

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS  
TO AID PUBLIC COMMENT**

*In the Matter of Mylan Inc., Agila Specialties Global Pte. Limited,  
Agila Specialties Private Limited, and Strides Arcolab Limited  
File No. 131-0112*

**Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Mylan Inc. (“Mylan”), Agila Specialties Global Pte. Limited and Agila Specialties Private Limited (collectively, “Agila”), and Strides Arcolab Limited (“Strides”) that is designed to remedy the anticompetitive effects that otherwise would have resulted in eleven generic injectable pharmaceutical markets from Mylan’s proposed acquisition of Agila. Under the terms of the proposed Consent Agreement, Mylan is required to divest either Mylan or Agila/Strides products as follows: (1) to Intas Pharmaceuticals Ltd. (“Intas”), Mylan’s fluorouracil injection and methotrexate sodium preservative-free injection; (2) to JHP Pharmaceuticals, LLC (“JHP”), Mylan’s etomidate injection, ganciclovir injection, meropenem injection, and mycophenolate mofetil injection and Agila/Strides’ amiodarone hydrochloride injection and fomepizole injection; and (3) to Sagent Pharmaceuticals, Inc. (“Sagent”), Agila/Strides’ acetylcysteine injection and mesna injection. In addition, Mylan is required to release all of its rights relating to labetalol hydrochloride injection to Gland Pharma Ltd. (“Gland”).

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, or make final the Decision and Order (“Order”).

Mylan proposes to acquire Agila for approximately \$1.85 billion pursuant to a Sale and Purchase Agreement dated February 27, 2013 (“Proposed Acquisition”). The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening current and future competition in eleven generic injectable pharmaceutical product markets in the United States. The eleven product markets are: (1) amiodarone hydrochloride injection; (2) etomidate injection; (3) fluorouracil injection; (4) labetalol hydrochloride injection; (5) mesna injection; (6) methotrexate sodium preservative-free injection; (7) acetylcysteine injection; (8) fomepizole injection; (9) ganciclovir injection; (10) meropenem injection; and (11) mycophenolate mofetil injection. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Proposed Acquisition.

## The Relevant Products and Structure of the Markets

Mylan's proposed purchase of Agila will lessen current and future competition in each of the eleven generic injectable pharmaceutical product markets, in part, because the Proposed Acquisition will reduce the number of suppliers competing for customers in each market. Injectable drugs are administered intravenously, usually via a syringe or hollow needle. Generic versions of these drugs are usually launched after a branded product's patents expire, or a generic supplier successfully challenges such patents in court or reaches a legal settlement with the branded manufacturer. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, the generic suppliers compete only against each other. Sometimes, however, a branded injectable drug manufacturer may choose to lower its price and compete against generic versions of the drug, in which case it would be a participant in the generic drug market.

The number of suppliers in generic pharmaceutical markets is critical because prices generally decrease as the number of competing generic suppliers increases. In addition, the injectable pharmaceutical industry generally, and the generic products at issue in this investigation in particular, are highly susceptible to supply disruptions caused by the inherent difficulties of producing sterile liquid drugs. Recent manufacturing problems have made it difficult for customers to obtain sufficient quantities of, and contributed to price increases of, several of the generic injectable products impacted by this transaction. By reducing the number of competitors in these markets, the Proposed Acquisition will likely create a direct and substantial anticompetitive effect on prices for each of the relevant products, absent the remedies required by the proposed Consent Agreement.

The Proposed Acquisition will reduce current (or imminent) competition in the markets for each of the following generic injectable products: (1) amiodarone hydrochloride injection; (2) etomidate injection; (3) fluorouracil injection; (4) labetalol hydrochloride injection; (5) mesna injection; and (6) methotrexate sodium preservative-free injection. The structure of these markets is as follows:

- Amiodarone hydrochloride injection is an anti-arrhythmic cardiac drug of last resort used to treat patients with frequently recurring ventricular fibrillation or unstable ventricular tachycardia. The market for amiodarone hydrochloride injection is highly concentrated with only three current suppliers for the drug – Mylan, Fresenius Kabi AG ("Fresenius"), and Hikma Pharmaceuticals PLC. Mylan has a 60% share of the market. Agila has an approved Abbreviated New Drug Application ("ANDA") from the U.S. Food and Drug Administration ("FDA") and is about to enter this market, as is one other firm. Thus, the Proposed Acquisition would reduce the number of suppliers of generic amiodarone hydrochloride injection from five to four.
- Etomidate injection is an anesthetic agent used to induce general anesthesia and sedation for surgical procedures. There are currently four significant suppliers in this highly concentrated market – Mylan, Agila (which distributes its product through Pfizer Inc. and Sagent), Hospira, Inc. ("Hospira"), and American Regent, Inc. Absent a remedy, the

Proposed Acquisition would substantially increase concentration in this market, provide the combined firm a market share of 46%, and reduce the number of suppliers of generic etomidate injection from four to three.

- Fluorouracil injection treats colon, rectal, breast, stomach, and pancreatic cancers. In this highly concentrated market, four firms have supplied fluorouracil injection in the recent past – Mylan, Fresenius, Teva Pharmaceutical Industries Ltd. (“Teva”), and Sandoz International GmbH. (“Sandoz”). A number of these suppliers, however, have experienced significant manufacturing issues. Agila is the only other company that currently holds an approved ANDA to sell generic fluorouracil in the United States. The Proposed Acquisition would reduce the number of firms capable of supplying generic fluorouracil injection from five to four.
- Labetalol hydrochloride injection treats severe hypertension. The market for labetalol hydrochloride injection is highly concentrated and only five firms are capable of supplying the drug today – Mylan, Agila, Hospira, Akorn, Inc., and Apotex Inc. Currently, Hospira and Akorn make most of the sales in this market, and Mylan, Agila, and Apotex are the only other firms with approved ANDAs and manufacturing facilities currently capable of producing this product. The Proposed Acquisition would reduce the number of firms capable of supplying generic labetalol hydrochloride injection from five to four.
- Mesna injection is a detoxifying agent used to prevent damage to the urinary tract caused by ifosfamide, a third-line chemotherapy drug used to treat germ cell testicular cancer. There are four current, significant suppliers of generic mesna injection – Mylan, Agila, Fresenius, and Baxter International Inc. The Proposed Acquisition would increase concentration in this market substantially, and reduce the number of current suppliers of generic mesna injection from four to three.
- Methotrexate sodium preservative-free injection treats several types of pediatric cancers, as well as certain autoimmune disorders such as rheumatoid arthritis and multiple sclerosis. Five firms currently supply the market for methotrexate sodium preservative-free injection – Mylan, Agila, Fresenius, Teva, and Hospira. The Proposed Acquisition would reduce the number of current suppliers of this drug from five to four.

In addition, the Proposed Acquisition will significantly reduce future competition in the markets for the following generic injectable products: (1) acetylcysteine injection; (2) fomepizole injection; (3) ganciclovir injection; and (4) meropenem injection. In each of these markets, either Mylan or Agila, or both, currently do not supply an existing generic product, but will likely do so in the near future, and entry by one or both of the parties will likely increase price competition in that market significantly absent the Proposed Acquisition. The structure of each of these markets is as follows:

- Acetylcysteine injection prevents or minimizes liver damage resulting from acetaminophen overdose. There are two generic acetylcysteine injection products currently on the market, and Mylan and Agila are two of only a limited number of firms

that have generic products in development. Therefore, the Proposed Acquisition would significantly reduce the number of likely future suppliers of generic acetylcysteine injection.

- Injectable fomepizole treats accidental poisoning caused by ethylene glycol or methanol ingestion. Three firms currently supply the highly concentrated market for generic fomepizole injection – Mylan, X-Gen Pharmaceuticals, Inc., and Sandoz. Agila is developing its own generic fomepizole injection product and likely would be the next firm to enter the market. As a result, the Proposed Acquisition would significantly reduce the number of suppliers of generic fomepizole injection in the near future.
- Ganciclovir injection is an antiviral medication used to treat patients with weakened immune systems, such as patients with HIV-AIDS and transplant recipients, to slow the growth of cytomegalovirus, a form of herpes virus that can lead to blindness. Currently, Roche Palo Alto, LLC (“Roche”) sells a branded product, Cytovene. Fresenius sells the only generic version of this drug. Mylan and Agila are two of only a limited number of firms that have this drug in development. Therefore, the Proposed Acquisition would result in the reduction of likely future suppliers of generic ganciclovir injection.
- Meropenem injection is an ultra-broad spectrum antibiotic used as a last resort to treat serious bacterial infections in an intensive care setting. There are currently four suppliers of the drug – AstraZeneca PLC, Fresenius, Hospira, and Sandoz. All four of these companies, however, obtain their supplies of meropenem from two manufacturers. Mylan and Agila are two of only a limited number of firms that have a generic meropenem injection product in development. They are also the only likely entrants that will source their meropenem products from alternative manufacturing facilities. As a result, the Proposed Acquisition would significantly reduce the number of marketers, as well as the sources of manufacturing, of generic meropenem injection in the future.

Finally, the Proposed Acquisition will significantly reduce potential competition in one generic market that does not yet exist – the market for mycophenolate mofetil injections. This market would be highly concentrated when Mylan and Agila would likely enter it in the future. Mycophenolate mofetil injection is an immunosuppressant used in transplant medicine to subdue T-cell and B-cell production, reducing the risk of transplant rejection. Today, Roche sells its branded product, CellCept. When generic entry occurs, Mylan and Agila would likely be among a limited number of suppliers. Thus, the Proposed Acquisition would significantly reduce the number of likely future suppliers of this drug to the detriment of consumers.

## **Entry**

Entry into each of these generic injectable product markets will not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the likely anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes well in excess of two years.

## **Competitive Effects**

Absent a remedy, the Proposed Acquisition would likely cause significant anticompetitive harm to consumers in the relevant generic injectable pharmaceutical markets, either by eliminating significant current or potential competition in concentrated existing markets, or by eliminating significant potential competition among a limited number of likely competitors in a future market. In each of these markets, Mylan and Agila are two of only a limited number of current or likely future suppliers of the drugs in the United States. The evidence shows that prices may continue to decrease even after a number of suppliers have entered a generic injectable drug market. Thus, although Mylan or Agila have not entered some of the markets at issue yet, both companies likely will compete in those markets in the future, and that competition is expected to reduce prices for consumers. The evidence also shows that the removal of an independent generic injectable drug supplier from the relevant markets in which Mylan and Agila currently compete would result in significantly higher prices post-acquisition. Therefore, by eliminating the significant current and future competition between the parties, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic injectable drugs, absent a remedy.

## **The Consent Agreement**

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, the parties are required to divest either Mylan's or Agila's rights and assets related to (1) amiodarone hydrochloride injection, (2) etomidate injection, (3) fluorouracil injection, (4) mesna injection, (5) methotrexate sodium preservative-free injection, (6) acetylcysteine injection, (7) fomepizole injection, (8) ganciclovir injection, (9) meropenem injection, and (10) mycophenolate mofetil injection. In addition, Mylan is required to release all of its rights and assets related to labetalol hydrochloride injection. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the acquisition.

The proposed Consent Agreement requires Mylan to terminate its contract with Gland and to release all rights related to labetalol hydrochloride injection. Gland, a global pharmaceutical company based in India, is Mylan's contract manufacturer for this drug. Given its experience with this drug, Gland is well positioned to replicate the competition that would otherwise have been lost as a result of the Proposed Acquisition. The proposed Consent Agreement also requires Mylan to divest assets related to fluorouracil injection and methotrexate sodium preservative-free injection to Intas and to divest assets related to etomidate injection, ganciclovir injection, meropenem injection, and mycophenolate mofetil injection to JHP. In addition, the proposed Consent Agreement requires Agila and Strides to divest assets related to acetylcysteine injection and mesna injection to Sagent and to divest assets related to amiodarone hydrochloride injection and fomepizole injection to JHP. Intas is a global pharmaceutical company based in India with approximately 79 prescription drugs approved for sale in the United States, as well as an active product development pipeline. JHP is a New Jersey based pharmaceutical company with approximately 22 approved ANDAs and an active product development pipeline. Finally, Sagent, a pharmaceutical company based in Illinois, has approximately 58 approved ANDAs and an active product development pipeline. With their

experience in generic markets, Intas, JHP, and Sagent are expected to replicate fully the competition that would otherwise have been lost as a result of the Proposed Acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Intas, JHP, Sagent, or Gland are not acceptable acquirers, or that the manner of the divestitures or releases is not acceptable, the parties must unwind the sale or release of rights to Intas, JHP, Sagent, or Gland and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan, Agila, and Strides to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan and Agila must transfer their respective manufacturing technologies for generic amiodarone hydrochloride injection, etomidate injection, and fomepizole injection to JHP and must supply JHP with these drugs during the transition period. Further, Agila and Strides must transfer the manufacturing technology for acetylcysteine injection and mesna injection to Sagent and must supply Sagent with the two drugs during the transition period.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.