

Our ref: AA1000592 Contact officer: Gavin Jones Contact phone: 03 9290 1475

21 June 2022

Prudence J Smith Partner Jones Day

Dear Ms Smith

Juno Pharmaceuticals Pty Ltd & Ors applications for authorisation AA1000592 – Request for further information

I refer to the above application for authorisation lodged by Juno Pharmaceuticals Pty Ltd (**Juno**), Natco Pharma Ltd (**Natco**), Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) (the **Applicants**).

In its letter of 6 June 2022, the ACCC requested further information from Celgene on a number of issues, including:



In its response of 15 June 2022, Celgene stated that:

- 2.5. ... a number of the matters raised by the ACCC clearly have no bearing on the nature and extent of competition including the ...
 2.6. Furthermore, Celgene is not in a position to provide the ACCC with information that would enable the ACCC to make an assessment of the nature and extent of competition which might exist without the Proposed Conduct, including
- 2.7. Celgene is not in possession of such information from generics and accordingly any views expressed by it would be mere speculation.
- 2.8. In any event, Celgene considers that the information sought by way of responses to the above questions is not necessary to assess the Application, whether from the perspective of understanding the nature of generic competition, or otherwise.

We intend to reach a conclusion as to whether the requested information has a 'bearing on the nature and extent of competition' or is 'necessary to assess the Application' once we have received it. However, our current expectation is that the requested information will meet both thresholds (which is why we have requested it). In any event, we do not accept your client's apparent premise that they need not provide information that they assert does not meet either of these thresholds, even where it has been specifically requested by the ACCC.

Further, the fact that Celgene considers this information to be confidential does not alter our desire to receive the requested information, and is not in and of itself a reason not to provide the information to the ACCC. As you are aware the ACCC is able to exclude information from our public register if we are satisfied that it is desirable to do so because of the confidential nature of the material. As noted in our 6 June 2022 letter, the ACCC expects that Celgene would

I also note, with respect to paragraph 2.7 of Celgene's response, the information requested in relation to these matters in the ACCC's 6 June 2022 letter did not include any information that would not be expected to be in Celgene's possession.

As such, the ACCC again requests that Celgene provide the following information:

1. With respect to lenalidomide:



Your response is required by 5pm (AEST) 27 June 2022.

With respect to your email dated 17 June 2022, responding to the ACCC's 10 June 2022 email, the fact that Celgene considers the information the subject of these emails to be confidential is not in and of itself a reason not to provide the information to the ACCC. Further, the ACCC expects that the information it has requested will be relevant to its assessment and to assess the substantiality of the claimed public benefit. Specifically, I refer to the ACCC's Guidelines:¹

The Act does not require the ACCC to quantify the level of public benefits and detriments likely to result from proposed conduct. However, where possible, and particularly with complex applications, the ACCC encourages applicants to quantify the size of claimed benefits and detriments. Quantification can provide guidance on the relative weight to be attributed to particular benefits and detriments in the ACCC's overall assessment.

Given Celgene has declined to provide this information despite it being in Celgene's possession, the ACCC will not be able to attribute as much weight to this public benefit as it may have otherwise.

A copy of this letter will be placed on the ACCC's public register once a response to the information request is received.

If you wish to discuss any aspect of this matter please do not hesitate to contact me on 03 9290 1973 or lyn.camilleri@accc.gov.au or Gavin Jones on 03 9290 1475 or gavin.jones@accc.gov.au.

Yours sincerely

Lyn Camilleri General Manager

Competition Exemptions

¹ ACCC Guidelines for Authorisation of Conduct (non-merger) March 2019, [8.12] to [8.13].