COMPETITION COMMISSION OF INDIA

(Combination Registration No. C-2013/04/116)

20.06.2013

Notice u/s 6 (2) of the Competition Act, 2002 given by:

- Mylan Inc.

Order under Section 31(1) of the Competition Act, 2002

A. INTRODUCTION

1. On 1st April, 2013 the Competition Commission of India (hereinafter referred to as the "**Commission**") received a notice under sub-section (2) of Section 6 of the Competition Act, 2002 (hereinafter referred to as the "**Act**"), given by Mylan Inc. (hereinafter referred to as "**Mylan**" or the "**Acquirer**"). The notice was given pursuant to the execution of a Sale and Purchase Agreement entered between Mylan, Strides Arcolab Limited (hereinafter referred to as "**SAL**"), Arun Kumar and Pronomz Ventures LLP (both Arun Kumar and Pronomz Ventures LLP are identified as promoters of SAL), on 27th February, 2013 (hereinafter referred to as the "**SPA**") (hereinafter Mylan, SAL, Arun Kumar and Pronomz Ventures LLP are collectively referred to as the "**Parties to the Agreement**").

2. In terms of Regulation 14 of the Competition Commission of India (Procedure in regard to the transaction of business relating to combinations) Regulations, 2011 (hereinafter referred to as the "**Combination Regulations**"), vide letter dated 5th April, 2013, the Acquirer was required to remove certain defects and provide information /document(s) in relation to the notice and the response of the Acquirer was received on 15th April, 2013.

3. In terms of sub- regulation (4) of Regulation 5 and sub-regulation (2) of Regulation 19 of the Combination Regulations, on 18th April, 2013, the Acquirer was required to furnish certain additional information/ document(s) by 30th April, 2013. The Acquirer sought extension of time till 17th May, 2013 to submit the required information and the response of the Acquirer, in this regard, was received on 15th May, 2013. However, as the said response of the Acquirer was incomplete, vide letter dated 17th May, 2013, the Acquirer was asked to furnish the complete information/documents by 28th May, 2013. The Acquirer sought extension of time till 30th May, 2013 to submit the required information and submitted a partial response on 30th May, 2013 with a request to grant extension till 31st May, 2013 to submit the complete information, which was duly submitted on 31st May, 2013.

B. PROPOSED COMBINATION

4. As per the information given in the notice, the proposed combination relates to the acquisition of the entire issued and outstanding share capital of Agila Specialties Private Limited (hereinafter referred to as "**Agila India**") by Mylan, directly or through one of its subsidiaries, wholly or substantially owned, directly or indirectly, by Mylan, pursuant to the SPA.

5. The proposed combination falls under Section 5(a) of the Act.

6. It has also been stated in the notice that Mylan has also entered into a separate Sale and Purchase Agreement with Agila Specialties Asia Pte Ltd, a company incorporated in Singapore, and certain shareholders of SAL, pursuant to which Mylan will purchase the entire issued and outstanding share capital of Agila Specialties Global Pte Ltd (hereinafter referred to as "**Agila SG**"), a company incorporated in Singapore and an indirect wholly owned subsidiary of

SAL and the holding company for SAL's rest of the world injectables business. It has been further stated in the notice that Agila SG does not have any turnover in India, either directly or through any of its subsidiaries and therefore, the proposed acquisition of shares of Agila SG by Mylan is exempt pursuant to the Government of India Notification S.O. 482(E) dated 4th March, 2011 as amended on 27th May, 2011.

C. PARTIES TO THE COMBINATION

7. As per the information given in the notice, Mylan is a company incorporated in Pennsylvania, USA and together with its subsidiaries, functions as a fully integrated global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals. It has been stated in the notice that Mylan ranks among the leading generic and specialty pharmaceutical companies in the world and provides its products to customers in approximately 140 countries around the world. Currently, Mylan markets a global portfolio of around 1,100 different products, covering a vast array of therapeutic categories. The specialty business of Mylan focuses on respiratory, allergy and psychiatric therapies. Mylan also offers a wide range of anti-retroviral (ARV) therapies, catering to the requirements of 40 per cent of HIV/AIDS patients in the developing countries of the world.

8. Mylan is stated to be actively present in India through its three Indian subsidiaries i.e. Mylan Laboratories Limited (hereinafter referred to as "**Mylan India**"), Astrix Laboratories Limited (hereinafter referred to as "**ALL**") and Mylan Pharmaceuticals Private Limited (hereinafter referred to as "**MPPL**"). Mylan has another wholly owned subsidiary in India i.e. Mylan Laboratories India Private Limited; however, as

per the information given in the notice, it currently does not carry on any business activities.

9. It has been stated that Mylan India manufactures and supplies high quality Active Pharmaceutical Ingredients (APIs) for use in the manufacture of Mylan's own pharmaceutical products, as well as for use by third parties, in a wide range of therapeutic categories. Mylan India is stated to be one of the world's prominent API manufacturers as measured by the number of drug master files (DMFs) filed with regulatory agencies. It also plays a significant role in supplying APIs for the manufacture of anti-retroviral (ARV) drugs, which are utilized in the treatment of HIV/AIDS. Mylan India also produces a line of finished dosage form (FDF) products in the ARV market, which are stated to be sold mostly outside India. Additionally, Mylan India manufactures non-ARV FDF products that are marketed and sold to third parties by other Mylan operations around the world.

10. ALL, a subsidiary of Mylan India, is stated to be engaged in the business of manufacturing and marketing of APIs, primarily in the anti-retroviral drugs therapeutic category.

11. MPPL, a wholly owned subsidiary of Mylan Group B.V., Netherlands, a Mylan group company, is stated to be actively involved in product sourcing and procurement, global business development projects, third-party research and development, in-licensing of products and evaluating new business opportunities. As per the information given in the notice, MPPL has launched a comprehensive portfolio of FDF ARV products for the treatment of HIV/AIDS in India since August 2012.

12. Agila India, a company incorporated under the provisions of the Companies Act, 1956, is a wholly owned subsidiary of SAL. It has

been stated in the notice that Agila India is involved in the development, manufacturing and supply of injectable products mainly for the export market. Agila India has six plants in India which are capable of manufacturing various injectable formats under different product categories including oncology, penicillin, cephalosporin and general injectables. Agila India also has a research and development centre in India which is involved in the development of generic injectable products for global markets.

13. Agila India has one wholly owned subsidiary i.e. Onco Therapies Limited (hereinafter referred to as "**OTL**"). It has been stated in the notice that OTL's core business is research, development and manufacturing of oncology related pharmaceutical products and other preparations, both in injectable and solid dosage forms. (Agila India and OTL are collectively referred to as the "**Target Enterprises**").

D. ASSESSMENT OF THE PROPOSED COMBINATION

14. It is observed from the information given in the notice and other documents placed on record that Agila India and OTL primarily cater to the export market and their sales in the domestic market in India (excluding intra group sales) contributed less than 5 per cent to their consolidated sales for the financial year ended 31st December 2012. The Target Enterprises, therefore, have insignificant presence in the domestic pharmaceutical market in India. It is further observed that Mylan also has limited presence in the domestic market in India. As per the data given by the Acquirer, more than 80 per cent of the consolidated sales of Mylan India are driven from exports.

15. It is noted from the information provided by the Acquirer that the products offered by Mylan and the Target Enterprises in the domestic market in India belong to different therapeutic categories except for a

few products which, although they belong to similar therapeutic categories, are entirely different in terms of their characteristics and intended use. It is stated that this is due to the fact that Mylan India supplies APIs (which are used for manufacturing the final product i.e. formulation) whereas the Target Enterprises supply formulations in these similar therapeutic categories. Thus, the Acquirer and the Target Enterprises are not engaged in providing similar or identical or substitutable products in the domestic market in India.

16. It is also observed that a majority of the domestic sales of the Acquirer relate to the sales of APIs whereas the entire domestic sales of the Target Enterprises relate to injectable formulations. However, the APIs manufactured and sold by the Acquirer in the domestic market in India are mostly non-sterile APIs which cannot be used for developing injectable formulations. Thus, the proposed combination is also not likely to result in any vertical integration of the Acquirer and the Target Enterprises in the domestic market in India. The Acquirer has also submitted that currently it does not have the capability to produce sterile APIs in India (which are required for developing injectables) and therefore, there are no plans to vertically integrate the manufacturing operations of Mylan and Agila India.

17. The Parties to the Agreement have also entered into a Restrictive Covenant Agreement on 5th April, 2013 with an effective date of 27th February, 2013 (hereinafter referred to as "**RCA**"). It has been stated in the notice that the SPA and the RCA provide that for a period of six years from the date of closing of the proposed combination, each of Arun Kumar, Pronomz Ventures LLP, SAL and any of SAL's group companies (collectively known as the "**Promoters**") shall not (whether alone or jointly with another and whether directly or indirectly) carry on or be engaged, concerned or interested economically or otherwise in any manner in the business of

developing, manufacturing, distributing, marketing or selling any injectable, parenteral, ophthalmic or oncology pharmaceutical products for human use, anywhere in the world.

18. The Acquirer has submitted that in accordance with the standard practice, it is necessary to impose non-compete obligations of the nature as contained in the SPA and the RCA, on the promoters of the Target Enterprises and the selling shareholders, at the time of their exit, in order to protect the business interests of the Acquirer and the future value of the Target Enterprises.

19. The Commission in its Order dated 21st December, 2012 in the notice bearing Comb. Reg. No. C-2012/09/79 had observed that "*non-compete obligations, if deemed necessary to be incorporated, should be reasonable particularly in respect of (a) the duration over which such restraint is enforceable; and (b) the business activities, geographical areas and person(s) subject to such restraint, so as to ensure that such obligations do not result in an appreciable adverse effect on competition.*"[1]

20. It was observed that in the instant case, the duration of the non-compete covenant was six years and inspite of the fact that the Target Enterprises are engaged in the business of injectable products belonging to a few therapeutic categories, the non-compete covenant sought to impose a blanket restriction covering injectable products across all the therapeutic categories. Moreover, the scope of the non-compete covenant covered all products under the oncology and ophthalmic categories even though there are products under these categories which are not being currently manufactured by the Target Enterprises. The non-compete covenant also placed restrictions on the

[1] *Paragraph 10 of the said Order*

development of new molecules which are presently non-existent. In this regard, it is observed that the scope of the non-compete covenant should cover only those products which are either being presently manufactured/sold or are under development, by the Target Enterprises. The Acquirer was, therefore, required to provide a detailed justification for the duration as well as scope of business activities restricted under the non-compete covenant. In their response, the Parties to the Agreement proposed certain modification(s) in the non-compete covenant, as contained in the SPA and the RCA, under the provisions of sub-regulation (2) of Regulation 19 of the Combination Regulations.

E. MODIFICATIONS OFFERED UNDER REGULATION 19(2) OF COMBINATION REGULATIONS

21. As stated, the Parties to the Agreement, vide their letters dated 7th June, 2013 and 12th June 2013, proposed the following modifications to the SPA and the RCA, in terms of sub-regulation (2) of Regulation 19 of the Combination Regulations, in the form of an undertaking.

i. Reducing the duration of the non-compete obligations under the SPA and the RCA as applicable to the Indian market only to a period of four (4) years from the date of closing of the proposed transaction;

ii. Restricting the scope of the non-compete as applicable to the Indian market only to the products that each of Agila India and OTL currently manufactures and to pipeline products in development.

iii. Permitting each of Arun Kumar, Pronomz Ventures LLP, SAL and any of SAL's group companies to conduct research, development and testing on such new APIs/molecules which

would result in development of new APIs/molecules for injectable formulations which are currently non-existent worldwide.

22. The Parties to the Agreement have also undertaken to amend the SPA and the RCA to reflect the revised scope of the non-compete obligations as set out above and to submit a copy of the amended SPA and RCA to the Commission within three (3) months from the date of the order of the Commission.

23. The Commission hereby accepts the modifications offered by the Parties to the Agreement under the provisions of sub-regulation (2) of Regulation 19 of the Combination Regulations and directs the Parties to the Agreement to make the necessary amendment(s) in the SPA and the RCA so as to incorporate the said modifications and submit a copy of such amended SPA and RCA, along with the relevant documents, to the Commission, within a period of three months from the date of this Order.

F. CONCLUSION

24. Considering the facts on record, the details provided in the notice given under sub-section (2) of Section 6 of the Act and the assessment of the proposed combination on the basis of the factors stated in sub-section (4) of Section 20 of the Act and the modifications proposed in the SPA and the RCA by the Parties to the Agreement under the provisions of sub-regulation (2) of Regulation 19 of the Combination Regulations, the Commission is of the opinion that the proposed combination is not likely to have an appreciable adverse effect on competition in India and therefore, the Commission hereby approves the proposed combination under sub-section (1) of Section 31 of the Act.

25. This approval is without prejudice to any other legal/statutory obligations as applicable.

26. This order shall stand revoked if, at any time, the information provided by the Parties to the Agreement is found to be incorrect.

27. The Secretary is directed to communicate to the Parties to the Agreement accordingly.

Sd/-
(Ashok Chawla)
Chairman

Sd/-
(Anurag Goel)
Member

Sd/-
(S.N. Dhingra)
Member

Sd/-
(S.L. Bunker)
Member