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Contact officer: Lily Xiao
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16 December 2021

Prudence Smith
Partner
Jones Day
Aurora Place
Level 41, 88 Phillip Street
Sydney NSW 2000

Dear Ms Smith

Re: Application for authorisation of conduct – Settlement and Licence Agreement between Celgene Corporation, Celgene Pty Ltd, Natco Pharma Ltd and Juno Pharmaceuticals Pty Ltd

I refer to the application lodged by Celgene Corporation, Celgene Pty Ltd, Natco Pharma Ltd and Juno Pharmaceuticals Pty Ltd (collectively, **the Applicants**) on 3 December 2021.

Information and document request

To assist the ACCC's assessment of the application, please respond to the information and document request at **Attachment A**.

The ACCC requests Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) to provide its response to the information and document request separately to Juno Pharmaceuticals Pty Ltd (**Juno**) and Natco Pharma Ltd (**Natco**). Several of the questions in Attachment A seek Celgene's views regarding issues relating to the relevant proceedings, including Celgene's views as to the likely outcome without the Agreement. The ACCC requires this information to be provided based on Celgene's current best views, and independent of any input from or influence by any other authorisation applicant. When responding to this information and document request please confirm that the response is Celgene's independent response.

Next steps

I request the information and documents in response to Attachment A by **17 January 2022**.

Subject to our consideration of any request for exclusion from the public register, a public version of your response to this letter will be placed on the ACCC's public register.

This letter will also be placed on the public register.

If you wish to discuss the information and document request contained in Attachment A, or wish to explain some of your responses to the requests, please contact Lily Xiao on (03) 9910 9413 or at lily.xiao@accc.gov.au.

Yours sincerely

Danielle Staltari
Director
Competition Exemptions

Attachment A – Information and document request

Definitions

In this letter, including Attachment A, unless the contrary intention appears:

'Agreement' means the Settlement and Licence Agreement between Celgene Corporation, Celgene Pty Ltd, Natco Pharma Ltd and Juno Pharmaceuticals Pty Ltd;

'Application' means the application lodged by Celgene Corporation, Celgene Pty Ltd, Natco Pharma Limited and Juno Pharmaceuticals Pty Ltd on 3 December 2021;

'ARTG' means the Australian Register of Therapeutic Goods;

'Authorised Launch Dates' means the authorised launch dates for the Generic Products as defined in the Agreement;

'Celgene Patents' means the patents listed in Attachment C of the Application;

'Celgene Products' means Revlimid® and Pomalyst®;

'Director' has the meaning given by section 9 of the *Corporations Act 2001* (Cth);

'Documents' means any documents in the possession, power or control of Celgene and includes economic analysis, decision documents, business plans or business strategy documents that was sent to or considered by a Director or Senior Manager of Celgene, or any other document the parties consider would be relevant to the ACCC's assessment of the Application;

'Generic Product(s)' means generic versions of Revlimid® and Pomalyst®, which Natco wishes to manufacture and Juno wishes to market and supply in Australia, prior to the expiry of the Celgene Patents;

'PBS' means the Pharmaceutical Benefits Scheme;

'Proposed Conduct' means the description of the proposed conduct in the Application at 3.7;

'Senior Manager' has the meaning given by section 9 of the *Corporations Act 2001* (Cth).

1. Rationale / Industry Background Information

Generic products

1.1. Explain Celgene's strategy in relation to actions taken in response to the proposed launch of any generic products that will compete with Celgene's originating products, either generally in relation to any generic products or in relation to Juno/Natco's products specifically, and either in Australia or in locations including Australia.

1.2. For each Celgene Product and indication provide the following:

a) annual sales volumes in Australia for the past 3 financial years;

b) projected sales volumes in Australia for the first 3 financial years under the Agreement;

c) total revenue in Australia for the past 3 financial years; and

d) projected revenue in Australia for the first 3 financial years under the Agreement.

Please provide Documents to support the response to this question.

The agreement

1.3. Explain the rationale, including the benefits and disadvantages, for entering into the Agreement. Please provide Documents to support the response to this question.

1.4. Provide the following information in relation to the Agreement and provide any Documents which support the responses to the following requested information:

a) any business case and cost-benefit analysis undertaken to assess whether to enter into the Agreement;

b) quantify the financial value of the Agreement for Celgene;

c) quantify the financial value to Celgene of Juno and Natco starting to supply the Generic Products by the Authorised Launch Dates;

2. Impact on Competition

Celgene Products

2.1. Provide a list of wholesale and retail prices for Celgene Products for each indication.

2.2. How does the price of Celgene Products compare to the products and suppliers identified in Table 1 of the Application at 4.14(a)?

Potential entrants

2.3. What impact will the Agreement have or be likely to have on or in relation to parties who enter or seek to enter with their own generic version of the Celgene Products before the Celgene Patents expire?

2.4. What other parties is Celgene aware of who may consider or may have considered an ‘at risk’ launch of the generic version of the Celgene Products? Please outline what monitoring Celgene has undertaken with regard to third parties’ ‘at risk’ launch of generic versions of the Celgene Products and to the extent available, provide as much detail of the parties, proposed launch date(s), products, indications, PBS listings, patent licences, and pending or anticipated litigation in relation to each launch.

2.5. To the extent known, other than Natco and Juno, what parties may or are likely to enter the market in the next 10 years with a generic version of the Celgene Products or a substitute to the Celgene Products. For each of these parties, please state when entry is likely to occur if known?

2.6. Does Celgene have any agreement or arrangement with any of the parties identified in response to 2.4 or 2.5 to supply products in Australia? If so, please provide a copy of the agreement.

2.7. Having regard to the Proposed Conduct, please explain the rationale for including [redacted] Please respond from the perspective of Celgene, as well as the perspective of Natco and Juno if known.

3. Counterfactual

3.1. Outline Celgene’s strategy and proposed steps in relation to the Generic Products (and other generic versions of the Celgene Products) if ACCC authorisation is not granted and the Agreement does not come into effect. Please provide Documents to support the response to this question.

3.2. Outline Celgene’s likely strategy if Natco and Juno or another third party were to proceed with an ‘at risk’ launch of generic versions of the Celgene Products. Please provide Documents to support the response to this question.