Our ref: AA1000592
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Dear Interested Party

Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd application for authorisation AA1000592 – interested party consultation

On 3 December 2021, the Australian Competition and Consumer Commission (the **ACCC**) received an application for authorisation from Juno Pharmaceuticals Pty Ltd (**Juno**), Natco Pharma Ltd (**Natco**), Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) (the **Applicants**). This letter is to invite you to comment. You are welcome to pass this letter on to others who may wish to make submissions.

The Applicants are currently involved in legal proceedings in the Federal Court of Australia in which Juno and Natco are seeking to invalidate a Celgene patent[1] relating to the cancer treatment drugs Revlimid and Pomalyst, and Celgene has filed a cross claim against Juno and Natco for threatened infringement of that patent and other Celgene patents,[2] (together, the **Celgene Patents**). The Applicants have agreed, subject to receiving authorisation, to enter into certain operative provisions of a Settlement and Licence Agreement (the **Agreement**) that would, among other things, end the current legal proceedings between the Applicants and enable Juno and Natco to bring to market generic versions of Revlimid and Pomalyst (the **Generic Products**) from an authorised launch date for each drug (**Authorised Launch Date**).

The application for authorisation

The Applicants are seeking authorisation[3] under the *Competition and Consumer Act 2010* (Cth). Authorisation would give the Applicants legal protection from competition laws to enter into, and to give effect to, specified operative provisions of the Agreement pursuant to which:

- Celgene will grant a non-exclusive, non-sublicensable, non-transferable licence to Juno and Natco under the Celgene Patents to manufacture, import and distribute the Generic Products from the relevant Authorised Launch Date for each drug
- Natco will be permitted to submit applications for the listing of the Generic Products on the Pharmaceutical Benefits Scheme, provided that such listings do not take effect until the relevant Authorised Launch Date for each drug
- Juno and Natco will not manufacture, import or distribute the Generic Products in Australia prior to the relevant Authorised Launch Date for each drug

[1] Australian Patent No. AU 715779 is for the chemical compound 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline, which is also known as "lenalidomide".

[2] Australian Patent Nos. 2003228508, 2012201727, 2003234626, 2006202316, 2012254881, 2013263799, 2007282027.

[3] For information about Authorisations, please see https://www.accc.gov.au/business/exemptions/authorisation.

- Juno and Natco will not export the Generic Products
- Juno covenants that it will not assign or transfer any registration on the Australian Register of Therapeutic Goods for the Generic Products to Natco (other than where it transfers all its rights under the Agreement to Natco) or to any third party without the prior written consent of Celgene
- Juno and Natco will not bring or participate in legal proceedings in Australia against Celgene alleging invalidity of the Celgene patents
- Celgene will not bring or participate in legal proceedings in Australia against Natco, Juno (or their suppliers, distributors, importers, wholesalers, or customers) in respect of the Generic Products after the relevant Authorised Launch Date for each drug
- Natco and Juno will not exercise any right of appeal which they may have from the Federal Court of Australia insofar as it relates to the infringement and validity of Australian Patent No. AU 715779
- The Applicants will each irrevocably and unconditionally release each other from all legal proceedings in Australia relating to the Celgene Patents,

  (together, the **Proposed Conduct**).

The Authorised Launch Date for the Generic Products is at least 2 months earlier than under any counterfactual involving Juno and Natco launching the Generic Products.

The Applicants are seeking authorisation until 2 August 2027, when the last of the Celgene Patents is due to expire. A copy of the application for authorisation is available on the ACCC's authorisations public register.

Invitation to make a submission

The ACCC is now conducting a public consultation process and invites you to make a submission commenting on the Applicants' application for authorisation. In particular, the ACCC is seeking submissions on the following issues:

- The likely public benefits and detriments arising from the Proposed Conduct, and other effects on competition.
- The likely impact of the Proposed Conduct on the entry of generic products into the market, including whether the Proposed Conduct will result in the earlier entry of generic products for the treatment of multiple myeloma and myelodysplastic syndromes.
- The likely impact of the Proposed Conduct on the future prices (including the level or extent of any discounts) of Revlimid and Pomalyst supplied by Celgene and the Generic Products to be supplied by Juno and Natco.
- Any other issues you consider relevant to the ACCC's assessment of this matter.

We request submissions by **21 January 2022**.

How to make a submission

Submissions should be emailed to exemptions@accc.gov.au, with the subject '*AA1000592 – Juno, Natco and Celgene – submission*'. Alternatively, if you would like to provide comments orally, please contact Sophie Mitchell or Lily Xiao via the details at the end of this letter.

If you wish to request an extension, please contact us on the details below as early as possible. Submissions after the due date (or after any extension granted) may not be taken into account.

Your submission **will** be placed on the ACCC's authorisation public register on the internet unless you have made a request (with reasons) for us to exclude part or all of the submission from the public register. See Guidelines for Excluding Information from the Public Register for more information on how to make a request and how we assess requests.

Timetable

The ACCC will progress its assessment of the application in a timely manner. An indicative timetable is set out below for your information, and an up to date version (including any changes) will be posted on the public register.

Indicative date	Stage in assessment process
3 December 2021	Lodgement of application and supporting submission.
15 December 2021	Public consultation process begins.
21 January 2022	Closing date for submissions about the application.
March/April 2022	Draft determination.
April 2022	Public consultation on draft determination including any conference if called.
June 2022	Final determination.

This letter has been placed on the ACCC's public register. If you have any questions or wish to discuss any aspect of this matter, please do not hesitate to contact Sophie Mitchell on (02) 9230 3843, Lily Xiao on (03) 9910 9413 or exemptions@accc.gov.au.

Yours sincerely

Susie Back
Director
Competition Exemptions