

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 manufactures by the requirement of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event should 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.

Michael I. Cragg, Ph.D. testified on behalf of Penick. Dr. Cragg concluded that Penick's reentry into the market will result in lower prices and a more reliable supply of narcotic products. Dr. Cragg relied upon theories of competition presented in economics literature to support the proposition that prices fall as the number of competitors increases. Dr. Cragg also testified that based upon the criteria used by the United States Department of Justice, competition in the narcotics industry is limited and Penick's reentry will increase competition. He found that at the critical stage of the production chain, competition is especially inadequate in the market for semi-processed APIs as there are only two importers and producers of semi-processed APIs, Johnson & Johnson and Mallinckrodt. Dr. Cragg explained that this situation creates a competitive bottleneck that affects all levels of the production chain. Despite this level of concentration, there has been no significant entry into the API market in the last decade. Furthermore, no entry has occurred despite the 150 percent increase in the size of the narcotics finished goods market from 1995 to 2000 and an almost five-fold increase in API revenues over that same period.

Dr. Cragg further testified that during this period of static duopoly, the prices of narcotic APIs have risen faster than when there were more competitors. From 1995 to 2000 estimated profits for narcotic APIs grew from \$26 million to \$246 million—a growth rate of 57 percent annually. Dr. Cragg concluded that these returns arose because

revenues were growing faster than costs during the period when the number of importers was limited to only two. With respect to Penick's reentry into the NRM and API markets, Dr. Cragg expected such entry to raise the level of competition in the API market and lead to lower API prices.

Mark A. King, a consultant, testified on behalf of Noramco. He testified that Dr. Cragg's conclusions were incorrect, because they were based largely upon (1) a failure to consider structural factors inherent in the narcotic market as a whole; and (2) inaccurate data for NRM and API prices, and/or (3) selective application of general free market economic theories to one of the world's most highly regulated industries. Mr. King argued, in part, that NRM price increases have consistently outstripped the prices charged for narcotic APIs by Noramco during the period from 1995 to 2000; therefore, the value-added margins of narcotic APIs produced have declined, not increased. Mr. King also testified that Dr. Cragg's analysis was faulty because (1) he relied on Mallinckrodt's list prices in place of actual prices, (2) that U.S. API prices are driven not by industry concentration, but by DEA's policy of prohibiting the domestic cultivation and processing of opium poppies and (3) there is no persuasive evidence that Noramco or Mallinckrodt have been able to exert inordinate power over purchasers of APIs.

Walter H.A. Vandaele, Ph.D. testified on behalf of Mallinckrodt. Dr. Vandaele concluded generally that there is considerable competition between Mallinckrodt and Noramco in the bulk narcotic API market. Dr. Vandaele argued that significant discounting of list price and frequent switching by large customers from one bulk supplier to another evidence a significant degree of competition in the current market. Significant increases in bulk API prices reflect higher marginal costs of supplying increased demand in the face of tight supplies of raw material. Bulk suppliers' partial downstream integration into finished products provides no increase in their ability to price anti-competitively. Dr. Vandaele further argued that Penick's entry as an NRM importer and bulk API supplier would provide an insignificant impact on the level of competition in either the bulk API market or the narcotic finished product market, and no measurable impact on consumer prices.

The Deputy Administrator agrees with the ALJ that Penick has demonstrated that the opiate API market was not operating under "adequately competitive conditions" as of the date of

the hearing. As the ALJ noted, it is undisputed that prices of APIs increased substantially during the 1990s. With respect to the other factors listed in 21 CFR 1301.34(d), The Deputy Administrator also agrees with the ALJ that the customer switches referenced in the records do not demonstrate strong competition. With respect to the other factors listed, the Deputy Administrator agrees with the ALJ that they are not relevant in this case or the record is not sufficient to warrant a finding. Having found that the market is not adequately competitive, the Deputy Administrator concludes that this factor weighs in favor of granting Penick's application, even though Noramco and Mallinckrodt are capable of maintaining an adequate and uninterrupted supply.

3. Compliance with Applicable State and Local Law;

Penick adduced evidence that it was substantially in compliance with state and local law, and Noramco and Mallinckrodt did not produce evidence to the contrary. The Deputy Administrator therefore finds that this factor weighs in favor of granting Penick's application.

4. Promotion of Technical Advances in the Art of Manufacturing these Substances and the Development of new Substances.

The evidence showed that Penick has patented processes to produce oxycodone and narcotic antagonists from morphine or codeine instead of thebaine, and has invented processes to produce hydrocodone and hydromorphone. There was also evidence that Penick has a more efficient process to produce oxycodone from thebaine in that Penick is able to utilize both opium and CPS as the raw materials for producing various opiate APIs. There was further evidence that Penick plans to upgrade its facilities and has committed at least \$30 million to the projects.

Noramco adduced evidence, on the other hand, that Penick's proposed technology for producing oxycodone is not as efficient as Noramco's technology, and both Noramco and Mallinckrodt emphasized that Penick's proposed processes have not been tested in commercial production. Noramco also claimed that Penick had not demonstrated the necessary commitment of resources to adequately upgrade its operation.

While there is controversy over the quality of Penick's proposed technology that cannot be resolved by the record in this matter, The Deputy Administrator concludes that Penick's patents and