MinterEllison.

30 May 2022

PUBLIC VERSION

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Australian Competition & Consumer Commission
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Dear Danielle

Response to additional public submissions after Draft Determination - Application for authorisation of conduct - Settlement and Licence Agreement between Celgene Corporation, Celgene Pty Ltd, Natco Pharma Limited and Juno Pharmaceuticals Pty Ltd

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

[redacted] is confidential to Applicants (not to be shared with the public)

1. Introduction

1.1 MinterEllison acts for Juno Pharmaceuticals Pty Ltd (**Juno**) and Natco Pharma Limited (**Natco**) (**Juno/Natco**).

1.2 On 3 December 2021, Juno/Natco and Celgene Corporation and Celgene Pty Ltd (together **Celgene**) lodged an application for authorisation (**Authorisation Application**).

1.3 On 23 March 2022, the Australian Competition and Consumer Commission (**ACCC**) issued a draft determination proposing to deny the authorisation (**Draft Determination**).

1.4 On 22 April 2022, Juno/Natco submitted material to respond to the Draft Determination. This included a response to a number of third party submissions.

1.5 Since that date, the ACCC has published the following additional third party submissions:

(a) the Tasmanian Department of Health's response to the ACCC's request for information dated 14 April 2022 (**Tasmanian DOH Response**);

(b) Dr Nick Murphy's response to the ACCC's request for information dated 14 April 2022 (**Dr Murphy Response**);

(c) the Society of Hospital Pharmacists of Australia's (**SHPA**) response to the ACCC's request for information dated 28 April 2022 (**SHPA Response**);

(d) the Northern Territory Government Department of Health's response to the ACCC's request for information dated 29 April 2022 (**NT DOH Response**); and

(e) a submission from RonaiPalombi dated 29 April 2022 (**RonaiPalombi Submission**)

(together, the **Further Submissions**).

1.6 The purpose of this letter is to provide Juno/Natco's response to the Further Submissions.

2. Responses to the ACCC request for information with respect to the risk management system

2.1 Juno/Natco note that the Tasmanian DOH Response, Dr Murphy Response, SHPA Response and NT DOH Response all respond to a specific ACCC request for information regarding the risk management system (**RMS**) that a sponsor of lenalidomide or pomalidomide is required to implement as a condition of regulatory approval by the TGA (together, the **RMS Responses**). For convenience, we have addressed the RMS Responses together.

2.2 As a starting point, it is clear that each of the RMS Responses is primarily concerned with the consequences of interacting with more than one RMS for pomalidomide or lenalidomide.[1] These concerns are properly viewed as directed to the way the requirement to have an RMS operates in Australia; being an inherent issue that is neither solved nor hindered by the ACCC granting authorisation. That is, the requirement for each brand to have in place an RMS is mandated by the Therapeutic Goods Administration (**TGA**) as a condition of regulatory approval. It is a requirement that must be addressed by any supplier of a pomalidomide or lenalidomide product, and will remain so with or without the Proposed Conduct.

2.3 Accordingly, Juno/Natco submit that this is not an issue on which the ACCC should place any weight in considering the Authorisation Application. It is entirely distinct from the questions that arise in respect of the Proposed Conduct, and the two should not be conflated.

2.4 In any event, the RMS Responses recognise that prescribers/pharmacists would be willing to switch to using a second or subsequent RMS.[2] In particular, the NT DOH Response states that: "*[s]hould a generic Lenalidomide and Pomalidomide product provide significant cost savings, it is likely health departments would consider switching preference to the generic and use its corresponding RMP. Alternatively, health departments may give consideration to operating two RMPs, if stakeholders considered that stocking both the originator and generic was appropriate and in the best interests of patients and the health service.*"

2.5 Further, Juno/Natco note that many of the RMS Responses refer to no more than a *preference* for one, or as a few as possible, RMSs.[3]

2.6 In this regard, however, Juno/Natco repeats its assertions in paragraph 3.4 of the Juno/Natco Submission on the Draft Determination, Annexure 1, dated 22 April 2022 (**Juno/Natco Submission**), by reference to the evidence before the ACCC, that "[a]*s noted in the Jaggers Affidavit, the REMS deals with a very small subset of patients and training in a supplier's REMS is simple, and even if there may be some advantage (from a convenience perspective) for a customer in having only one, or a small number of, REMSs, this is a very minor issue compared to the cost savings potentially available from switching to a more competitively priced supplier. Even if a given customer did not wish to use 3-4 REMSs, this does not mean that the market for a given drug could not support 3-4 different suppliers.*"

2.7 Juno/Natco otherwise repeat their submissions regarding the RMS in paragraphs 7.47 – 7.52 of the Juno/Natco Submission and 3.1 – 3.6 of Annexure 1 of the Juno/Natco Submission.

2.8 Juno/Natco note the assertion in the NT DOH Response that the TGA requirement to develop a new RMS "*may serve as an additional barrier for generic entry, given the cost to develop, operate and maintain these programs. The 'first mover' generic Cipla [sic] and Natco would potentially have an advantage when entering the market, with the assurance of market share, whereas other generics may not recoup expenses of establishing and operating an RMP if market share capture does not eventuate.*" Juno/Natco repeat their submissions in paragraph 4.2 of Annexure 1 of the Juno/Natco Submission. In summary, this purported concern is misconceived because:

(a) first, as is clear from the Juno/Natco Submission, the Proposed Conduct (if authorised) is not intended to and will not confer any anti-competitive first mover advantage on Juno/Natco.[4] [redacted]

[1] See Dr Murphy Response, response to Q3; SHPA Response, response to Q3 and NT DOH Response, response to Q3.
[2] See Tasmanian DOH Response, response to Q3; Dr Murphy Response, response to Q3; and NT DOH Response, response to Q3.
[3] See SHPA Response, response to Q4; and Tasmanian DOH Response, response to Q4.
[4] Please refer to Juno/Natco's Submission, paragraphs 7.33 – 7.46 on first mover advantage.

[redacted]

(b) second, an RMS is not in and of itself a barrier to entry; and

(c) third, even if the requirement to implement an RMS *was* a barrier to entry, this arises with or without the Proposed Conduct.

3. RonaiPalombi Submission

3.1 The RonaiPalombi Submission responds to the Generic and Biosimilar Medicines Association's (**GBMA**) submission dated 8 April 2022 (**GBMA Submission**).

3.2 The RonaiPalombi Submission asserts that the GBMA is ill equipped to comment on the potential impact of the Proposed Conduct on competition in the Australian market. This assertion appears to be based on the premises that the GBMA does not represent the individual commercial interests of any one company, and does not have capacity to provide an independent commercial analysis of an individual company's business. However, Juno/Natco submit that, as the peak representative body of generic and biosimilar medicine suppliers in Australia, the GBMA is therefore very well placed to provide a sector-wide perspective.[5]

3.3 The RonaiPalombi Submission questions whether the "*GMBA's support for the Application may be unintentionally biased*" given that Juno is one of the members of GMBA. There is no foundation for this entirely speculative assertion. Juno is but one of nine generic pharmaceutical suppliers who are GBMA members, all of whom supply generic and biosimilar medicines in Australia, and the other eight of whom are not applicants for authorisation in this case. In fact, both Natco and the other joint applicant for authorisation, Celgene, are not GBMA members.

3.4 Juno/Natco disagree that there is any flaw with the GBMA's assertion of a potential chilling effect on patent settlements should the Proposed Conduct not be authorised.[6] Rather, Juno/Natco submit that there is nothing inherently anti-competitive in a settlement of this nature. In that respect, Juno/Natco repeat their submission in paragraph 8.1 of the Juno/Natco Submission.

3.5 More specifically, Juno/Natco reject the unsubstantiated assertion that patent settlements of this nature "*deny market entry to other competitors, effectively shutting out competition.*"[7] Juno/Natco repeat their submissions in paragraphs 7.56 – 7.59 of the Juno/Natco Submission. In summary, the Proposed Conduct does not change the likelihood of 'at risk' entry by other generic suppliers of either lenalidomide or pomalidomide, and there is no aspect of the Agreement that denies market entry to other competitors.

3.6 Juno/Natco further assert that there is no proper basis to disregard the GBMA's reliance on "*the existing ARTG registrations for lenalidomide as indicative of likely entry by a number of other generic suppliers.*"[8] While it is correct that the mere existence of an ARTG registration does not *guarantee* market entry, each registration ought properly be characterised as indicative of an intention to enter the market, otherwise there would be no need or incentive for a generic supplier to take such a step. With respect, the fact that applying for or obtaining regulatory approval, or applying for PBS listing, are not acts of "exploitation" for the purpose of determining patent infringement has no bearing on the relevance of those other ARTG registrations for the ACCC's consideration of the Proposed Conduct.

3.7 The RonaiPalombi Submission also asserts that the TGA's requirement for an RMS is a barrier to entry.[9] Juno/Natco repeat their submission above at paragraphs 2.4 to 2.8.

3.8 Juno/Natco submit that the assertions made in paragraphs 10 to 17 of the RonaiPalombi Submission are entirely speculative and/or misconceived, and irrelevant to the Authorisation Application, and should be given no weight for at least the following reasons:

(a) the Agreement is not a 'pay-for-delay' arrangement;

(b) there is no legislative mechanism to support "*testing the limits of retrospectivity of patents*", and no legal basis upon which the Commonwealth could *"claw back from the*

[5] RonaiPalombi Submission, paragraph 1.
[6] RonaiPalombi Submission, paragraph 4.
[7] RonaiPalombi Submission, paragraph 4.
[8] RonaiPalombi Submission, paragraph 5.
[9] RonaiPalombi Submission, paragraph 8.

patentee the economic benefit derived from its exploitation of the patent rights" (relevantly, the RonaiPalombi Submission does not identify any cause of action upon which the Commonwealth could rely to make such a claim);

(c) further, Juno/Natco are not aware of any legislative or law reform proposals that, if implemented, would support such a claim by the Commonwealth in the future;

(d) any purported comparison to the Commonwealth's claims for damages for losses arising from an interlocutory injunction found to have been improperly granted is misconceived, because in that scenario there is a proper legal basis for such a claim, namely the undertaking that a patentee gives to the Court for the benefit of any third party adversely affected by the interlocutory injunction; and

(e) the assertions in these paragraphs of the RonaiPalombi Submission are wholly premised on the validity of the Celgene Patents being successfully challenged, such that they are all found to be invalid. There are currently no other proceedings on foot in Australia whereby a generic is seeking to invalidate the Celgene Patents, and as a practical matter the likelihood of that occurring is substantially, if not entirely, diminished as patent expiry approaches.

4. Summary

4.1 In summary, Juno/Natco submit that in its consideration of the Authorisation Application the ACCC should place no weight on the TGA's regulatory requirement with respect to an RMS, as this is a requirement that applies both to the Proposed Conduct and the counterfactual (ie without the Proposed Conduct). Further, the Agreement does not guarantee a first mover advantage for Juno, which appears to be the underlying premise of some or all of the RMS Responses.

4.2 Finally, with respect, the ACCC should disregard the RonaiPalombi Submission, as it is entirely speculative, and premised on either hypothetical scenarios or positions for which there is no proper legal basis.

Please contact us if the ACCC requires further information.

Yours faithfully
MinterEllison

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