UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of	)	
	)	Docket Number 99-27
JOHNSON MATTHEY, INC.	)	

MEMORANDUM OF THE ANTITRUST DIVISION OF THE UNITED STATES DEPARTMENT OF JUSTICE AS AMICUS CURIAE IN SUPPORT OF THE APPLICATION OF JOHNSON MATTHEY, INC.

Competition is a rough, often inelegant process by which winners and losers -- whether products, firms, or technologies -- are chosen by decisions made in the marketplace. In that process, economic actors are constantly challenged to improve on price, cost, and technology -- or exit. The end result is economic efficiency and increased technological innovation. Properly understood, the various challenges to the application of Johnson Matthey, Inc. ("Johnson Matthey") raised by Mallinckrodt, Inc. ("Mallinckrodt") and Noramco of Delaware, Inc. ("Noramco") rest on one ground: their fervid desire to avoid such competition and the challenges it would pose to them. Should their efforts to block Johnson Matthey's entry into the market succeed, the result will almost certainly be a less efficient and less innovative market and, ultimately, higher prices for consumers.

For that reason, assuming that the DEA can appropriately regulate Johnson Matthey's facilities to avoid illegal diversion, the Antitrust Division (the "Division") supports this application for registration.[1] More importantly, the Division strongly recommends that the DEA avail itself

[1] The Division defers to the DEA on whether Johnson Matthey can be appropriately regulated so as to avoid unlawful diversion of the narcotic material it seeks to import.

of this opportunity to clarify yet again its commitment to competition by lowering the regulatory barriers to entry consistent with the need to prevent unlawful diversion. As discussed below, where a market cannot sustain numerous participants -- whether because of production requirements, economies of scale, or government regulation -- its competitiveness depends significantly on facilitating the potential for entry. By clearly articulating the appropriate standard to be used in these proceedings, and by placing the burden of proof where it properly belongs, the DEA will be able to discourage the continuing use of its procedures by those who seek to hinder the development of competition.

ISSUES

The Court framed the issues to be addressed in this proceeding in its October 20, 1999 Prehearing Ruling (ALJ Exh. 4, p.1):

1. Whether the amounts of raw opium and poppy straw concentrate proposed to be imported by Johnson Matthey are necessary to provide for medical, scientific, or other legitimate purposes pursuant to 21 U.S.C. § 952(a)(1); and
2. Whether the application of Johnson Matthey for registration as an importer of Schedule II controlled substances raw opium and poppy straw concentrate is in the public interest as that term is defined in 21 U.S.C. §§ 958(a) and 823(a).

ANALYSIS

As it appears essentially uncontested that the opium and concentrate of poppy straw ("CPS") Johnson Matthey seeks to import "are necessary to provide for medical, scientific, or

other legitimate purposes pursuant to 21 U.S.C. § 952(a)(1),"[2] the only remaining issue is whether its registration is in the public interest as that term is defined in 21 U.S.C. §§ 958(a) and 823(a). There is, however, considerable confusion in the parties' Proposed Findings of Fact over the meaning of that requirement and where the burden of proof lies. Mallinckrodt and Noramco have argued, for example, that Johnson Matthey's burden includes demonstrating that the market is not currently competitive (and that its entry will make it so); that its registration will not adversely affect supplies; and that its technological processes are efficient.

In fact, as both precedent and regulation make clear, Noramco and Mallinckrodt bear the burden of proof on all of the issues and objections to the application raised by them. More specifically, they bear the burden of demonstrating that Johnson Matthey's registration as an importer of these substances would be anticompetitive. That burden has not been met.

I. The Burden Of Proof

Mallinckrodt and Noramco have attempted to impose on Johnson Matthey requirements of proof that are inconsistent with the applicable statutes and precedents, and that are contrary to Congress's intent in mandating that the DEA foster competition in this industry. The DEA should once again affirm what the statute and its own precedents make clear: Mallinckrodt and Noramco are to carry the burden of proof in this hearing. In doing so, the DEA can limit the ability of

[2] The record makes clear that there are no meaningful substitutes for the drugs made from opium and CPS. (Exh. J-50, 3-8; Tr. 126-28). Since the United States also prohibits both the cultivation of these crops within its borders (Exh. N-2, pp.4, 6) and the importation of purified narcotic alkaloid or finished active pharmaceutical ingredients ("APIs") based upon them, 21 U.S.C. § 952(a)(2), opium and CPS must be imported to meet U.S. demand. Neither Noramco nor Mallinckrodt meaningfully contests this issue. *But see* footnote 3, *supra.*

incumbent firms to delay or thwart entry and thereby substantially facilitate the development of competition in this market.

A. The Administrator Must First Determine That The Substances To Be Imported Are Necessary For Medical, Scientific, Or Other Legitimate Purposes

Before accepting an application for registration as an importer of crude opium and CPS, both Schedule II narcotic substances, 21 U.S.C. § 812 (1999), the DEA, and ultimately its Administrator, must be satisfied that the substances may be imported into the United States, and under what circumstances. The applicable statute for importing opium and CPS, 21 U.S.C. § 952 (1999), provides in pertinent part, that:

> "[S]uch amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes . . . may be so imported under such regulations as the Attorney General shall prescribe . . . ."

21 U.S.C. § 952(a)(1). It is essentially uncontested that the narcotic raw materials ("NRMs") Johnson Matthey seeks to import are necessary for "medical, scientific, or other legitimate purposes." See note 2, above.[3]

What is important is that Johnson Matthey is *not* required to satisfy 21 U.S.C. § 952(a)(2), which applies to the importation of all *other* " . . . controlled substances in Schedule I or II or any narcotic drug in Schedule III, IV, or V," not covered under § 952(a)(1). *Id*. This distinction is

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[3] Noramco does assert, in its Proposed Findings of Fact, ¶¶ 20-23, that Johnson Matthey failed to demonstrate that the quantities it will import are "necessary to provide for medical, scientific, or other legitimate purposes . . ." because it and Mallinckrodt provide "an adequate and uninterrupted supply." In so arguing, Noramco has confused § 952(a)(1) and § 823(a)(1): nothing in § 952(a)(1) limits the number of importers to the smallest number that can provide an "adequate and uninterrupted supply" of these substances.

significant, for in contrast to subsection (a)(1), subsection (a)(2) allows for the importation of the other substances only in three specific instances:

> "(A) during an emergency in which domestic supplies . . . are found . . . to be inadequate,
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> (B) [whenever] competition among domestic manufacturers . . . is inadequate and will not be rendered adequate by the registration of additional manufacturers . . . , or
>
> (C) [whenever] . . . such controlled substances [are] in limited quantities . . . ."

Id. Both subsections (a)(1) and (a)(2) create exceptions to the general rule that it is unlawful to import into the U.S. any controlled substance in Schedule I or II or any narcotic drug in Schedules III, IV, and V. But once the requirements of § 952(a)(1) are met, the requirements of § 952(a)(2) pertaining to other controlled substances are not relevant, and Johnson Matthey need not prove that competition is currently inadequate.[4]

[4] Likewise, 21 C.F.R. § 1301.34 is not applicable: it applies only to "an application for registration . . . to import a controlled substance . . . *under the authority of . . . 21 U.S.C. § 952(a)(2)(B).*" 21 C.F.R. § 1301.34(a) (emphasis added). Applications for registration under 21 U.S.C. § 958(a)(1) (as well as those under 21 U.S.C. § 952(a)(2)(A) and (C)) are thus specifically excluded. For that reason, the factors to be considered by the Administrator listed in 21 C.F.R. §1301.34 -- for example, the extent of price rigidity, the extent of service and quality competition, the existence of substantial differentials between domestic and foreign prices -- are not relevant. *Cf. Roxane Labs, Inc.*, 63 Fed. Reg. 55, 891 (Oct. 19, 1998). Johnson Matthey is not required to make any showing under the provisions of 21 C.F.R. §1301.34, nor is Johnson Matthey required under any other statute or regulation to address the issue of whether "competition among the domestic manufacturers of [cocaine] is [currently] adequate . . . ."

B. The Administrator Must Then Determine Whether The Registration Requirements To Import Schedule II Controlled Substances Are Satisfied

Once it is determined that an applicant may legally import the substances specified in the application, the DEA must be satisfied that the registration requirements provided in 21 U.S.C. § 958(a) (1999) are met:

> The Attorney General shall register an applicant to import or export a controlled substance in schedule I or II if he determines that such registration is *consistent with the public interest* and with United States' obligations under international treaties . . . . In determining the public interest, the factors enumerated in paragraph [sic] (1) through (6) of section 823(a) of this title shall be considered.

Id. (emphasis added). Leaving aside the issue of whether the registration would be consistent with the nation's international obligations (and no credible evidence was offered to demonstrate that it wouldn't be), the DEA's task here is to determine whether Johnson Matthey's registration is consistent with the public interest.

In assessing that question, the DEA is required to *consider* the six factors enumerated in 21 U.S.C. § 823(a):

> (1) maintenance of effective controls against diversion . . . by limiting the importation . . . to a number of establishments which can produce an adequate and uninterrupted supply . . . under adequately competitive conditions . . . ;
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> (2) compliance with . . . State and local laws;
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> (3) promotion of technical advances in . . . manufacturing these . . . and develop[ing] new substances;
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> (4) prior conviction record of applicant . . . ;
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> (5) past experience in the manufacture of controlled substances and the establishment of effective controls against diversion; and
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> (6) . . . other factors . . . relevant to and consistent with the public health and safety.

Id. at § 823(a)(1)-(6). The DEA may accord each factor the weight it deems appropriate. *See Johnson Matthey, Inc.*, 60 Fed. Reg. 20,600, 20,652 (1995), *aff'd, MD Pharms., Inc. v. DEA*, 72 F.3d 920 (D.C. Cir. 1996); *Roxane Labs, Inc.*, 63 Fed. Reg. 55,891 (1998).[5]

Section 823(a)(1) is essentially a mandate to the Attorney General (or his/her designee, the DEA) to balance the need to prevent diversion against the need to ensure an adequate supply of controlled substances at reasonably competitive prices. The legislative history clearly bears this out:

> In effect, the Attorney General must seek out a balance between safeguarding against diversion and allowing for sufficient competition among manufacturers to insure reasonable prices for consumer protection.

S. Rep. No. 91-613, at 7 (1969).

As the statute provides, the DEA is also required to limit the number of importers of Schedule II substances to "a number of establishments which can produce an adequate and uninterrupted supply under adequately competitive conditions . . . ." 21 U.S.C. at § 823(a)(1). Nowhere is it stated, however, that the DEA is required to limit the number of competitors to the lowest number that can adequately provide the controlled substances. In fact, the DEA has publicly and emphatically stated the exact opposite.

In 1974, for example, when it sought to codify its interpretation and actual enforcement practice of 21 U.S.C. § 823(a)(1), the DEA proposed two changes to Part 1301 of Title 21 of the Code of Federal Regulations. 39 Fed. Reg. 12,139 (Apr. 3, 1974). Although the changes would have applied specifically to applicants who would manufacture, rather than import or export, a

[5] Since competitive issues are implicated only in § 823(a)(1), paragraphs (2) - (6) will not be addressed here.

Schedule I or II controlled substance, 21 C.F.R. § 1301.43 (redesignated § 1301.33, 62 Fed Reg. 13,938, 13,953 (Mar. 24, 1997)) and § 1301.58, the underlying issue -- how to interpret § 823(a) -- was the same.

> The Drug Enforcement Administration [hereinafter "DEA"] of the United States Department of Justice interprets the statute [21 U.S.C. § 823(a); hereinafter "the statute"] as *requiring* the registration of otherwise qualified applicants to manufacture any controlled substance, as long as the total number of registrants remains within the effective control by [sic] the Administration (emphasis added).
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> [The DEA] believe[s] that the statute permits the DEA to restrict entry to a number of registrants *only when actually necessary to maintain effective controls against diversion*. Stated conversely, the statute *requires* the DEA to register an applicant who meets all the other statutory requirements, *without regard to the adequacy of competition*, if the Administrator determines that registering another manufacturer will not increase the difficulty of maintaining effective controls against diversion (emphasis added).
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> The legislative history of the statute clearly supports this construction of the statute. The sole purpose of [the statute] was the prevention of diversion. Nowhere in the legislative history of the statute is there any indication that Congress based [the statute] on a determination that fully effective competition of controlled substances or entry into these markets is itself undesirable. *Nor is the Administrator aware of any reason to limit competition to an "adequate" level in the absence of a danger to the maintenance of effective controls against diversion* (emphasis added).

39 Fed. Reg. 12,138 (Apr. 3, 1974).

On May 17, 1974, the Antitrust Division submitted its comments in support of the DEA's proposed changes, adding its own comments on the proper interpretation of 21 U.S.C. § 823(a):

> [The Antitrust Division] believe[s] that the proposed [changes] are supported by the legislative history of [21 U.S.C. § 823(a)(1)] and consistent with the national policy in favor of competition. . . . The legislative history highlights the fact that effective control against diversion was the overriding objective of the registration provisions. Nowhere in the legislative history of [21 U.S.C. § 823(a)(1)] is there any indication that the requirement for adequate supplies under adequately competitive conditions was intended to restrict the level of entry below that necessary for control.

McNeilab's Memorandum Re: Competitive Conditions, *In the Matter of Argon Research Corp., and In the Matter of McNeilab, Inc.*, at 18 (Oct. 4, 1978).[6]

Moreover, 20 years ago, in response to an application by McNeilab, now Noramco, to import and manufacture certain Schedule II narcotics, Judge Young held that the Attorney General is directed by statute only to limit the importation and manufacture to that number of establishments which can produce the desired results:

> [S]uch a number could be three, or five, or seven just as long as the number registered could produce an adequate and uninterrupted supply . . . under adequately competitive conditions. . . . To go beyond this is to engraft onto the statute requirements which Congress simply did not put onto it. . . . *[A]ll the statute requires is that the administrator determine whether or not the number which would exist if the pending application is granted is a number which can produce the desired result and be effectively controlled so as to prevent diversion.*

In the Matter of McNeilab, Inc. ("McNeilab"), No. 78-13, at 24 (Aug. 20, 1980) (J. Young, Administrative Law Judge, DEA) (emphasis added).[7]

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[6] While the proposal to amend § 1301.43 and to enact § 1301.58 was ultimately withdrawn (to be considered for publication in a general review of the entire set of drug enforcement regulations), 39 Fed. Reg. 26,031 (Jul. 16, 1974), no substantial changes to 21 U.S.C. § 823(a)(1) have been enacted, nor have there been any substantial changes to the related regulations, at 21 C.F.R. §§ 1301 *et seq*., since the DEA's statement in 1974.

[7] *Roxane* is not to the contrary. In 1995, Roxane Laboratories, Inc. ("Roxane") applied to the DEA for registration as an importer of cocaine, a Schedule II controlled substance. *See* 63 Fed. Reg. 55,891 (Oct. 19, 1998). Since cocaine is not one of the controlled substances listed in 21 U.S.C. § 952(a)(1), Roxane had to show that its proposed importation of cocaine fell under one of the three exceptions listed in 21 U.S.C. § 952(a)(2)(A)-(C). Roxane satisfied neither subsection (a)(2)(A), as there was no emergency, nor subsection (a)(2)(C), as cocaine was not in limited quantities, but argued that it qualified under subsection (a)(2)(B): the existing competition among domestic manufacturers of cocaine was inadequate and would not be made adequate if additional manufacturers of cocaine were registered. The DEA granted Roxane's application, specifically rejecting Mallinckrodt's claim that the DEA could not grant a registration under § 952 (a)(2)(B) since it, Mallinckrodt, was able to meet the legitimate needs of the domestic market:

> An extensive reading of the legislative history reveals that the protection of the

Furthermore, *McNeilab* expressly rejected the claim made by Mallinckrodt at the time that its ability to fully satisfy demand requires that the DEA refuse to register additional importers. As the court explained:

> The statutory language does *not* require that the number of establishments be limited to the smallest number of them which can produce the stated results. Any number may be registered, the statute says, so long as that number will produce an adequate and uninterrupted supply, under adequately competitive conditions, for legitimate purposes while permitting the maintenance of effective controls.

Id., at 22 (emphasis in original).

C. Mallinckrodt And Noramco Have The Burden Of Proving That Johnson Matthey's Registration Is Not In The Public Interest

At the time of the evidentiary hearing in this matter, the DEA had not yet reached its provisional determination on the application for registration,[8] and the hearing was held solely in response to the demand made by incumbent importers and manufacturers. In such situations, the parties opposing the registration have the burden of proof. *McNeilab at 19; see also* 21 C.F.R. § 1301.44 ("Any other person participating in the hearing . . . shall have the burden of proving any

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> American consumer was of primary importance to Congress, and such protection was its intent in drafting the inadequate competition exception to the general ban on importation of Schedule I and II controlled substances. The Acting Deputy Administrator finds that it would be inconsistent with Congress' intent to interpret the statute as Mallinckrodt suggests, as such an interpretation would prevent the agency from protecting the American consumer when a domestic manufacturer is able to meet the legitimate needs of the United States, even where an egregious state of inadequate competition results in a tremendous cost to the consumer.

63 Fed. Reg. at 55,893.

[8] After the hearing, the DEA indicated that Johnson Matthey had satisfied its requirements for registration. *Government's Proposed Findings of Fact, Conclusions of Law, and Argument* at 45-46.

propositions of fact or law asserted . . . at the hearing.").[9] Consequently, Noramco and Mallinckrodt must bear the burden of proving their claim that Johnson Matthey's registration will not be in the public interest.

More specifically, they have the burden under § 823(a)(1) of demonstrating, by a preponderance of the evidence, that Johnson Matthey's registration "would result in conditions *not* adequately competitive to produce an adequate and uninterrupted supply." *McNeilab* at 43 (emphasis in original). In effect, they must demonstrate that Johnson Matthey's registration will be sufficiently anticompetitive as to jeopardize the adequacy and continuity of the supply of these substances.

II. Noramco And Mallinckrodt Failed To Demonstrate That Johnson Matthey's Registration Will Not Be In The Public Interest

Noramco and Mallinckrodt argue that Johnson Matthey's registration will not be in the public interest because, *inter alia*: (i) the market is already adequately competitive; (ii) Johnson Matthey's registration will exacerbate the "chronic shortage" of NRMs and adversely impact the

[9] *McNeilab*, interpreting what is now 21 C.F.R. §1301.44 and related regulations, held that where a hearing is conducted in response to a show cause order issued to the applicant after the DEA has determined to deny the application, the burden is on the applicant to satisfy the § 823(a) standards. Where the hearing is held solely at the request of those opposed to the registration, the opposers bear the burden of proof. However, where the hearing is "held in response both to requests from third parties and the request of an applicant who had received a show cause order proposing to deny his application, . . . the applicant has the burden *vis-a-vis* the agency, and the third party participants would have the burden with respect to propositions . . . asserted by them." *Id.* at 19. In effect, under *McNeilab* an applicant would have a burden of proof in a hearing under § 952 only where it requested the hearing in response to a show cause order proposing to deny its application. In all other instances, including the one here, the burden is on those who oppose the registration. While subsequent changes were made in 21 C.F.R. § 1301.44, in particular the addition of §1301.44(c), the regulation regarding the burden of proof remains the same as when *McNeilab* was decided. Section 1301.44(c) had been 21 C.F.R. §1311.53. The proposed renumbering was noticed at 61 Fed. Reg. 8503 (March 5, 1996).

"adequate and uninterrupted supply" that currently exists; (iii) limiting the number of importers keeps the price of NRMs low, to the benefit of consumers; and (iv) Johnson Matthey has failed to demonstrate a serious commitment to importing and processing both opium and CPS. These arguments demonstrate not only a misunderstanding of what must be proven here, but also a profound misunderstanding of the nature of competition and of the antitrust laws.

There is nothing in the record that even remotely suggests that three importers of opium and CPS would be less able than two to produce an adequate and uninterrupted supply, or that all three importers cannot be effectively controlled so as to prevent diversion. There is simply no indication that Johnson Matthey's registration would have any anticompetitive effect. Indeed, its presence in the market, in the absence of any showing of anticompetitive conduct, is almost certainly salutary.[10] The objections of Mallinckrodt and Noramco should be dismissed and Johnson Matthey's application approved.

A. Noramco And Mallinckrodt Failed To Demonstrate Johnson Matthey's Registration Will Be Anticompetitive

Noramco and Mallinckrodt argue that the market is already competitive and that there is no need to register a third importer. In support, they cite, *inter alia,* their declining "processing margins" in the face of sharp increases in the cost of the NRMs and their frequent loss of customers to each other. *McNeilab, Roxane,* and the DEA's own regulations, however, make clear that Johnson Matthey's registration does not require a showing that competition is currently inadequate, nor does proof of its current adequacy warrant a refusal to register. *See above*, pp. 9-

[10] As stated by the court in *McNeilab,* "There are competitive benefits to be anticipated from registering McNeilab to import the raw material and manufacture bulk codeine from it. *[A]ny new entrant reduces concentration and increases rivalry, thus tending to diminish any existing profits or inefficiencies.*" *McNeilab* at 49-50 (emphasis added).

10. What Mallinckrodt and Noramco must show is that Johnson Matthey's registration will be actually anticompetitive. This, Mallinckrodt and Noramco have failed to do.

Congress's preference for competition in the Controlled Substances Act ("CSA"), and in the antitrust laws more generally, is based on the belief that competition can make substantial contributions to economic performance by promoting efficiency in the use and allocation of economic resources and by engendering a "progressiveness" in the development of efficient techniques and new and improved products and services. *See* Areeda, Hovenkamp & Solow, *Antitrust Law*, ¶ 401; *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition."); *National Soc'y of Prof'l Eng'rs v. U.S.*, 435 U.S. 679, 695 (1978) ("The Sherman Act reflects a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services."). More specifically, competition fosters operating efficiency by forcing each firm to produce at the least possible cost; it promotes allocative efficiency by moving price toward marginal cost, maximizing consumer welfare. *Areeda* at ¶ 402b.

While it is clear that concentration alone, *i.e.*, the number of sellers (or buyers) in a market, is only one of the factors affecting the competitiveness of a market, it remains a useful place to start. High concentration, while not dictating non-competitive performance, can bring about "the structural prerequisites for non-competitive pricing, reducing its costs while increasing its chances for success." *Id.* at ¶ 404e. Concentration facilitates collusion or, where products are highly differentiated, even allows for unilateral anticompetitive actions. *Id.* at ¶ 409. For this reason, the Horizontal Merger Guidelines ("Guidelines"), issued jointly by the Federal Trade

Commission and the Department of Justice in 1992 (revised in 1997), begin with the calculation of market concentration in assessing the effect of a transaction on a market.[11]

The Guidelines state that markets with a HHI concentration below 1,000 (roughly translating to a market with 10 firms or more) do not typically pose a threat of anticompetitive conduct, and thus transactions resulting in HHIs of less than 1,000 would not be challenged absent exceptional circumstances. Even markets with a HHI up to 1,800 are deemed not to pose a problem unless the transaction results in a significant increase in concentration. However, markets with HHIs of 1,800 or greater are deemed to pose at least a threat of anticompetitive effects -- including higher prices, lower quality, and diminished innovation.[12] Currently, the HHI in the market for importing NRMs exceeds 5,000, clearly a highly concentrated market, and just as clearly one that has the "structural prerequisites" for anticompetitive conduct.[13]

Yet, concentration tells only part of the story. Even a highly concentrated market can be competitive where entry barriers are low. *Areeda* at ¶ 420. Monopolists (or oligopolists) are less able to extract supracompetitive prices where competitors could easily and quickly enter the

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[11] The HHI, or Herfindahl-Hirschman Index, is a standard economic measure of market concentration. It is defined as the sum of the squares of the market shares of all market participants (*i.e.*, HHI = $S_1^2 + S_2^2 + .. + S_n^2$), where n is the number of competitors in the market and S_1 is the market share of competitor 1). For the most concentrated market possible, a monopoly, S_1 = 100% and HHI = 10,000. For a more competitive market, say one that is characterized by 10 equal sized competitors, S_1 = 10% and HHI = 1,000. As the HHI rises from below 1,000 toward 10,000 (monopoly), the market power of the competitors increases as does their ability to raise price above cost.

[12] "When concentration is low . . . supracompetitive pricing is virtually unthinkable. As concentration rises . . . the risk of tacit price coordination increases. When [the HHI] exceed[s] . . . 1600, the danger becomes more severe." *Areeda* at ¶ 404e.

[13] The HHI would also exceed the standards set forth in the Guidelines if we calculated it for the relevant APIs derived from opium and CPS. *See Exh. J-45* at 6-7.

market. Even if potential competitors do not actually enter the market, the threat of entry can constrain monopolistic (or oligopolistic) pricing, provided entry barriers are low. Where, as here, entry barriers are substantial,[14] however, high concentration strongly increases the likelihood of supracompetitive prices.[15] *See, e.g.,* F. M. Scherer and D. Ross, *Industrial Market Structure and Economic Performance (3d ed. 1990)* at 17-18. A highly concentrated market with substantial entry barriers is, thus, presumptively not "adequately competitive." It is this simple fact that underlies both the *McNeilab* decision and the earlier DEA interpretation of § 823(a), both of which advocate registration for whatever number of firms the DEA can effectively regulate. Competition will be fostered by lowering the barriers to entry and increasing the number of actual -- or potential -- competitors in the market.

Moreover, what little evidence Noramco and Mallinckrodt do offer does not demonstrate that the domestic market is already adequately competitive. They argue, *inter alia,* that the fact that their "processing margins" (price of outputs minus price of inputs) have declined over the past few years as NRM costs have increased, *Noramco's Proposed Findings of Fact,* ¶¶ 36-47; *Mallinckrodt's Proposed Findings of Fact,* ¶¶ 149-155; *Mallinckrodt's Proposed Conclusions of*

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[14] The principal barrier to entry, in addition to the significant costs required by any would-be entrant for factories, distribution, and security, is the lengthy period between the time an outside firm determines to enter the market and when it can actually begin making sales. *See Mallinckrodt's Proposed Findings of Fact,* ¶¶ 82-94; *Noramco's Proposed Findings of Fact,* ¶¶ 160-64. This period is significantly expanded here by the ability of incumbents to compel the entrant to submit to a burdensome hearing on the competitive significance of having more, rather than fewer, competitors.

[15] While not relevant to this case, it is worth noting that the Guidelines in this respect are fully consistent with 21 C.F.R. §1301.34(f), which states that the existence of only a few participants does not demonstrate, in and of itself, inadequate competition. High concentration in conjunction with significant entry barriers, however, is highly conducive to an inadequately competitive outcome.

Law, ¶49, and that they lose customers to each other, *Noramco's Proposed Findings of Fact*, ¶¶ 48-54; *Mallinckrodt's Proposed Findings of Fact*, ¶¶ 137-40, prove that there is vigorous competition between them. It does nothing of the kind. Their declining processing margins as the cost of raw materials has increased may reflect nothing more than that they were already capturing supracompetitive profits. If an entity is charging supracompetitive prices, it is less able to profitably raise those prices in response to input cost increases. Thus, a monopolist (or oligopolist) already charging supracompetitive prices can expect to see the lowering of its margins in the event of a substantial increase in input costs. In contrast, in a competitive market, where price more closely approaches marginal cost, any input price increases would more typically be fully reflected in increases in the price of the finished good.[16]

Noramco's and Mallinckrodt's second argument, that their loss of customers to each other demonstrates vigorous competition, is likewise suspect. Rather than offer evidence of a meaningful shift in market shares, they merely point out the movement of some customers from one company to another. Such shifts in individual customer selection can occur whether or not the industry is competitive. What is important is the reason for, and magnitude of, the shift -- in

[16] Much effort was expended during the hearing comparing foreign and domestic prices, and the causes of those differences. The more interesting question is how Noramco and Mallinckrodt can continue to sell in the international market, where prices are lower, if their costs are so much greater than that of their foreign (non-U.S.) competitors. Their willingness to sell into that market in the face of substantially higher input and regulatory costs, assuming those sales are profitable, suggests that the margins earned on domestic sales significantly exceed the competitive price. In any event, Noramco and Mallinckrodt clearly failed to demonstrate that their domestic prices reflect a competitive market.

particular, whether the shift was in response to a significant price increase. Merely pointing out the loss of a few individual accounts does not suffice. [17]

Thus, the evidence Mallinckrodt and Noramco offer does not support the suggestion that the current market is competitive. It certainly does not suggest that granting Johnson Matthey's application would be anticompetitive.

B. Mallinckrodt's And Noramco's Claim That Johnson Matthey's Registration Will Exacerbate The "Chronic Shortage Of NRMs" And Adversely Impact The "Adequate and Uninterrupted Supply" That Currently Exists Makes No Economic Sense And Is Unsupported on the Record

Noramco's and Mallinckrodt's argument that Johnson Matthey's registration will exacerbate the "chronic shortage of NRMs" also makes little economic sense. First, while it is true that Johnson Matthey will have to build its inventory, that inventory would normally reflect its projected sales. As such, the need to create this inventory should not result in a substantial increase in market-wide demand for NRMs, as any increase attributable to Johnson Matthey's projected sales should result in a comparable decrease in inventory required by Mallinckrodt and/or Noramco.

Likewise, the claim that Johnson Matthey's registration will exacerbate the supply problem because its technology for converting NRMs to APIs is less efficient and will result in substantial wastage has little support in the record and, more importantly, has little support in economic theory. There is nothing in the record that demonstrates that Johnson Matthey's technology is substantially less efficient than that of Noramco and Mallinckrodt. Moreover, even

[17] Mallinckrodt also argues that the fact it typically sells its products at less than the list price demonstrates the competitiveness of the market. *Mallinckrodt's Conclusions of Law* at ¶ 47. It doesn't. Discounts off a list price tell us little about whether the actual price charged is the competitive price.

if it is potentially less efficient, there is little reason to expect any substantial supply disruptions in the short run since Johnson Matthey is unlikely to process substantial quantities of NRMs before the market has a chance to determine whether it can do so efficiently. Finally, and most importantly, a substantial purpose of fostering competition is to allow the market to choose the most efficient producers. If Noramco and Mallinckrodt are right, Johnson Matthey will quickly be out of business. If they are wrong, they may themselves be out of business. The point is to allow the market to decide.

Both Mallinckrodt, in its *Proposed Findings of Fact* at ¶¶ 39-81, and Noramco, in its *Proposed Findings of Fact,* at ¶¶ 20-23, argue at length that they have maintained an adequate and uninterrupted supply of APIs and that there is no reason to register Johnson Matthey. In doing so they miss the point. Congress expressly mandated that the DEA encourage competition in order to bring its benefits to consumers of these products. *Roxane,* 63 Fed. Reg. at 55,893. The objective is not only to ensure an adequate and uninterrupted supply, but to do so through a competitive market.

C. Noramco And Mallinckrodt Failed To Demonstrate That Limiting The Number Of Importers Keeps The Price Of NRMs Low, To The Benefit Of Consumers

Noramco's and Mallinckrodt's claim that limiting the number of NRM importers helps contain NRM prices, an advantage that would be lost if Johnson Matthey is allowed to register, is unpersuasive. *See Noramco's Proposed Findings of fact,* ¶¶ 136-142; *Mallinckrodt's Proposed Findings of Fact,* ¶¶ 61-65. First, Johnson Matthey's registration is unlikely to increase demand

for NRMs, but will merely redistribute the demand among three rather than two providers.[18] Second, there is no good basis for believing the market will be substantially improved by countering monopoly power (*i.e.*, the power held by India and Turkey due to the DEA's 80/20 rule) with monopsony power in the hands of Noramco and Mallinckrodt. Indeed, the ability of Noramco and Mallinckrodt to extract lower than competitive prices from foreign producers of opium and CPS can only come from their ability to suppress purchases below the level that would be set by a competitive market. The end result of that power would almost certainly be higher prices for domestic APIs, to the detriment of consumers.[19] Third, the suggestion that Johnson Matthey's application should be rejected because it would limit Mallinckrodt's and Noramco's ability to negotiate better terms with the large API users is perverse, suggesting that cartelization of the market is somehow procompetitive. What Mallinckrodt and Noramco fail to recognize is that Congress made it clear that it intended to bring competition into these markets, and to provide consumers of these products with the benefits of that competition. *See Roxane*, 63 Fed. Reg. at 55,893.

[18] Unless, of course, the competition provided by Johnson Matthey actually lowers the prices for both NRMs and stimulates legitimate demand.

[19] Claims, such as the one made here, that the monopoly power held by sellers can be effectively neutralized by permitting monopsony power on the part of the buyers have little credibility. First, there is no compelling reason to believe that fewer buyers will result in lower prices for input goods where the sellers have market power. Second, even if prices for inputs did drop, there is little reason to believe that the price of finished prices to consumers will fall since, in the absence of competition, producers like Mallinckrodt and Noramco could simply retain the benefits of the lower input prices for themselves.

D. Noramco And Mallinckrodt Have Failed To Demonstrate That Johnson Matthey Is Required To Import And Process Both Opium And CPS

Finally, Noramco and Mallinckrodt claim that Johnson Matthey failed to demonstrate a serious commitment to import and process both opium and CPS and that its failure to do so will drive up the price of APIs in the United States. *Noramco's Proposed Findings of Fact*, ¶¶ 151-167; *Mallinckrodt's Proposed Findings of Fact*, ¶¶ 82-103*; Mallinckrodt's Conclusions of Law*, ¶¶62-64. While the claim is largely unsupported -- Johnson Matthey has clearly represented to the DEA that it intends to process both opium and CPS (*see Johnson Matthey's Proposed Findings of Fact*, ¶¶ 143-47) -- there is, more importantly, no statutory or regulatory requirement that it do so. Indeed, such a requirement would be inconsistent with a competitive market. Compelling Johnson Matthey to process both opium and CPS may well require excess investment (from the perspective of the economy as a whole) in assets devoted to the processing of opium. The DEA should not mandate this investment, but allow this decision to be made by as large a set of actual and potential suppliers as possible.

CONCLUSION

Provided the DEA believes it can effectively regulate Johnson Matthey to avoid unlawful diversion of the NRMs it seeks to import, Johnson Matthey's application for registration should be approved. In addition, the DEA should avail itself of this opportunity to state again its commitment to implementing the Congressional mandate to assure competitive markets for NRMs consistent with the need to prevent their unlawful diversion. It can do so here by affirming that those incumbent firms that oppose the registration must bear the burden of demonstrating, by a preponderance of the evidence, that the proposed registration will reduce or eliminate

competition. In doing so, the DEA may finally discourage incumbent firms from exploiting its procedures to thwart or delay additional competition to the detriment of consumers.

Respectfully submitted,

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