MinterEllison.

4 March 2022

Danielle Staltari
Director, Competition Exemptions
Australian Competition & Consumer Commission
Level 17, 2 Lonsdale St
Melbourne VIC 3000

BY EMAIL: danielle.staltari@accc.gov.au

Dear Danielle

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

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 15 December 2021, the Australian Competition and Consumer Commission (**ACCC**) started the public consultation process and the deadline for interested party consultation was on 23 February 2022.

1.4 To date, the ACCC has published the following submissions:

(a) submission from IP Australia dated 14 January 2022 (**IP Australia Submission**);

(b) submission from Myeloma Australia and its Medical and Scientific Advisory Group (**MSAG**) dated 28 January 2022 (**Myeloma Australia Submission**);

(c) file note of meeting with Myeloma Australia and MSAG dated 10 February 2022 (**Myeloma Australia Meeting**);

(d) file note of meeting with Dr Nick Murphy, Consultant Haematologist at Royal Hobart Hospital dated 11 February 2022 (**Dr Nick Murphy Meeting**);

(e) PBS data provided by the Department of Health on 11 February 2022 (**PBS Data);**

(f) file note of meeting with The Society of Hospital Pharmacists of Australia dated 16 February 2022 (**SHPA Meeting**);

(g) file note of meeting with Tasmanian Department of Health dated 21 February 2022 (**Tasmanian DOH Meeting**); and

(h) file note of meeting with The Pharmacy Guild of Australia dated 14 February 2022 (**PGA Meeting**).

(together, the **Submissions**)

1.5 The purpose of this letter is to respond to the Submissions.

2. Juno / Natco's response

2.1 In general, the Submissions do not oppose the Authorisation Application and generally acknowledge the public benefits of the Proposed Conduct. For example, the Submissions confirm the following consequences of the first generic brand of a particular medicine entering the market:

(a) PBS price reductions associated with the first generic brand being listed in the Schedule of Pharmaceutical Benefits;[1]

(b) a consequential reduction in the financial burden on the health system generally and, in particular, the Commonwealth health budget;[2]

(c) competitive price reductions (for supply outside the PBS) which will enable public hospitals and state / territory public health boards to procure more medicines, more efficiently, and improve the timeliness of medicines supply to hospital patients in all settings of care;[3]

(d) the possibility of a lower price for the medicine enabling some patients to use that medicine in multiple drug combinations that are not eligible for PBS reimbursement, or alternatively, providing a basis upon which such multiple drug combinations may in fact be approved for reimbursement.[4]

2.2 However, there are a number of specific points Juno / Natco wish to respond to as outlined below.

IP Australia Submission

2.3 Juno / Natco respectfully note the comments provided by the Deputy Commissioner of Patents. In particular, in respect of re-examination, Juno / Natco agree that re-examination requests had been made in respect of certain of the Celgene Patents, but did not proceed during the pendency of the litigation in accordance with ss 97(4)-(5) of the *Patents Act 1990* (Cth).

2.4 However, Juno / Natco also note that reg 9.2(5) of the *Patents Regulations 1991* (Cth) provides that, a person who has made a request for re-examination may withdraw that request before the Commissioner reports the outcome of the re-examination.

2.5 Insofar as the Deputy Commissioner of Patents' submission implies some likelihood that the scope of protection of the Celgene Patents would be varied notwithstanding withdrawal of the re-examination requests, Juno / Natco respectfully disagree. Rather, Juno / Natco consider that the status of the Celgene Patents would be akin to any other granted patent, in respect of which the Commissioner has the power to undertake re-examination of her own volition at any time (but only if an adverse re-examination report will issue).

2.6 We summarise below the re-examination status for all of the Celgene patents expiring after the lenalidomide compound patent (AU715779 expiry 24 July 2022). At the start of the pendency of the litigation, mentioned in 2.3 above:

(a) one re-examination report had issued (patent AU2010201484 expiry 16 May 2023) which was an adverse report to the scope of protection of that Celgene patent to multiple myeloma label of pomalidomide;

(b) no re-examination reports had issued for the four re-examination requests submitted on behalf of Juno / Natco against Celgene Patents to the multiple myeloma label of lenalidomide and pomalidomide (AU2003234626, AU2012254881, AU2013263799 and AU2006202316 expiry 16 May 2023); and

(c) no re-examination requests to the two of the Celgene Patents (AU2012201727 and AU2003228508 expiry 13 April 2023) to the multiple dysplastic syndrome indication of lenalidomide or to the Celgene Patent (AU2007282027 expiry 2 August 2027) to the

[1] For example, recognised in Myeloma Australia Submission, Dr Nick Murphy Meeting, Tasmanian DOH Meeting.
[2] Recognised in Myeloma Australia Submission.
[3] Recognised in SHPA Meeting.
[4] Recognised in Myeloma Australia Submission, Dr Nick Murphy Meeting, Tasmanian DOH Meeting.

mantle cell lymphoma indication of lenalidomide had been submitted on behalf of Juno / Natco, or any other party.

Myeloma Australia Submission

2.7 Juno / Natco note the comments that Myeloma Australia is unable to quantify the significance of the public benefit. However, the information for this assessment is available to the ACCC. In any event, Myeloma Australia acknowledges the public benefits of early access to the Generic Products, including "reduced costs for patients, reduced financial burden on the health system and potential for the drugs to be removed from the high cost label and therefore used in new combinations".

2.8 Further, Juno / Natco respectfully disagree that "no timeline for other generic providers to enter the marketplace" is a relevant consideration (let alone a factor that is detrimental to competition, as may be implied in the Myeloma Australia Submission), as that could not be an outcome provided for in an agreement of this nature.

Myeloma Australia Meeting

2.9 Juno / Natco note the following comments:

The 25% price reduction which will occur with Juno/Natco entering with their generic products will not make any real difference to increasing the access of lenalidomide and pomalidomide for patients. These drugs are expensive that only a small proportion of the population could afford to access them (unsubsidised). It will only make a difference if there is true price competition from a number of generic competitors entering.

The co-payment by the patient for generic lenalidomide and pomalidomide will not change as a result of generic entry lowering the price. The main effect will be lowering the cost to the PBS.

2.10 Juno / Natco note that no public benefit claim has been made on the basis that the co-payment payable by patients for PBS prescriptions will be reduced as a result of the Proposed Conduct (and further note that even with "a number of generic competitors entering" such an outcome will not eventuate, contrary to the Myeloma Australia Submission). Rather, a public benefit arises from the direct savings achieved for the Commonwealth Health budget, which allows for potential reallocation of scarce public resources to approving other medicines for listing in the Schedule of Pharmaceutical Benefits, or other beneficial public uses. In addition, there are further benefits from the certainty of earlier generic competition occurring, including diversity of supply and price competition for the unsubsidised patient population. Juno / Natco would accept that the unsubsidised patient population is however small relative to the subsidised patient population.

2.11 Juno / Natco respectfully disagree that the statement "pharmacies will be aware of when a drug is coming off patent and when a generic is entering" is necessarily applicable in all cases (including in respect of lenalidomide and pomalidomide), particularly because of the care that must be taken by generic suppliers so as to avoid conduct prior to patent expiry that might amount to exploitation (and hence infringement) of a relevant patent, for example, this precludes any offer before patent expiry even for supply on a date after patent expiry.

2.12 In any event, however, in the hospital environment, customers – whether procuring an originator medicine through a negotiated pricing arrangement (as typically applies to state / territory public health tender boards), or under a contract (as typically applies to private hospital networks) – have the contractual right and/or practical ability to respond to *first* generic entry by requiring the originator to reduce its price and/or moving to purchasing the generic brand in place of the originator. That is, the ability to respond quickly to generic entry does not typically require prior knowledge of that event being likely to eventuate.

Dr Nick Murphy Meeting

2.13 Juno / Natco note the following comment:

As lenalidomide and pomalidomide are Pharmaceutical Benefits Scheme (PBS) funded treatments, price reductions associated with generic entry will not make a difference to the price paid by most patients

2.14 Juno / Natco repeat the observations made at paragraph 2.10 above.

2.15 Juno / Natco note the following comment:

Generally, pharmacies will know when patents for expensive drugs will expire and would be mindful of that fact when negotiating the length of any tender.

2.16 Juno / Natco repeat the observations made at paragraph 2.11 to 2.12 above, and emphasise that when a first generic brand enters the market, a hospital purchasing body or state / territory public health tender board will typically have the ability to respond quickly, in terms of (re)negotiating pricing and/or moving to the generic supplier.

SHPA Meeting

2.17 Juno / Natco note the following comment regarding inpatients at public hospitals (for whom PBS reimbursement is not applicable):

If a high-priced medicine becomes significantly less expensive due to generic entry, that may improve access for inpatients, as there are generally less budgetary restrictions on lower-cost medicines for inpatient use.

However, if the price reduction for lenalidomide and pomalidomide (due to generic entry) is modest, it is unlikely to make a material difference on how public hospitals prescribe these drugs for inpatients, as it would still be denoted as a high cost medicine

2.18 Juno / Natco note that while the exact quantum of any public benefit by way of price reduction for non-PBS funded public hospital supply will depend on the outworking of competitive processes, it is a material public benefit to have earlier potential for price competition to occur in that setting and this will be facilitated by the Proposed Conduct.

Tasmanian DOH Meeting

2.19 Juno / Natco note the following comment:

There tends to be more generics entering/generic competition in low value drugs, rather than high value drugs.

2.20 Juno / Natco do not agree with this statement. While the extent of generic entry/competition depends on a range of factors, an important consideration is the size and value of the addressable market for the generic entrant, and 'high value' medicines can for that reason alone represent attractive targets for generic entry.

This agreement between Celgene-Juno/Natco will not have an impact on the co-payment price paid by the patient for PBS indications, or indications approved for funding by the Department.

2.21 Juno / Natco repeat the observations made at paragraph 2.10 above.

2.22 Juno / Natco note the following comment:

The Department sees some negatives to this agreement, in terms of the potential future viability of the market. The Department noted that in the high-cost oncology space, it has previously seen originators pull out of the market when generics enter. This caused the market to destabilise and created supply shortages. Patients who were not going to be switched to the generic product or were in access regimes with the originator were affected.

2.23 In Juno / Natco's view, this comment is purely theoretical and there is no basis to consider that such a situation would arise in these circumstances. If the Authorisation is granted, the generic product will enter the market pursuant to a licence agreement with the originator and [redacted]

2.24 Further, the TGA operates a medicines shortages database which is publicly available and a scheme by which companies must inform the TGA (for the purpose of publication by the TGA) impending stock shortages of prescription medicines as soon as they are aware of such an event being likely. As such, if withdrawing from the market is the originator's intention, then this should be

made public as soon as the proposed agreement moves forward, and as such should provide sufficient time for Juno and/or further generic suppliers to manage market stock requirements.

2.25 Accordingly, Juno / Natco reject the suggestion that the Agreement could have any negative effect on the future viability of the market.

2.26 In contrast, Juno / Natco note that the Agreement will facilitate increased competition and supply in the relevant markets (by comparison to the status quo, under which continuity and reliability of supply is currently dependent on a single supplier), which is inherently beneficial to the market. The entry of Generic Products in the relevant markets ensures certainty of an additional source of supply of pharmaceutical products for the treatment of multiple myeloma and mantle cell lymphoma, thereby increasing security of domestic supply and availability.

PGA Meeting

2.27 Juno / Natco note the following comments:

Higher cost drugs take a lot longer to reduce in price as a result of discounting. The volume of patients is not there – therefore, there is no economies of scale that they can absorb at the wholesale level.

There are deeper price reductions when there are multiple generics that enter at the same time.

2.28 This observation appears directed to both the relative level of competitive discounting for higher cost drugs (in which case Juno / Natco does not agree that the comment is applicable in all high cost drug scenarios), and the extent of the subsequent PBS price reductions that may arise as a result of the PBS price disclosure regime. As previously submitted, the initial public benefits from PBS price reductions on first generic entry are certain and easily quantifiable. While the exact quantum of further public benefit by way of further in market discounts and / or price disclosure-related PBS price reductions will depend on the outworking of competitive processes, these are nonetheless material public benefits arising from the Proposed Conduct.

Pharmacies can discount a co-payment up to $1.00. It will make no difference whether it is a generic or branded product, the maximum discount is the same.

2.29 Juno / Natco repeat the observations made at paragraph 2.10 above, and notes that, to the extent that comments such as this one made in the PGA meeting pertain to community pharmacy supply, community pharmacies are not a significant supplier of Revlimid and Pomalyst (as was confirmed by the PGA). Further, a discount to the co-payment amount most often arises in the context of medicines for which there is generic competition, and hence to the extent it is encouraged by the Proposed Conduct it gives rise to a further public benefit.

Please contact us if the ACCC requires further information.

Yours faithfully
MinterEllison

Contact: Tatum Joseph T:

Partner: Geoff Carter T: