

18 July 2022

PUBLIC VERSION

Gavin Jones
Director, Competition Exemptions
Australian Competition & Consumer Commission




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Dear Gavin

Juno Pharmaceuticals Pty Ltd & Ors applications for authorisation AA1000592 – information requested from Celgene on 6 June and 21 June

The following colour coding denotes confidential information and the associated disclosure restrictions:

-  is confidential to Juno/Natco (not to be shared with Celgene or the public)
-  is confidential to Celgene (not to be shared with Juno/Natco or the public)
-  is confidential to the ACCC, Celgene and Juno/Natco (not to be shared with the public)

1. Introduction

- 1.1 We act for Juno Pharmaceuticals Pty Ltd (**Juno**) and Natco Pharma Limited (**Natco**) (**Juno/Natco**).
- 1.2 We refer to the Australian Competition and Consumer Commission's (**ACCC**) email dated 29 June 2022 with respect to the application for authorisation dated 3 December 2021 (the **Application**). The email of 29 June responds to Juno/Natco's request for a meeting with the ACCC on behalf of the Applicants.
- 1.3 We understand from this email that the ACCC is not prepared to meet with the Applicants in advance of the ACCC's final determination on the Application unless and until the Applicants provide the 'additional information that [the ACCC] considers is likely to be important to [the ACCC's] assessment which... [the ACCC has] been advised will not be provided'.
- 1.4 In the ACCC's email of 21 June 2022, the ACCC confirmed it has no outstanding information requests of Juno/Natco. As such, we assume that the 'additional information' referred to in the ACCC's 29 June 2022 email is a reference to information requested of Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) only, which has not been provided to the ACCC by Celgene. Please let us know if our understanding is incorrect.
- 1.5 In this letter, Juno/Natco take this opportunity to address key aspects of the Applicants' prior submissions (including those oral submissions made by Juno/Natco's counsel in our meeting on 23 May 2022), ahead of the ACCC making its final determination.
- 1.6 Defined terms in this letter have the same meaning as set out in the Application and Juno/Natco's response to the ACCC's draft determination dated 22 April 2022.

2. Legal test for authorisation

- 2.1 The ACCC must not make a determination granting an authorisation under section 88 of the *Competition and Consumer Act 2010* (Cth) (**CCA**) in relation to conduct unless the Commission is 'satisfied in all the circumstances' that (i) the conduct would result, or be likely to result, in a benefit to the public; and (ii) the benefit would outweigh the detriment to the public that would result, or be likely to result, from the conduct.¹
- 2.2 The level of satisfaction required is not a state of perfection. It is satisfaction 'in all the circumstances'. As the Australian Competition Tribunal (**Tribunal**) explained in *Port of Newcastle*, there must be a factual basis for authorisation (i.e. per facts disclosed 'in all the circumstances').²
- 2.3 For the reasons set out in the Applicants' responses to the Draft Determination, and addressed by Juno/Natco's counsel in our meeting of 23 May 2022, there is a clear factual basis here for concluding that significant public benefits are likely to result from the Proposed Conduct. These benefits have been defined, described with ample precision and supported by evidence, both in qualitative and (to the extent possible) quantitative terms specifically in relation to the First New Brand Statutory Price Reduction of 25%, in-market discounting and the price disclosure related price reductions.
- 2.4 In these circumstances, the absence of the 'additional information' is not a bar to the ACCC's assessment of public benefit.
- 2.5 Moreover, it would be a clear error if the ACCC were to regard the absence of the 'additional information' as somehow nullifying all of the factual circumstances established by the Applicants in support of the Application. In this regard, and consistent with legal reasoning, the ACCC cannot assume the 'additional information' (were it to be provided) would be somehow negative for the Application.
- 2.6 The legal position in relation to the appropriate approach to be taken when assessing the value of asserted public benefits is clear. That is, an applicant is not required to quantify in precise terms the benefits claimed to arise if authorisation is granted, although there must be a factual basis for concluding that the public benefits are likely to result.³
- 2.7 In *Qantas*, the Tribunal observed, among other matters, that:
- (a) the public benefits need to be defined with a degree of precision which lies somewhere between quantification in numerical terms at one end of the spectrum, and general statements about possible or likely benefits at the other end of the spectrum;⁴ and
 - (b) while, all things being equal, detailed quantification of the benefits is ideal, there are diminishing returns to any cost quantification exercise, and the costs should be quantified only to the extent that the exercise enlightens the Tribunal more than the alternative of qualitative explanation.⁵
- 2.8 These observations were endorsed by the Tribunal in *Port of Newcastle*.
- 2.9 In sharp contrast to *Port of Newcastle*, this is not a matter in which the benefits identified by the Applicants have been put largely at the 'general statements' end of the spectrum.⁶ Not only have the Applicants articulated a clear factual basis for concluding that significant public benefits are likely to result from the Proposed Conduct, they have also quantified those benefits.
- 2.10 There is simply no legal or factual foundation for the ACCC to reject the various public benefits identified by the Applicants, due to non-provision of the 'additional information', or concerns about the ACCC's ability to quantify those public benefits with precision.

¹ Section 90(7) and (8) CCA

² *Application by Port of Newcastle Operations Pty Limited* (No 2) [2022] ACompT 1 (**Port of Newcastle**)

³ *Re Qantas Airways Ltd* [2004] ACompT 9; (2005) ATPR 42-065 (**Qantas**); *Port of Newcastle*, at [34]

⁴ *Qantas*, at [204]

⁵ *Qantas*, at [208]

⁶ *Port of Newcastle*, at [37]

3. Sufficiency of information submitted by the Applicants

- 3.1 With respect to the benefits asserted by the Applicants, Juno/Natco submit that it is incontrovertible that there will be additional competition with respect to both lenalidomide and pomalidomide relative to any possible counterfactual. [REDACTED]

- 3.2 With respect to detriments, Juno/Natco submit that there is no factual basis for concluding there is a real chance of any public detriments arising. To the contrary, there is ample evidence that there is no real chance of the speculative public detriments identified by the ACCC in the Draft Determination (being detriments not identified by market participants) eventuating, and these must be dismissed.

4. Conclusion

- 4.1 Juno/Natco submits that, on the basis of the material before it, the ACCC should be satisfied the Proposed Conduct satisfies the net public benefit test. For the reasons given above, this proposition remains valid, even without the ACCC receiving the requested 'additional information' from Celgene.

Yours faithfully

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