MinterEllison.

15 June 2022

PUBLIC VERSION

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Dear Susie

Juno Pharmaceuticals Pty Ltd & Ors applications for authorisation AA1000592 – Extension to statutory timeframe and request for further information

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

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

[redacted] is confidential to Juno/Natco (not to be shared with Celgene or the public)

[redacted] is confidential to Juno (not to be shared with Natco, Celgene or the public)

1. Introduction

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

1.2 Thank you for the Australian Competition and Consumer Commission's (**ACCC**) information request dated 6 June 2022 with respect to the application for authorisation dated 3 December 2021 (the **Application**).

1.3 This letter comprises Juno/Natco's response to the information requested. 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 (**Response to the Draft Determination**).

2. Juno / Natco's response

2.1 Question 1: Supply contracts

1. Provide the three most recent supply contracts Juno has entered into with each of the following categories of customers:

a. public hospitals;

b. private hospitals;

c. pharmacies;

d. state procurement entities; and

e. any other customer category Juno/Natco considers relevant,

where those supply contracts include a 'price refresh' clause and/or 'market dynamics' clause.

2.2 [redacted]

2.3 In response to question 1(e), [redacted]

2.4 As explained in paragraph 7.45 of the Response to the Draft Determination, a first generic entrant would be unable to "lock up" volumes due to:

(a) tenders and contracts not being synchronised across customers; and

(b) the fact that a majority of the contracts are likely to contain a clause which would allow the contract to be re-tendered following a change in market circumstances (which typically include when other generic suppliers enter the market at patent expiry). This is referred to as a 'market dynamics' clause.[1]

[redacted]

2.6 In addition, as explained in paragraph 7.46 of the Response to the Draft Determination, there is typically a 'price review' (or 'price refresh')[3] clause in these contracts, which means that suppliers will continue to be constrained by the pricing behaviour of other generic suppliers.

[redacted]

[1] This is defined in the Expert report of George Siolis, 22 April 2022, [68].

[redacted]

[3] This is defined in the Expert report of George Siolis, 22 April 2022, [68].

[redacted]

2.8 A summary of Juno's supply contracts containing a 'price refresh' clause, and/or a 'market dynamics' clause, which are responsive to question 1, is set out in Table 1 below.

2.9 It is important to understand that other provisions of Juno's customer contracts contribute to an insecurity of business for Juno (and indeed other suppliers answering tenders on like terms), which mean that Juno (and other suppliers) will continue to be constrained by the behaviour of their competitors even without the customer exercising its rights under a 'market dynamics' or 'price refresh' clause. These provisions include:

[redacted]

Table 1 – Juno supply contracts

Customer category	Customer counterparty	Price refresh clause	Market dynamics clause	Other relevant clause	Confidential Annexure #
[redacted]					

[redacted]

Lenalidomide

2.10 ***Question 2: Commercial strategy for pricing its generic lenalidomide products***

2. Juno/Natco's economic expert report submits that [redacted] Provide Juno/Natco's commercial strategy for pricing its generic lenalidomide products. For lenalidomide, describe how this strategy changes in the following circumstances:

> ***a. Juno/Natco is the only generic manufacturer who enters on the authorised launch date;***
>
> ***b. Juno/Natco enters with one other generic manufacturer on the authorised launch date;***
>
> ***c. Juno/Natco enters with two other generic manufacturers on the authorised launch date;***
>
> ***d. Juno/Natco enters with three or more other generic manufacturers on the authorised launch date.***

2.11 As explained in paragraphs [9] to [12] of the Affidavit of Mark Jaggers affirmed on 15 June 2022 (**Jaggers Second Affidavit**), Juno's pricing strategy for lenalidomide is [redacted] Juno's internal financial forecasts adopt a number of assumptions about the likely competitive landscape around the lenalidomide authorised launch date, [redacted] Juno's current forecasted price for lenalidomide is based on the assumption that there will be [redacted]

2.12 In response to questions 2(a)-(d), Juno would [redacted]

2.13 It should be noted that Juno's entry on the authorised launch date in the scenarios in questions 2(a)-(d) will also have the same impact on its competitors; [redacted].[7] The RBB Report notes that discounting will be two-way[8] and this logic applies equally

[4] Jaggers Second Affidavit, paragraph [13].
[5] Jaggers Second Affidavit, paragraph [15].
[6] Jaggers Second Affidavit, paragraph [9]. See also the RBB Report, paragraph [59].
[7] Jaggers Second Affidavit, paragraph [17].
[8] RBB Report, paragraph [162].

to all generic suppliers (as well as Celgene), given that Juno is a reliable, high value and credible competitor.[9]

Juno/Natco's entry will drive down the price of pomalidomide and lenalidomide products

2.14 The general proposition that more competitors entering a market will lead to lower prices is a fundamental principle of orthodox economic theory. It is applicable to both the lenalidomide and pomalidomide products, as supported by the expert economic evidence given on behalf of the Applicants. For example, Mr O'Toole states:

> *"56. Based on my experience and knowledge of the legislation and mechanics of price disclosure, in my view generic competition consistently exerts significant downward pressure on the price of PBS listed pharmaceuticals.*
>
> *57. It has also been my observation that the greater the market density (that is, the more numerous the PBS listed generic brands of a pharmaceutical), the greater the downward pressure on the PBS price. In practice, a pharmaceutical operating in a market with numerous PBS listed generic competitors is more likely to have its first price disclosure reduction occur at an earlier stage and also to experience price reductions in excess of the statutory discount threshold of 10% compared to pharmaceuticals with fewer PBS listed generic competitors."*
>
> *"105. Based on these matters and the discussion at paragraphs 91 - 96 above, it is my opinion that notwithstanding that individual pharmaceuticals will exhibit individual behaviours having regard to matters such as the nature of the pharmaceutical, the market for that pharmaceutical and the capacity of individual companies to compete in the market, the analysis demonstrates a likely association between the number of competing PBS brands and the occurrence of price disclosure reductions. That is, the greater the number of brands listed at first generic entry, the earlier the cycle at which the first price disclosure reduction will occur (an example of which is bosentan, referred to in paragraph 100 above). In addition, even if a small number of brands is listed at first generic entry, the subsequent participation of additional brands increases the likelihood of a price disclosure reduction (an example of which is azacitadine, referred to in paragraph 97 above)."*[10]

2.15 Similarly, the RBB Report notes:

> *"159. I also consider it highly likely that Juno/Natco's entry will lead to discounts over and above the statutory 25% price reduction immediately and that such discounts will be material. This is for two reasons.*
>
> *160. Firstly, to the extent that they have contracts with Celgene (instead of procuring from Celgene on an order-by-order basis), customers' current contracts will generally enable them to seek a lower price or re-tender in response to a change in market conditions, such as entry by the first generic supplier. In this way, Celgene will face competitive pressure from Juno/Natco from early on.*
>
> *161. Secondly, to win customers from Celgene Juno/Natco will need to give these customers a reason to switch. The statutory 25% price decrease applies equally to Celgene's prices and Juno/Natco's prices and therefore customers are unlikely to switch to Juno/Natco unless it prices even lower. Given Juno/Natco is a generic supplier and the main way generics compete with originators is through prices, I would expect Juno/Natco to offer a material discount over and above the statutory 25% price decrease in order to win customers from Celgene.*
>
> *162. For avoidance of doubt, I would expect this discounting to be two-way. As I mentioned earlier in section 3.2, I would expect Celgene to respond to Juno/Natco's entry by lowering the prices it offers customers for its lenalidomide and pomalidomide products. I understand that in theory it can be, under certain conditions, profit-maximising for an originator to continue selling at high prices to a price-insensitive/brand-conscious segment of the market*

[9] Jaggers Second Affidavit, paragraph [17].
[10] Statutory Declaration of Gregory O'Toole, paragraphs [56], [57] and [105].

and forego sales to the price-sensitive segment of the market. However, I do not consider this likely to arise in the present markets given branding is not an important source of differentiation (with these drugs generally being prescribed by doctors and hospital patients having limited choice over their prescriber's choice of brand)."[11]

2.16 [redacted]

2.17 In-market discounting occurs independently of the PBS price disclosure regime, through progressive discounting across sequential tenders via the process of competition which is described above. This generates immediate benefits to state and territory health authorities and hospitals in the form of retained income (the difference between the PBS reimbursed price and the discounted price paid).[13] In-market discounting is a public benefit in and of itself, even before secondary savings to the Commonwealth are generated (which will occur after in-market discounting reaches the requisite level to trigger PBS price reductions via the PBS price disclosure regime).

2.18 Therefore, the Proposed Conduct will likely lead to both in-market discounting and significant secondary savings to the Commonwealth as a result of the competitive pressures arising from generic entry by Juno/Natco. These benefits arise regardless of whether there is another supplier of generic lenalidomide or pomalidomide products from the same launch date as Juno/Natco. The ACCC has accepted that PBS cost savings may constitute a public benefit in its draft determination[14] and in Juno / Natco's view, there is no basis on which the equivalent public benefit of in-market discounting ought not to be accepted as a public benefit in its final determination.

2.19 **Question 3: Commercial strategy if other generic(s) enter**

3. Does the response to questions 2(b)-(d) differ if the other generic(s) enter after the Juno/Natco authorised launch date?

2.20 [redacted].[15]

Pomalidomide

2.21 **Question 4: Commercial strategy for pricing its generic pomalidomide products**

4. Juno/Natco's economic expert report submits that [redacted] ***Provide Juno/Natco's commercial strategy for pricing its generic pomalidomide products. For pomalidomide, describe how this strategy changes in the following circumstances:***

a. Juno/Natco is the only generic manufacturer who enters on the authorised launch date;

b. Juno/Natco enters with one other generic manufacturer on the authorised launch date;

c. Juno/Natco enters with two other generic manufacturers on the authorised launch date;

d. Juno/Natco enters with three or more other generic manufacturers on the authorised launch date

[11] RBB Report, paragraphs [159] to [162].
[12] Jaggers Second Affidavit paragraph [20].
[13] Jaggers First Affidavit, paragraph [60].
[14] ACCC Draft Determination, paragraph [4.48].
[15] Jaggers Second Affidavit, paragraph [16].

2.22 Juno's pricing strategy for pomalidomide is [redacted] Juno's internal financial forecasts use a number of assumptions about the likely competitive landscape around the pomalidomide authorised launch date to take into account [redacted] Juno's forecasted price for pomalidomide is based on the assumption that there will be around [redacted].[16]

2.23 In response to questions 4(a)-(d), Juno would [redacted]

2.24 For the same reasons as given above in paragraph [2.13], Juno's entry on the authorised launch date in the scenarios in questions 4(a)-(d) will also have the same impact on its competitors: [redacted]

2.25 The evidence and reasoning in paragraphs [2.14] to [2.18] above apply equally to pomalidomide.

2.26 **Question 5: Commercial strategy if other generic(s) enter**

5. Does the response to questions 4(b)-(d) differ if the other generic(s) enter after the Juno/Natco authorised launch date?

2.27 [redacted][20]

2.28 **Question 6: Alternative settlement in counterfactual**

6. [redacted] ***and in circumstances where there is*** [redacted] ***please advise whether or not you still consider that an alternative settlement could not be reached in the counterfactual, and why this is the case?***

2.29 [redacted]

3. Supplementary submissions on the effect of contractual provisions regarding pre-launch activities

3.1 On 27 May 2022, the ACCC requested the Applicants to confirm whether they agreed to extend the date by which the ACCC would be required to make a determination in relation to the Authorisation Application to 29 July 2022. The Applicants confirmed on 27 May 2022 that they agreed to the extension of the relevant period until 29 July 2022 (**Extended Determination Deadline**). If the

[16] Jaggers Second Affidavit, paragraphs [9] to [11], [18] and [19].
[17] Jaggers Second Affidavit, paragraph [21].
[18] Jaggers Second Affidavit, paragraph [9]. See also the RBB Report, paragraph [59].
[19] Jaggers Second Affidavit, paragraph [23].
[20] Jaggers Second Affidavit, paragraph [22].

ACCC were to grant authorisation of the Proposed Conduct on, for example, 15 July 2022, it will not come into effect until at least 6 August 2022 (assuming no third party appeal to the Australian Competition Tribunal), being 21 days from an authorisation decision that is not appealed.

3.2 The operative provisions of the Settlement Agreement, [redacted] only come into effect when the ACCC condition precedent is satisfied, [redacted]

3.3 The purpose of this submission is to explain to the ACCC that by virtue of the Extended Determination Deadline, there is no longer any possible basis for the ACCC to find any potential detriment with respect to the operation of [redacted] of the Settlement Agreement. Accordingly, to the extent the ACCC is making any market enquiries as to any possible detrimental effect of these clauses, they must reflect this fact.

Proposed Conduct does not give rise to any detriment

3.4 As established in paragraph 7.3 of the Response to the Draft Determination, Juno/Natco are of the view that the Proposed Conduct would not result, or be likely to result, in any material public detriment.

3.5 Paragraph 7.4 of the Response to the Draft Determination [redacted] As the Extended Determination Deadline causes the effective date for authorisation to be extended to potentially as late as 19 August 2022, [redacted]

3.6 That is, the Extended Determination Deadline provides absolute certainty that any decision granting authorisation cannot give rise to [redacted] ith respect to lenalidomide, the Extended Determination [redacted] cannot give rise to [redacted]

3.7 The ACCC can therefore have no basis for finding public detriment of this kind as a result of authorisation of the Proposed Conduct.

No detriment as it relates to pomalidomide

3.8 Juno/Natco's position with respect to a potential detriment as it relates to pomalidomide, expressed in paragraphs 7.4 and 7.11 to 7.14 of the Response to the Draft Determination, remains unchanged.

3.9 Juno/Natco are of the view that the Proposed Conduct simply does not give rise to any public detriments from contractual restrictions in relation to pomalidomide. As depicted in Figure 1 below, the timing of the Extended Authorisation Deadline [redacted] That is, once the ACCC condition precedent is met [redacted] Prior to the ACCC condition precedent being met, there is no contractual restriction in force on Juno/Natco under [redacted] Therefore, should authorisation be granted and the Settlement Agreement comes into force, it is certain that there are and will be no relevant contractual restrictions on Juno/Natco preventing them from undertaking competitive activity [redacted]

3.10 Please see Figure 1 below, which illustrates there is no detriment as it relates to pomalidomide using an example final determination date of [redacted]

Figure 1 – Pomalidomide key dates

No detriment as it relates to lenalidomide

3.11 Juno/Natco's position with respect to any perceived potential detriment as it relates to lenalidomide, expressed in paragraphs 7.4 and 7.6 to 7.10 of the Response to the Draft Determination, remains unchanged.

3.12 Due to the Extended Determination Deadline, it is similarly almost virtually certain that, like pomalidomide, the operative provisions in of the Settlement Agreement will only come into force on a date after once the ACCC condition precedent is satisfied Once the ACCC condition precedent is met,

3.13 If the ACCC were to decide to authorise the Proposed Conduct on, for example, authorisation would not come into effect until at the earliest. Thus of the Settlement Agreement could only come into effect on (at the earliest), being the date on which the ACCC condition precedent is met. In that case, there is no possible basis for the ACCC to maintain any concerns about any public detriment as to any contractual restrictions preventing Juno/Natco from undertaking competitive activity, since Juno/Natco

3.14 In fact, should the ACCC decide to authorise the Proposed Conduct on any date from onwards, the effective date for authorisation will remain no earlier than Again, as noted above, prior to the ACCC condition precedent being met, there is no contractual restriction in force on Juno/Natco under Therefore, should authorisation be granted and come into effect from there are and will be no relevant contractual restrictions on Juno/Natco

3.15 In the unlikely event that the ACCC decided to authorise the Proposed Conduct prior to the contractual restriction in relation to lenalidomide still does not give rise to any public detriment, for the reasons explained in paragraph 7.4 of the Response to the Draft Determination.

3.16 Please see Figure 2 below, which illustrates there is no detriment as it relates to lenalidomide using an example final determination date of [redacted]

Figure 2 – Lenalidomide key dates

4. Conclusion

4.1 Juno/Natco submit that the evidence provided by the Applicants substantiates a clear, unambiguous and compelling case for authorising the Proposed Conduct. The ACCC should be satisfied the Proposed Conduct would not, or would not likely, result in any public detriments and would, or would likely, result in material and substantial public benefits. Even if the ACCC was satisfied only of the public benefits consisting of in-market discounting and secondary price effects (which result in substantial and immediate savings to the public health sector and relieving the burden on the provision of critical public health services) these are clearly sufficient in and of themselves to satisfy the net public benefit test for authorisation of the Proposed Conduct.

Yours faithfully

MinterEllison

Contact: Jacqui Ellul T: [redacted]

Partner: Geoff Carter T: [redacted]

Affidavit

In the matter of:

An Application for authorisation under section 88(1) of the Competition and Consumer Act 2010 (Cth)
Lodged by: Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd

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

[redacted] is confidential to Juno/Natco (not to be shared with Celgene or the public)

Affidavit of: Mark Jonathan Jaggers

Address: Juno Pharmaceuticals Pty Ltd, 42 Kelso Street, Cremorne, VIC 3121

Occupation: Chief Commercial Officer

Date: 15 June 2022

I, Mark Jonathan Jaggers of 42 Kelso Street, Cremorne, VIC 3121, affirm:

1. I am the Chief Commercial Officer of Juno Pharmaceuticals Pty Ltd (**Juno**).

2. Juno is one of the parties seeking authorisation by the Australian Competition & Consumer Commission (**ACCC**) to give effect to certain provisions of a Settlement and Licence Agreement (the **Agreement**) in relation to pharmaceutical products (the **Authorisation Application**). The Authorisation Application is made jointly by Juno, Natco Pharma Ltd (**Natco**), and Celgene Corporation and Celgene Pty Ltd (referred to jointly in this affidavit as **Celgene** unless the context requires otherwise).

3. This is my second affidavit. My first affidavit was affirmed on 21 April 2022 and submitted to the ACCC on 22 April 2022.

4. I am aware that the ACCC issued a request for information to Juno and Natco on 6 June 2022, which contained questions around Juno's commercial strategy for pricing its

intended generic lenalidomide and pomalidomide products. The purpose of this affidavit is to respond to those questions.

5. This affidavit is based on my own knowledge and on information obtained from the business records of Juno and its related entities.

Juno's commercial strategy for pricing

6. As explained by Mark Crotty in paragraph [20] of his affidavit sworn on 21 April 2022 (**Crotty Affidavit**), Juno focusses on supplying generic medicines that are primarily administered and used in a hospital setting (as opposed to medicines primarily dispensed in retail pharmacies). For public hospitals in Australia, a centralised medicines procurement agency in each state or territory (in some states this may be the State Health Department) manages the procurement of medicines through a contracting or tender process. Similarly, private hospital pharmacy groups run tenders, and award contracts primarily on price, although they are more likely to enter post tender negotiations with preferred suppliers. I agree with the descriptions of procurement processes for public and private hospitals set out in paragraphs [39] to [52] of the Crotty Affidavit.

7. State and hospital procurement bodies are highly sophisticated customers and will have knowledge of any anticipated market entry via their monitoring activities, both formal and informal (for example, monitoring for new ARTG registrations and subsequent PBS listings, and communications with sales representatives of pharmaceutical suppliers or wholesalers). As explained in paragraphs [47] and [50] of the Crotty Affidavit, supply contracts entered into by state departments and other hospital groups typically include a 'price refresh' and/or 'market dynamics' clause. This means that customers are able to reopen price discussions with an incumbent supplier and/or open up a tender process when they believe they are justified depending on their contract terms. These customer groups will often initiate a tender process in response to the entry of the first generic brand of a medicine, and tend to do so within a short time frame of the launch. In some cases the tender will be called in advance of a launch if the date of generic competition is perceived to be certain. Other customers may wait until a later date, either to allow for the entry of more generic suppliers, in an effort to achieve a more competitive price, or to align with their regular procurement cycles. The result is that not all tenders are called at the same time, and tender outcomes tend to have improved prices (for the customer) on a sequential (rather than volume) basis, given that state authorities publish their tender results. That is, a tender body would generally not accept a supplier proposing a more expensive price for a particular medicine than that supplier has provided to another

customer. It is often in response to improved market prices over time that various purchaser bodies (be they public or private) complete their tender processes, and the price as a result starts to move downwards. Prior to that, while sole supplier products (typically those subject to patent protection) are sometimes listed in a competitive tender, this usually results in the customer purchasing the product at full list price in any event, because there is no competition for supply of the product and therefore no reason for the supplier to offer a discount.

8. A tender is a highly competitive process amongst medicine suppliers. For most state and territory hospital procurement bodies, price will be a key (if not the only) determinant in selecting the supplier for any given medicine. A major tender issued by a state health authority will typically include a substantial number of medicines (it is not uncommon to issue what is referred to as an "A-Z" tender, which means a tender seeking a supplier for every pharmaceutical item purchased by the state procurement body or private hospital group). Accordingly, any such tender will typically have multiple successful suppliers. Even where a procurement body takes into account factors other than price (i.e. a preferred supplier approach), their key consideration is still typically price. However, in such a situation they may use the submitted tender responses as a starting point for post-submission price negotiations with "preferred" suppliers, as opposed to simply awarding the contract to the supplier which offered the lowest price initially. Alternatively, they may award the tender for that product to a supplier with a price close to, but slightly higher than, the lowest offered price, due to the tender body's view of the suppliers in question.

9. Juno's commercial strategy for pricing is directed to winning as many contracts as possible. [redacted] the originator price (which in the case of a PBS listed medicine is, subject to any confidential pricing arrangements such as a special pricing arrangement (**SPA**), the existence of which is public knowledge through the PBS listing process, although its terms are not and are treated as confidential between the supplier and the Department of Health.), [redacted]

[redacted]

10. [redacted]

11. [redacted]

Commercial strategy for pricing generic lenalidomide products

12. Juno's commercial strategy for pricing generic lenalidomide products will follow the general approach set out above at paragraphs [9] to [11]. I do not anticipate that Juno will [redacted].

13. Juno's internal financial forecasts provided for [redacted]

14. [redacted]

15. I am aware that the ACCC asked Juno how its pricing strategy would differ if hypothetically one, two, three, or more generic suppliers were authorised to supply generic lenalidomide products from Juno/Natco's authorised launch date. [redacted]

16. If other generic suppliers commenced supplying lenalidomide after Juno/Natco's authorised launch date, whether before or after patent expiry, [redacted]

17. For completeness, I note that in my experience, Juno has a reputation for being a reliable, high value generic supplier and is likely to be regarded by other generic

suppliers as a strong and reliable competitor. [redacted]

Commercial strategy for pricing generic pomalidomide products

18. Juno's commercial strategy for pricing generic pomalidomide products will follow the general approach set out above at paragraphs [9] to [11]. I do not anticipate that Juno will [redacted].

19. Juno's internal financial forecasts provide for [redacted]

20. [redacted]

[redacted]

21. I am aware that the ACCC asked Juno how its pricing strategy would differ if hypothetically one, two, three or more generic suppliers were authorised to supply generic pomalidomide products from Juno/Natco's authorised launch date. [redacted]

22. If other generic suppliers commenced supplying pomalidomide after Juno/Natco's authorised launch date, whether before or after patent expiry, [redacted]

23. [redacted]

Affirmed by the deponent)
at)
in)
on)

Signature of deponent

Before me:

Signature of witness

Name of authorised witness

Capacity in which authorised witness takes affidavit

of 447 Collins Street, Melbourne
An Australian Legal Practitioner
within the meaning of the Legal Profession Uniform Law (Victoria)

A person authorised under section 19(1)(o)
of the *Oaths and Affirmations Act 2018* (Vic)
to take an affidavit.

And as an authorised affidavit taker, I state the following matters in accordance with the requirements of s 27(1A) of the *Oaths and Affirmations Act 2018* (Vic):

1. This affidavit was signed electronically and sworn by the deponent before me by audio visual link;
2. I have used an electronic copy of the affidavit for the purposes of complying with the requirements of section 26 and 27 of the *Oaths and Affirmations Act 2018* (Vic).