Executive Summary

The ACCC proposes to deny authorisation to Juno Pharmaceuticals Pty Ltd (**Juno**), Natco Pharma Ltd (**Natco**), Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) to enter into and give effect to certain provisions of a settlement and licence agreement in relation to the pharmaceutical products Revlimid® and Pomalyst®.

Celgene is the manufacturer of Revlimid® (active ingredient lenalidomide) and Pomalyst® (active ingredient pomalidomide), which are immunomodulatory drugs indicated for the treatment of some blood cancers. Celgene owns several patents in relation to each of its products, comprising the compound patent and seven method of medical treatment patents for Revlimid® and Pomalyst®.

Juno is a Victorian-based supplier of marketing and distribution services to pharmaceutical manufacturers and specialises in post-patent pharmaceuticals (i.e. generic products). Natco is an Indian-based pharmaceutical manufacturer, which operates in countries including Australia for the purpose of selling and distributing Natco-manufactured pharmaceutical products.

On 9 November 2020, Juno/Natco commenced proceedings against Celgene in the Federal Court of Australia, wherein Juno/Natco sought to invalidate the compound patent for Revlimid®. On 29 January 2021, Celgene filed a cross claim against Juno/Natco for threatened infringement of the method of treatment patents.

The Applicants submit that they entered into the proposed settlement and licence agreement in order to avoid a lengthy and complex legal dispute, and to provide Juno/Natco with certainty regarding when they can enter the market with generic versions of Revlimid® and Pomalyst®.

Under the settlement and licence agreement, Celgene would grant licences to Juno/Natco to supply the generic products from specified launch dates (these dates are confidential). The Applicants submit that this will enable the supply of the generic products before the relevant Celgene patents expire, which would otherwise be known as ‘at risk’ entry.

The ACCC invited submissions from a range of potentially interested parties and received limited written responses. The Applicants provided very few internal documents and have claimed confidentiality over much of the information provided to the ACCC to date.

The ACCC has considered the Applicants’ claims that the settlement and licence agreement is likely to give rise to a public benefit in the form of cost savings to the Australian Government, greater supply security, and litigation cost savings.

The Applicants claim that what they characterise as ‘early launch’ of Juno/Natco’s generic products which is said to be brought about by the settlement and licence agreement would trigger an immediate and substantial 25% price reduction of Revlimid® and Pomalyst® under the Pharmaceutical Benefits Scheme. The ACCC does not have sufficient evidence, including from the Applicants or the PBS, as to the significance of any potential PBS savings. Based on information currently available, the ACCC considers it is uncertain whether, and if so the extent to which, the settlement and licence agreement is likely to result in cost savings to the Australian Government under the Pharmaceutical Benefits Scheme. [redacted]

[redacted]

The ACCC also notes that in the event that the litigation is recommenced absent the settlement and licence agreement and it resulted in a favourable outcome for Juno/Natco, it is still open to the Australian Government to seek damages against Celgene to recover PBS expenditure which would affect the extent of any PBS savings that can be attributed to the agreement. This further demonstrates that it is uncertain whether, and if so the extent to which, the Proposed Conduct is likely to result in cost savings under the Pharmaceutical Benefits Scheme.

The ACCC is not satisfied that the settlement and licence agreement will result in greater supply security for lenalidomide and pomalidomide, as it has no evidence of any supply issues in the past and considers the patient cohort being treated with these products is unlikely to change significantly in the foreseeable future. The ACCC is also unable to be satisfied that Juno/Natco's entry with the generic products is likely to give rise to a public benefit [redacted]

The ACCC is not satisfied that the litigation would proceed without the Proposed Conduct. In all the circumstances, the ACCC is not satisfied that litigation cost savings would result in a public benefit.

The ACCC considers the settlement and licence agreement is likely to result in public detriment by reducing competitive tension in relation to generic entry in the supply of lenalidomide and pomalidomide. The ACCC considers the settlement and licence agreement provides Celgene with greater control and certainty over the timing of generic entry by Juno/Natco, seeks to confer on Juno/Natco a 'first mover advantage', may deter other generic entry, [redacted]

The ACCC considers the threat of generic entry, including the possibility of 'at risk' entry, and any subsequent response to entry is a key driver of competition. The settlement and licence agreement replaces some of the competitive tension among generic manufacturers of lenalidomide and pomalidomide which are looking to enter the market, by seeking to establish Juno/Natco as the first generic to market. It also affects Celgene's response to generic entry by removing elements of commercial risk, which, in the absence of the settlement and licence agreement, might generate a more competitive response from Celgene to competitive actions of generic manufacturers. There is a risk that affecting the structure of the relevant markets in this way will result in a public detriment. Given the lack of information received from interested parties on the competitive implications of the settlement and licence agreement, and the extent of confidential information under consideration that the ACCC could not test through public consultation, the nature and extent of such detriments is unclear.

The ACCC also considers that the settlement and licence agreement has the potential to result in public detriments by [redacted]

Given the public benefits are uncertain, minimal or unlikely to arise at all, and that the ACCC cannot be satisfied of the extent and significance of the public detriment that would arise

from the settlement and licence agreement, in all the circumstances and based on the current information the ACCC is not satisfied that the net public benefit test is met. As the Act specifies that the ACCC must not grant an authorisation unless it is satisfied that the likely public benefit will outweigh the likely public detriment, the ACCC proposes to deny authorisation.

The ACCC notes that proposing to deny authorisation does not prevent the Applicants from settling the proceedings. Proposing to deny authorisation means that the Applicants are not permitted to engage in cartel or other anti-competitive conduct.

The ACCC invites submissions in relation to this draft determination by 6 April 2022 before it makes its final determination.