UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright

In the Matter of	)	
MYLAN INC., **a corporation;**	)	
AGILA SPECIALTIES GLOBAL PTE. LIMITED, **a corporation;**	)	
AGILA SPECIALTIES PRIVATE LIMITED, **a corporation;**	)	**Docket No. C-4413**
and	)	
STRIDES ARCOLAB LIMITED, **a corporation.**	)	

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Mylan Inc. ("Mylan"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Agila Specialties Global Pte. Limited and Agila Specialties Private Limited (collectively, "Agila"), entities subject to the jurisdiction of the Commission, from Strides Arcolab Ltd. ("Strides") in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Mylan is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its corporate office and principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

2. Respondent Agila Specialties Global Pte. Limited, a wholly owned subsidiary of Strides, is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Singapore, with its corporate office and principal place of business located at 3 Tuas South Avenue 4, Singapore 637610.

3. Respondent Agila Specialties Private Limited, a wholly owned subsidiary of Strides, is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of India, having its corporate office and principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore 560-076, India.

4. Respondent Strides is a corporation organized, existing, and doing business under and by virtue of the laws of India, having its corporate office and principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore 560-076, India.

5. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

6. Under the terms of a Sale and Purchase Agreement with an effective date of February 27, 2013 ("Agreement"), Mylan proposes to acquire all of the voting securities of Agila for approximately $1.85 billion from Strides (the "Acquisition"). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT PRODUCT MARKETS

7. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic injectable pharmaceutical products:

a. amiodarone hydrochloride injection;

b. etomidate injection;

c. fluorouracil injection;

d. labetalol hydrochloride injection;

e. mesna injection;

f. methotrexate sodium preservative-free injection;

g. acetylcysteine injection;

h. fomepizole injection;

i. ganciclovir injection;

j. meropenem injection; and

k. mycophenolate mofetil injection.

IV. THE RELEVANT GEOGRAPHIC MARKET

8. For the purposes of this Complaint, the United States is the relevant geographic market in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

9. 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 Acquisition would reduce the number of suppliers of generic amiodarone hydrochloride injection from five to four.

10. 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. The Acquisition would substantially increase concentration in this market and reduce the number of suppliers of generic etomidate injection from four to three.

11. Fluorouracil injection treats colon, rectal, breast, stomach, and pancreatic cancers. Four firms currently supply fluorouracil injection in this highly concentrated market – Mylan, Fresenius, Teva Pharmaceutical Industries Ltd. ("Teva"), and Sandoz International GmbH. ("Sandoz"). Agila is the only other company that currently holds an approved ANDA to sell generic fluorouracil in the United States. As a result, the Acquisition would reduce the number of firms capable of supplying generic fluorouracil injection from five to four.

12. Labetalol hydrochloride injection treats severe hypertension. The market for labetalol hydrochloride injection is highly concentrated. Only Mylan, Agila, Hospira, Akorn, Inc., and Apotex Inc. have approved ANDAs and manufacturing facilities currently capable of producing generic labetalol hydrochloride injection. The Acquisition would reduce the number of firms capable of supplying generic labetalol hydrochloride injection from five to four.

13. 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 Acquisition would increase concentration in this market substantially, and reduce the number of current suppliers of generic mesna injection from four to three.

14. 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 with methotrexate sodium preservative-free injection – Mylan, Agila, Fresenius, Teva, and Hospira. The Acquisition would reduce the number of current suppliers of the drug from five to four.

15. 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 Acquisition would reduce the number of likely future suppliers of generic acetylcysteine injection.

16. 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 Acquisition would reduce the number of suppliers of generic fomepizole injection in the near future.

17. 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, and Fresenius is the only generic competitor. Mylan and Agila are two of only a limited number of firms that have this drug in development. Therefore, the Acquisition would reduce the number of likely future suppliers of generic ganciclovir injection.

18. 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 only two manufacturing facilities. Mylan and Agila are two of only a limited number of firms that have a generic meropenem injection product in development and plan to procure their meropenem supplies from different manufacturing facilities. As a result, the Acquisition would reduce the number of marketers, as well as the sources of manufacturing, of generic meropenem injection in the future.

19. Mycophenolate mofetil injection is an immunosuppressant used in transplant medicine to subdue T-cell and B-cell production, reducing the risk of transplant rejection. The market for generic mycophenolate mofetil injection does not yet exist. Roche currently sells a branded version of the product, CellCept. When generic entry occurs, Mylan and Agila would likely be among a limited number of suppliers. Thus, the Acquisition would reduce the number of likely future suppliers of generic mycophenolate mofetil injection.

VI. ENTRY CONDITIONS

20. Entry into the relevant markets described in Paragraphs 7 and 8 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. Although a limited number of firms other than Respondents plan to begin competing in some relevant markets in the future, such entry would not be sufficient to prevent the competitive harm likely to result from the Acquisition. In addition, no other entry is likely to occur for a substantial amount of time that would eliminate the price increases that will occur after consummation of the Acquisition.

VII. EFFECTS OF THE ACQUISITION

21. The effects of the Acquisition, if consummated, would likely be to substantially lessen competition and tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

a. by eliminating actual, direct, and substantial competition between Mylan and Agila and reducing the number of competitors in the markets for (1) amiodarone hydrochloride injection; (2) etomidate injection; (3) fluorouracil injection; (4) labetalol hydrochloride injection; (5) mesna injection; and (6) methotrexate sodium preservative-free injection, thereby: (a) increasing the likelihood that Mylan will be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices; and

b. by eliminating future competition between Mylan and Agila and reducing the number of generic competitors in the markets for (1) acetylcysteine injection; (2) fomepizole injection; (3) ganciclovir injection; (4) meropenem injection; and (5) mycophenolate mofetil injection, thereby: (a) increasing the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

VIII. VIOLATIONS CHARGED

22. The Agreement described in Paragraph 6 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

23. The Acquisition described in Paragraph 6, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-sixth day of September 2013, issues its Complaint against said Respondent.

By the Commission.

Donald S. Clark
Secretary

SEAL: