Level 17, 2 Lonsdale Street
Melbourne Vic 3000

GPO Box 3131
Canberra ACT 2601

tel: (03) 9290 1800

www.accc.gov.au

Our ref: AA1000592
Contact officer: Lily Xiao
Contact phone: 03 9910 9413

16 December 2021

Geoff Carter
Partner
Minter Ellison
Collins Arch
447 Collins St
Melbourne VIC 3000

Dear Mr Carter

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 (**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 Natco Pharma Ltd (**Natco**) and Juno Pharmaceuticals Pty Ltd (**Juno**) to provide its response to the information and document request separately to Celgene Corporation and Celgene Pty Ltd (together, **Celgene**). Several of the questions in **Attachment A** seek Natco and Juno's views regarding issues relating to the relevant proceedings, including their views as to the likely outcome without the Agreement. The ACCC requires this information to be provided based on Natco and Juno'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 Natco and Juno'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 Natco or Juno 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 Natco or Juno, 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 Natco and/or Juno's strategy in relation to actions taken by patent holders or their licensees in response to Natco or Juno's proposed launch of any generic products that will compete with originating products, either generally in relation to any originator's products or in relation to Celgene specifically, and either in Australia or in locations including Australia.

1.2. Identify all Generic Products, and for each product identify the indications, that Natco and Juno intend to apply for on the PBS.

1.3. For each Generic Product and indication identified in response to 1.2, provide the following:

a) projected sales volumes for the first 3 financial years under the Agreement;

b) projected revenue for the first 3 financial years under the Agreement.

Please provide Documents to support the response to this question.

1.4. For each patent associated with Revlimid®, as identified in Attachment C of the application, identify the patents for which a licence is required to enable Natco and Juno to produce and supply a generic version of Revlimid® and describe why each licence is required.

1.5. For each patent associated with Pomalyst®, as identified in Attachment C of the application, identify the patents for which a licence is required for Natco and Juno to produce and supply a generic version of Pomalyst® and describe why each licence is required.

The agreement

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

1.7. 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 Natco and Juno;

c) quantify the financial value for Natco and Juno of supplying the Generic Products by the Authorised Launch Dates;

2. Impact on Competition

Potential entrants

2.1. 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?

2.2. What other parties is Natco or Juno 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 Natco or Juno 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.

2.3. 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 of the Celgene Products. For each of these parties, please state when entry is likely to occur if known.

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

2.5. Explain whether Natco and Juno would be able to assign or transfer any ARTG registration without the Agreement (per paragraph 3.7(5) of the application)?

3. Counterfactual

3.1. Outline Natco and Juno's strategy and proposed steps for the Generic 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. Provide the following information in relation to an 'at risk' launch of the Generic Products for each indication, if ACCC authorisation is not granted and the Agreement does not come into effect, and provide Documents to support the responses:

a) What are the risks associated with an 'at risk' launch for Natco and Juno for each of the Generic Products?

b) What is the anticipated or proposed 'at risk' launch date for each of the Generic Products?

c) What is the likelihood of Natco and Juno executing an 'at risk' launch for each of the Generic Products?

d) How would Natco and Juno measure or assess the success or failure of an 'at risk' launch for each of the Generic Products, and the likelihood of a successful 'at risk' launch at this time?

e) What are the likely indications for the Generic Products under an 'at risk' launch (if they differ from the indication listed in response to 1.2 above).

3.3. Explain the practical and commercial steps required for Natco and Juno to pursue an 'at risk' launch of the Generic Products for each indication and provide a timeline of any anticipated or potential launch (i) with the Agreement and (ii) without the Agreement. In relation to (ii) please identify which steps Natco and Juno have taken to date, and which steps they intend to take irrespective of the Agreement. Please provide Documents to support the response to this question.

4. Public Benefit Claims

Natco/Juno would be able to execute certain and early launch of Generic Products

4.1. Please outline Natco and Juno's plans to launch the Generic Products in Australia if the Agreement is executed, including:

a) Natco and Juno's capabilities to launch the Generic Products for each indication on the Authorised Launch Dates under the Agreement;

b) the pre-launch activities involved in launching the Generic Products for each indication including any regulatory and commercial steps;

c) the volumes of Generic Products for each indication to be manufactured and distributed at launch.

Please provide Documents to support the response to this question.