From: McIntyre, Dylan G.

Sent: Friday, 8 July 2022 1:14 PM

To: Ng, Andrew < Andrew.Ng@accc.gov.au>

Cc: Camilleri, Lyn < lyn.camilleri@accc.gov.au>; Jones, Gavin < gavin.jones@accc.gov.au>; Haly, Anthony

< Anthony.Haly@accc.gov.au>; Kolacz, Miriam < miriam.kolacz@accc.gov.au>; Xiao, Lily < lily.xiao@accc.gov.au>;

Jones Day Authorisation Australia

Jonathan Kelp

; Tatum Joseph

; Geoff Carter

; Miranda Noble

; Jacqui Ellul

Subject: Juno & Ors application for authorisation - Correction to public register

Dear Andrew.

## Public register entry

We refer to the public register entry in respect of this matter available at the following URL: <a href="https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-registers/authori

We have noticed that the description of the Federal Court Proceedings between the Applicants in the 'Summary' section of the public register does not accurately describe the set of Celgene Patents which are the subject of the Federal Court Proceedings. Accordingly, we propose the following amendments be made (with additions underlined and deletions in strikeout) to the public register:

On 3 December 2021, 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) (altogether, the Applicants). The Applicants are currently involved in legal proceedings in the Federal Court of Australia in which Juno and Natco are seeking sought to invalidate a Celgene primary patent relating claiming inter alia the compound lenalidomide (marketed by Celgene as Revlimid®) (Compound Patent), and are seeking to invalidate a number of several patents claiming inter alia the treatment of disease conditions through the administration of lenalidomide and/or pomalidomide (marketed by Celgene as Pomalyst®) (MOT Patents) to the cancer treatment drugs Revlimid® and Pomalyst® and. Celgene has filed a cross claim against Juno and Natco inter alia for threatened infringement of that primary patent and other Celgene the Compound Patent and the MOT Patentsthose patents. On 27 October 2021, the Applicants (ie both Juno/Natco and Celgene) discontinued the proceedings insofar as they related to the Compound Patent.

We do not consider these amendments to have any impact on the ACCC's consideration of the Proposed Conduct however our clients consider it is important to correct these matters for the record. The solicitors for Juno/Natco have consented to the above edits to the 'Summary' section of the public register and are copied on this email.

## Other references to Celgene Patents

Another matter in connection with references to the Celgene Patents which Celgene wishes to draw your attention to is that, as you know, the timeframe within which any proceedings challenging the validity of the Celgene Patents are likely to be finally determined is relevant to the ACCC's assessment of the counterfactual to the Proposed Conduct.

Celgene has submitted that	, including
specifically at paragraph 4.26 of Celgene's response to the draft determination dated 13 May 2022	and paragraph 7.4
of Celgene's response to interested party submissions dated 8 March 2022.	

Although it is already apparent from the context of the statements referenced above and statements elsewhere in the Authorisation Application (including paragraph 1.3(b) & footnote 5 of Confidential Annexure E to the joint Authorisation Application), for the avoidance of any doubt, Celgene notes, that

(noting, as stated in paragraph

4.4(a) and 4.14(b) of the Authorisation Application, Revlimid® is not commercially available for the mantle cell lymphoma indication but only supplied through Celgene's compassionate access program for this indication).

We note that the confidential paragraphs marked green should be excluded from the public register and not shared with any third party (including Natco/Juno) on the basis that they contain commercially and competitively sensitive information about Celgene's legal position which are not publicly available, and their disclosure would provide an advantage to competitors and/or generic manufacturers.

If you have any questions in relation to the above please let us know.

Kind regards,

Dylan

## **Dylan McIntyre**

Associate
JONES DAY® - One Firm Worldwide®
Riverside Centre
Level 31, 123 Eagle Street
Brisbane QLD 4000 Australia
Office +61.7.3085.7038
Mobile