, however, "puts the cart before the horse." *Cellular Mobile Sys. of Penn., Inc. v. FCC*, 782 F.2d 182, 207–08 (D.C. Cir. 1985). It is the DEA's position here to which it will be held in the later decisions. *Id.* In any event, views expressed by staff do not constitute authoritative agency action. *See WHX Corp. v. SEC*, 362 F.3d 854. 860 (D.C. Cir. 2004). Accordingly, we deny Noramco's motion to file a supplemental brief in No. 02–1211 and grant Penick's motion to strike the supplemental appendix filed in No. 03–1060.

DEA's findings of fact, "if supported by substantial evidence, shall be conclusive." 21 U.S.C. § 877; *see MD Pharmaceutical, Inc. v. DEA*, 133 F.3d 8, 14 (D.C. Cir. 1998). We conclude that the challenged portions of the DEA's decision are supported by substantial evidence in the record.

Noramco and Mallinckrodt first assert that substantial evidence does not support the DEA's finding, in support of registration, that competition among NRM importers that process APIs is not adequate.[9] *See* 21 U.S.C. § 823(a)(1) (directing DEA to consider "maintenance of effective controls against diversion of [controlled substances and their compounds] into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes"). The ALJ concluded that competition was inadequate based on the undisputed evidence that "the prices of active pharmaceutical ingredients rose steeply from 1991 to 2000," concluding that "[t]his price increase, absent specific explanation, is strong evidence of a lack of competition in the active pharmaceutical ingredient market." ALJ Op. II at 92. The ALJ acknowledged that during the period there were a number of "switches" by purchasers from one of the bulk suppliers (Noramco and Mallinckrodt) to the

[9] Mallinckrodt also complains that the DEA's decisions are inconsistent regarding whether the Agency is required to analyze the adequacy of competition and supply before issuing a registration, noting that, while the DEA performed such an analysis in this case, it did not do so in *Johnson Matthey*. We reject this argument for two reasons. First, whatever injury Mallinckrodt may claim from this inconsistency occurred not in this case but in *Johnson Matthey*, in which Mallinckrodt elected not to participate before this court. In any event, as noted *supra* pp. 8–9 & n.2, the DEA has long adhered to the policy that it need not address adequacy of competition if, as the DEA found in the case of Johnson Matthey's registration, effective diversion controls are in place.

other but concluded they "do not demonstrate strong competition."[10] *Id.*

Noramco and Mallinckrodt argue, as they did before the agency, that the price increases are attributable to rising costs of raw materials, rather than lack of competition, and cite their expert's testimony before the ALJ that their profit

[10] The ALJ analyzed the adequacy of competition under the factors set out in 21 C.F.R. § 1301.34(d), which provides:

> (d) In determining whether competition among the domestic manufacturers of a controlled substance is adequate within the meaning of paragraphs (b)(1) and (b)(6)(iii) of this section, as well as section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall consider:
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> (1) The extent of price rigidity in the light of changes in:
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> (i) raw materials and other costs and
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> (ii) conditions of supply and demand;
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> (2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including:
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> (i) Shifts in market shares and
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> (ii) Shifts in individual customers among domestic manufacturers;
>
> (3) The existence of substantial differentials between domestic prices and the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his/her supply;
>
> (4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and
>
> (5) Such other factors as may be relevant to the determinations required under this paragraph.

margins actually decreased between 1988 and 2000. The ALJ, however, found the increases in API prices and NRM costs "do not correlate strongly," *id.*, and this finding is supported by the evidence. Penick's expert economic witness, Michael I. Cragg, disputed the opinions of Noramco's and Mallinckrodt's experts, explaining they had compared apples with oranges. Cragg testified that the comparison of API prices and NRM costs "does not account for the relative importance of NRM inputs in overall costs" because "[a] kilogram of API and a kilogram of NRM are not comparable—the mistake is analogous to comparing the price of a gallon of gasoline to the price of a gallon of crude oil." JA 193 (Written Revised Direct Testimony of Michael I. Cragg, Ph.D.). The ALJ credited Cragg's testimony over the other experts', *see* ALJ Op. II at 89 ("[T]he two types of increases [costs of NRMs and prices of APIs] seem to be only loosely related when the proportion of the price of the active pharmaceutical ingredient that is attributable to the narcotic raw material is taken into consideration."), and our review of her choice among the " 'disputing expert witnesses' " is "particularly deferential." *Fla. Mun. Power Agency v. FERC.* 315 F.3d 362, 368 (D.C. Cir. 2003) (quoting *Wis. Valley Improvement Co. v. FERC,* 236 F.3d 738, 746–47 (D.C. Cir. 2001)). Moreover, it is not surprising that profit margins declined somewhat after 1994 when Noramco joined Mallinckrodt in the market, transforming it from a monopoly to a duopoly—but this does not mean the minimal competition between two market participants was adequate. Noramco and Mallinckrodt also cite the evidence of customer switches between them as evidence of competition but, as the ALJ noted, citing Cragg's testimony, there was no evidence these switches were related to changes in API prices. Last, Noramco and Mallinckrodt assert that increased competition will not reduce the price of drugs to the consumer. This may be true but expanding the playing field may yield other benefits such as reduced prices for bulk API purchasers and improved product quality, reliability of supply, financial terms and conditions and order lead times.

Finally, Noramco challenges the DEA's finding that Penick's registration will promote technical advances. Specifically, Noramco asserts that Penick's morphine-based production technology is less efficient than Noramco's high-thebaine poppy technology. This argument overlooks the substantial evidence that Penick has developed and patented numerous other processing technologies. *See, e.g.*, JA 42–43, 72, 2384–85, 2696. Accordingly, we reject this argument as well.

* * *

For the foregoing reasons, the petitions for review in these cases are denied.

So ordered.