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3 December 2021

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

Green	is confidential to the Applicants (not to be shared with the public)
Turquoise	is confidential to Juno/Natco (not to be shared with Celgene or the public)
Grey	is confidential to Celgene (not to be shared with Juno/Natco or the public)
Yellow	is outstanding/ further data is requested

1. Summary

1.1 This is a joint application to the Australian Competition & Consumer Commission (**ACCC**) made by Juno Pharmaceuticals Pty Ltd (**Juno**), Natco Pharma Ltd (**Natco**), Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) (the **Applicants**) seeking authorisation to engage in conduct which is described in section 3.7 below (the **Proposed Conduct**).

1.2 Celgene is the manufacturer of Revlimid®, containing the active ingredient lenalidomide, and Pomalyst® containing the active ingredient pomalidomide. Celgene is the owner of patents granted by IP Australia that claims the compound lenalidomide; the use of lenalidomide in the treatment of certain disease states, including multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma and the use of pomalidomide in the treatment of certain disease states, including multiple myeloma (the **Celgene Patents**).[1] Natco wishes to manufacture, and Juno wishes to market and supply, generic versions of Revlimid® and Pomalyst® in Australia (**Generic Products**), prior to the expiry of the Celgene Patents.

1.3 Natco / Juno filed proceedings against Celgene (Federal Court proceedings VID 718 of 2020) seeking to revoke certain claims of the Celgene Patents. Celgene filed a cross-claim against Juno / Natco for infringement of the Celgene Patents (see sections 2.18 and 2.19 below). In order to avoid continuing a costly, lengthy and complex dispute, and to provide Juno/Natco with commercial certainty for market entry, the Applicants have reached a commercial agreement to grant Natco / Juno licences of the Celgene Patents (see section 2.23 below) to allow Natco / Juno to commence supply of the Generic Products prior to expiry of the Celgene Patents (the **Agreement**). The sections of the Agreement relevant to the Proposed Conduct are subject to a condition precedent that the ACCC grant authorisation under section 88 of the CCA. A copy of this Agreement is attached to this Application at **Confidential Annexure A**.

1.4 The Proposed Conduct has clear and substantial public benefits compared to any other counterfactual that would enable Natco/Juno to launch the Generic Products free from the risk of being exposed to substantial damages (namely, Natco/Juno being successful in the Proceedings; or waiting until the expiry of the term of the Celgene Patents).The Proposed Conduct will enable supply of the Generic Products well prior to the expiry of the Celgene Patents. Natco/Juno will be permitted to enter the market on [redacted] This is significantly earlier than the expiry dates for the Celgene Patents being: 13 April 2023, 16 May 2023 and 2 August 2027. In addition, the launch of Natco/Juno's Generic Products (assuming they are the first generic lenalidomide and pomalidomide to market), will trigger an automatic, immediate and substantial (25%) reduction in the price of branded Revlimid® and Pomalyst® under the Pharmaceutical Benefits Scheme (**PBS**) as well as follow on price reductions (see sections 5.13 – 5.18 below). There are therefore substantial public benefits and, given there are no public detriments to the Proposed Conduct, authorisation should be granted.

[1] The Celgene Patents are nos. 7175779, 2003234626, 2012254881, 2013263799, 2003228508, 2012201727, 2006202316, 2010201484 and 2007282027.

2. Background

Celgene and the Celgene Patents

2.1 Celgene is a global biopharmaceutical company committed to improving the lives of patients worldwide and is a wholly owned subsidiary of the Bristol-Myers Squibb Company. Celgene Pty Ltd is a wholly-owned subsidiary of Celgene Corporation. For the purposes of this Application, Celgene Corporation and Celgene Pty Ltd will be referred to as 'Celgene' unless identification of the precise legal entity is necessary. Celgene focuses on, and invests heavily in, the discovery, development and commercialisation of cancer and immunology-related pharmaceutical products for the treatment of severe and life-threatening conditions.

2.2 Celgene is a world leader in the treatment of many such life-threatening diseases, including cancer. Among other life-saving medications developed by Celgene, Celgene supplies in Australia the branded products:

(a) Revlimid®, which is currently indicated on the Australian Register of Therapeutic Goods (**ARTG**) for the treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma; and

(b) Pomalyst®, which is currently indicated on the ARTG for the treatment of multiple myeloma.

2.3 The Celgene Patents directed to the compound lenalidomide and used in the treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma are due to expire over the course of 2022, 2023 and 2027, while the Celgene Patents directed to Pomalyst® for the treatment of multiple myeloma are due to expire in 2023. Further details of the Celgene Patents in Australia in respect of lenalidomide and pomalidomide are provided in Attachment C below.

Revlimid®

2.4 Celgene's Revlimid® product is registered on the ARTG for the treatment of the following indications: multiple myeloma; myelodysplastic syndromes; and mantle cell lymphoma, in accordance with the treatment regimen for each of these indications set out in the Revlimid® Product Information.[2]

2.5 Celgene invented lenalidomide and was granted Australian Patent No. 715779, inter alia in respect of this compound (the **Compound Patent**). Under the Compound Patent, Celgene has the exclusive right to make, import, use and sell and offer to sell lenalidomide in Australia during the term of the Compound Patent (which expires on 24 July 2022).

2.6 In addition, Celgene is the registered proprietor of several patents claiming methods of treatment as follows (the **Lenalidomide Method of Treatment Patent Claims**):

(a) Australian Patent Nos. 2003234626, 2012254881 and 2013263799, claiming *inter alia*, the administration of lenalidomide for the treatment of multiple myeloma. These patents expire on 16 May 2023;

(b) Australian Patent Nos. 2003228508 and 2012201727 claiming *inter alia*, the administration of lenalidomide for the treatment of myelodysplastic syndromes. These patents expire on 13 April 2023;

[2] https://www.tga.gov.au/sites/default/files/auspar-lenalidomide-190506-pi.pdf

(c) Australian Patent No. 2007282027, claiming *inter alia*, the administration of lenalidomide for the treatment of mantle cell lymphoma. This patent expires on 2 August 2027; and

(d) Australian Patent No. 2006202316 claiming inter alia, the administration of lenalidomide for the treatment of multiple myeloma and mantle cell lymphoma. This patent expires on 16 May 2023.

2.7 The Lenalidomide Method of Treatment Patent Claims are in force, granted by IP Australia on the basis that they disclose and claim, inter alia novel, useful, and inventive methods of treating specific disease states. Under the Lenalidomide Method of Treatment Patent Claims, Celgene has the exclusive right to *inter alia* supply lenalidomide in the treatment of specific disease states according to the methods claimed (and authorise others to do so).

2.8 Celgene's position is that a pharmaceutical company seeking to supply lenalidomide in Australia prior to 24 July 2022 would infringe the Compound Patent and for the treatment of disease states by the methods claimed in the Lenalidomide Method of Treatment Patent Claims, during the term of the Lenalidomide Method of Treatment Patent Claims, would infringe the Compound Patent and the Lenalidomide Method of Treatment Patent Claims absent a licence from Celgene to supply such a product. A finding of patent infringement would entitle Celgene to seek remedies against Natco/Juno including:

(a) a permanent injunction restraining Natco/Juno from infringing the Compound Patent and Lenalidomide Method of Treatment Patent Claims during their term including by supplying for use; importing and/or making, offering to make; offering for supply or sale; supplying; selling; using or keeping, in Australia any pharmaceutical composition which includes the active ingredient lenalidomide falling within the claims of the Compound Patent or in accordance with the instructions in any Product Information provided by Natco/Juno for a use falling within the Lenalidomide Method of Treatment Patent Claims;

(b) Damages; and

(c) Costs.

2.9 In addition, Celgene may be entitled to an interlocutory injunction in the terms set out in paragraph 2.8(a) above (or similar), pending final determination of its patent infringement claims.

Pomalyst®

2.10 Celgene's Pomalyst® product is registered on the ARTG for the treatment of patients with multiple myeloma in accordance with the treatment regimen set out in the Pomalyst® Product Information.[3]

2.11 Celgene is the registered proprietor of Australian Patent Nos. 2012254881 and 2010201484 claiming inter alia the administration of pomalidomide for the treatment of multiple myeloma (the **Pomalidomide Method of Treatment Patent Claims**) which expire on 16 May 2023.

2.12 The Pomalidomide Method of Treatment Patent Claims are in force, granted by IP Australia on the basis that they disclose and claim, inter alia novel, useful, and inventive methods of treating specific disease states. Under the Pomalidomide Method of Treatment Patent Claims, Celgene has the exclusive right to, *inter alia*, supply pomalidomide in the treatment of specific disease states according to the methods claimed (and authorise others to do so).

[3] https://www.tga.gov.au/sites/default/files/auspar-pomalidomide-131014-pi.pdf

2.13 Celgene's position is that a pharmaceutical company seeking to supply pomalidomide in Australia for the treatment of disease states by the methods claimed in the Pomalidomide Method of Treatment Patent Claims, during the term of the Pomalidomide Method of Treatment Patent Claims, would infringe the Pomalidomide Method of Treatment Patent Claims absent a licence from Celgene to supply such a product. A finding of patent infringement would entitle Celgene to seek remedies against Natco/Juno including:

(a) a permanent injunction restraining Natco/Juno from infringing the Pomalidomide Method of Treatment Patent Claims during their term including by supplying for use; importing and/or making, offering to make; offering for supply or sale; supplying; selling; using or keeping, in Australia any pharmaceutical composition which includes the active ingredient pomalidomide for use in accordance with the instructions in any Product Information provided by Natco/Juno for a use falling within the claims of the Pomalidomide Method of Treatment Patent Claims;

(b) Damages; and

(c) Costs.

2.14 In addition, Celgene may be entitled to an interlocutory injunction in similar terms to those set out in paragraph 2.13(a) above, pending final determination of its patent infringement claims.

Natco and Juno

2.15 Juno is a supplier of marketing and distribution services to pharmaceutical manufacturers, and specialises in post-patent pharmaceuticals (i.e. pharmaceutical substances in respect of which relevant patents have expired, such that generic brands may be supplied). Juno distributes generic pharmaceutical products obtained from third party manufacturers pursuant to supply arrangements; it does not manufacture pharmaceutical products itself. Juno currently has two products in Australia that are registered on the ARTG for the treatment of multiple myeloma and mantle cell lymphoma under the brands *Bortezomib JN* and *Bortezomib Juno*. However, Juno supplies *Bortezomib Juno* in the market, which is listed on the PBS for the treatment of multiple myeloma. Bortezomib Juno is also registered on the ARTG for the treatment of mantle cell lymphoma and, though not PBS listed, is available to be supplied in Australia.

2.16 Natco is an Indian-based pharmaceutical manufacturer, which operates in countries including Australia for the purpose of selling and distributing Natco manufactured pharmaceutical products.

2.17 Juno wishes to market and supply the Generic Products in Australia pursuant to its existing supply and distribution arrangements. Natco will manufacture the Generic Products for Juno. A list of Juno's ARTG listings relating to lenalidomide and pomalidomide is attached to this Application at **Annexure** D.

The Proceedings and Agreement

2.18 Juno and Natco commenced proceedings[4] against Celgene in the Federal Court of Australia on 9 November 2020 (amended on 24 June 2021). In those proceedings, Juno and Natco sought revocation of certain claims of the Celgene Patents (**Proceedings**). In parallel, between 18 November 2020 and 23 December 2020, JH Corporate Services Pty Ltd filed with the Australian Patent Office, requests for re-examination of certain of the Celgene Patents (**Re-Examination Requests**).

[4] No VID 718 of 2020 in the Federal Court of Australia.

2.19 Celgene filed a cross claim against Juno and Natco on 29 January 2021 (amended on 9 July 2021) for threatened infringement of certain claims of the Celgene Patents and for associated breaches of the Australian Consumer Law (**Cross-Claim**[5]).

2.20 The Proceedings insofar as they relate to Australian Patent No. 715779 (one of the Celgene Patents) and the Cross-Claim insofar as it relates to the same patent and alleged breaches of the Australian Consumer Law, were discontinued by the parties by consent on 27 October 2021. Orders were made on 25 October 2021 staying the Proceedings and the Cross Claim insofar as they relate to the remainder of the Celgene Patents, until 9 May 2022.

2.21 If Celgene's Cross-Claim were successful, Natco and Juno would be prevented from marketing the Generic Products in Australia until the expiry of the Celgene Patents which would be later than provided for under the Proposed Conduct (as set out below in section 3.7).

2.22 On 19 March 2021, Juno and Natco provided undertakings in the Proceedings *"that, until such time as the [Federal] Court delivers its reasons for judgment at first instance in this proceeding on the validity of claims 1, 4 and 9 of Australian patent 715779 or the proceeding is earlier terminated or until further order, they will give to [Celgene] at least four months' written notice prior to, in Australia: (a) offering to supply; supplying; or (c) achieving listing on the Pharmaceutical Benefits Scheme of, any pharmaceutical product containing lenalidomide as the active pharmaceutical ingredient."* These undertakings are no longer on foot following the matters discussed in paragraph 2.20 above.

2.23 Under the Agreement, as consideration for Natco and Juno upholding their obligations under the Agreement, Celgene has agreed to grant non-exclusive, non-transferable [redacted] licences: to Natco to manufacture; and to Juno to import, keep, use or dispose of (including, but not limited to, selling) or offer to dispose of Natco-manufactured Generic Products in Australia from the relevant Authorised Launch Date for each product (which is earlier than the Celgene Patent expiry dates and earlier (and with more certainty) than if Juno and Natco continued to pursue their present litigation but which also recognises the value of the Celgene Patents).

2.24 In a future without the Proposed Conduct, it is unlikely that Juno / Natco would be able to launch the Generic Products for supply to customers and patients before expiry of the Celgene Patents which is later than is the case with the Proposed Conduct.

Confidentiality

The public version of this document excludes information provided to the ACCC on a confidential basis. Confidential information has been removed and replaced with the word 'CONFIDENTIAL'.

The Applicants request that the ACCC treat the information marked as 'CONFIDENTIAL', as commercially sensitive and strictly confidential. The Applicants acknowledge that, in accordance with its usual confidentiality regime, the ACCC requires that:

(a) there is no restriction on the internal use, including future use, that the ACCC may make of the information consistent with its statutory functions;

(b) the confidential information may be disclosed to the ACCC's external advisers and consultants on the condition that its advisers and consultants will be informed of the obligation to treat the information as confidential; and

[5] All proceedings between the parties are referred to collectively as the **Federal Court Proceedings**.

(c) the ACCC may disclose this confidential information to third parties (in addition to its external advisers or consultants) if compelled by law or in accordance with section 155AAA of the CCA.

3. Parties to the proposed conduct

3.1 Applicants for authorisation:

(1) Juno Pharmaceuticals Pty Ltd (ACN 156 303 650)

Address (registered address)	Contact person	Description of business activities
42 Kelso Street, Cremorne, Victoria, 3121, Australia	c/o Geoff Carter Partner MinterEllison Collins Arch 447 Collins St Melbourne VIC 3000 Solicitor for Juno [redacted]	Supplier of marketing and distribution services to pharmaceutical manufacturers.

(2) Natco Pharma Ltd

Address (registered address)	Contact person	Description of business activities
Natco House, Road No. 2, Banjara Hills, Hyderabad, 500 034, India	c/o Geoff Carter Partner MinterEllison Collins Arch 447 Collins St Melbourne VIC 3000 Solicitor for Natco [redacted]	Pharmaceutical manufacturer.

(3) Celgene Corporation

Address (registered address)	Contact person	Description of business activities
Celgene Corporation 86 Morris Avenue Summit, New Jersey 07901 USA	Penne Carter Head of Commercial Legal & Compliance, Australia & New Zealand Bristol Myers Squibb Level 2, 4 Nexus Court, Mulgrave, Victoria 3170 Australia [redacted]	Developer and commercialiser of cancer and immunology-related pharmaceutical treatments.

(4) Celgene Pty Ltd (ACN 118 998 771)

Address (registered address)	Contact person	Description of business activities
Celgene Pty Ltd Level 15, 60 City Road, Southbank, 3006, Victoria Australia	Penne Carter Head of Commercial Legal & Compliance, Australia & New Zealand Bristol Myers Squibb Level 2, 4 Nexus Court, Mulgrave, Victoria 3170 Australia [redacted]	Developer and commercialiser of cancer and immunology-related pharmaceutical treatments.

3.2 Description of business activities

(1) Juno

Juno is a supplier of marketing and distribution services to pharmaceutical manufacturers, and specialises in generic products. Juno distributes generic pharmaceutical products obtained from third party manufacturers pursuant to supply arrangements; it does not itself manufacture pharmaceutical products.

In Australia, Juno has two products that are registered on the ARTG for multiple myeloma and mantle cell lymphoma under the brands *Bortezomib JN*[6] and *Bortezomib Juno*[7]. Juno supplies *Bortezomib Juno* in the market, which is listed on the PBS for the treatment of multiple myeloma and, though not PBS listed, it is also available for the treatment of mantle cell lymphoma.

(2) Natco

Natco is an Indian-based pharmaceutical manufacturer, which also operates in countries including Australia for the purpose of selling and distributing Natco manufactured pharmaceutical products.

(3) Celgene

[6] 303982, 283342 and 283341.
[7] 303979, 283343 and 283340.

Celgene is wholly owned by the Bristol-Myers Squibb Company (**BMS)** and is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions. Celgene is a world leader in the treatment of many such diseases, including cancer. Celgene's products include treatments for diseases such as multiple myeloma, myelodysplastic syndrome, chronic lymphocyte leukaemia, non-Hodgkin's lymphoma, glioblastoma, and ovarian, pancreatic, and prostate cancer.

In addition to Revlimid® and Pomalyst®, Celgene currently markets and supplies the following products in Australia: Istodax® (romidepsin), Thalomid® (thalidomide), Vidaza® (azacitidine), Azamyelidine® (azacitidine), Celazadine™ (azacitidine) and Zeposia® (ozanimod) as well as Reblozyl® (luspatercept) and Zeposia® (ozanimod hydrochloride) in the restricted listing scheme, the 'Black Triangle Scheme'.

More details on Celgene's Australian operations can be found at: https://www.celgene.com.au/

3.3 Email address for service of documents in Australia

For Juno and Natco:

Geoff Carter
Partner, MinterEllison
[redacted]

For Celgene:

Prudence Smith
Partner, Jones Day
[redacted]

Matthew Bull
Partner, Jones Day
[redacted]

3.4 Details of other classes of persons on whose behalf authorisation is sought

3.5 Authorisation is sought on behalf of

(a) the Applicants and any successor or assignee of the rights or obligation of any of the applicants under the Agreement; and

(b) any person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, an Applicant. For the purposes of this definition, "control" means the power of a person to secure, directly or indirectly, (whether by the holding of shares, possession of voting rights or by virtue of any other power conferred by the articles of association, constitution, partnership deed or other documents regulating another person or otherwise) that the affairs of such other person are conducted in accordance with its wishes.

3.6 Description of the Proposed Conduct

3.7 The Applicants seek authorisation under section 88 of the CCA to enter into, and to give effect to, the following provisions of the Agreement, each of which is a provision that is subject to a condition precedent in the Agreement to the effect that the Applicants will not enter into / give effect to those provisions unless and until authorisation under section 88 of the CCA has first been obtained from the ACCC or the Australian Competition Tribunal:

(1) Celgene will grant a non-exclusive, non-sublicensable, non-transferable, [redacted] licence under the Celgene Patents:

i. in the case of Natco: to manufacture, import or keep the Generic Products in Australia;

ii. in the case of Juno: to import or have imported by Natco, keep, use, dispose of (including, but not limited to selling), or offer to dispose of the Generic Products in Australia from the relevant Authorised Launch Dates (as defined in the Agreement) (each an Authorised Launch Date);

iii. in the case of Natco: submit applications for the listing of the Generic Products on the PBS, provided that such listing is not to take effect until the relevant Authorised Launch Date;

(2) Celgene will not (or will not cause, authorise or assist any person to) make or assert any claim or otherwise commence, bring or participate in any action or proceeding (including judicial and administrative proceedings) against Natco and Juno in Australia, or any of their suppliers, distributors, importers, wholesalers or customers (including doctors, pharmacists and patients) in respect of the Generic Products after the relevant Authorised Launch Date;

(3) in turn, Juno and Natco undertake to Celgene that they each:

i. will not make, import, keep, use, dispose of or offer to dispose of the Generic Products in Australia prior to the relevant Authorised Launch Date;

ii. will not (and will procure their respective affiliates to not) export or sell for subsequent export the Generic Products (other than to New Zealand subject to a valid licence from Celgene or its affiliate) and shall immediately cease supplying the Generic Products to any person they have reasonable grounds to believe is permitting or otherwise facilitating export (other than to New Zealand subject to a valid licence from Celgene or its affiliate);

(4) Natco and Juno will not (or will not assist, cause, procure, authorise or encourage any person to) either directly or indirectly, make or assert any claim or commence, bring or participate in any action or proceeding (including judicial, regulatory and administrative proceedings, including re-examination proceedings) alleging the invalidity of the Celgene Patents in Australia (assuming that the ACCC Condition Precedent of authorisation under section 88 of the CCA and as defined in the Agreement, is satisfied);

(5) Juno covenants that it will not assign or transfer any registration on the ARTG for the Generic Products to Natco (other than where it transfers all its rights under the Agreement to Natco) or to any third party without the prior written consent of Celgene;

(6) the Applicants will also each irrevocably and unconditionally release each other in relation to all claims, actions or proceedings (including judicial, administrative proceedings and re-examination proceedings), or liability that they now have, at any time had, may have in the future or (but for the Agreement) might have had arising out of, in connection with or as alleged in the Proceedings and Cross-Claim; and

(7) the Agreement provides that Natco and Juno will not exercise any right of appeal which they may have from the decision of the Federal Court of Australia insofar as it relates to the infringement and validity of Australian Patent No. AU 715779,

(together the **Proposed Conduct**).

[redacted]

3.9 The Proposed Conduct is limited in scope and period, specifically:

(1) it is limited to conduct infringing the Celgene Patents,; and

[redacted]

3.10 Accordingly, the Proposed Conduct has the narrowest and shortest possible application while also allowing early supply of the Generic Products and facilitating the statutory price reductions while not imposing any restrictions or constraints on any other generic manufacturers.

3.11 The Applicants seek, through authorisation under section 88 of the CCA, the certainty of statutory protection in respect of the relevant provisions of the Agreement. The relevant provisions of the CCA for which authorisation is sought are the operative provisions prohibiting the making or giving effect to a contract, arrangement or understanding that may include a cartel provision, specifically sections 45AF, 45AJ, 45AG and 45AK of the CCA.

Rationale for the Proposed Conduct

3.12 The rationale for the Proposed Conduct is to enable Natco and Juno, following the relevant Authorised Launch Dates, **to sell the Generic Products earlier** than they could otherwise with the Celgene Patents on foot without the risk of liability from infringing the Celgene Patents.

3.13 The Proposed Conduct will avoid further unnecessary costs, business disruption and uncertainty of lengthy and complex patent litigation that would result were:

(a) Celgene, Natco and Juno to continue the Federal Court Proceedings; or

(b) Natco and Juno commence supply of product the subject of the Celgene Patents while they are on foot (with the risk associated with continuing with the patent infringement action).

3.14 The Applicants believe that the Agreement is a fair compromise of their respective litigation positions given, *inter alia*, the uncertainties, costs and burdens associated with litigation, and the other benefits described herein.

3.15 The Proposed Conduct will allow the Applicants to invest the costs and time that would have been directed towards the Federal Court Proceedings to other business-as-usual functions.

3.16 Term of authorisation sought and reasons for seeking this period of time

3.17 Authorisation is sought to engage in the Proposed Conduct for a period of 6 years (specifically, until at least 2 August 2027, being the date of the expiry of the last of the Celgene Patents).

3.18 Provide documents submitted to the applicant's board or prepared by or for the applicant's senior management for purposes of assessing or making a decision in relation to the proposed conduct and any minutes or record of the decision made.

3.19 Documents to be provided by the Applicants separately.

3.20 Names of persons or classes of persons who may be impacted by the Proposed Conduct and details of how / why they might be impacted

3.21 The classes of persons that the Applicants reasonably consider may be potentially affected by the Proposed Conduct are:

(1) Purchasers of pharmaceutical products for the treatment of multiple myeloma or myelodysplastic syndromes including hospitals, pharmacies, clinics and wholesalers and the Commonwealth government under the PBS and Repatriation Pharmaceutical Benefits Scheme (**RPBS**). For such purchasers, there will be increased choice in manufacturers and suppliers of pharmaceutical products for the treatment of multiple myeloma or myelodysplastic syndromes in Australia. In addition, there will be a price reduction of up to 25% of the price of Revlimid® and Pomalyst® (assuming that the Generic Products are the first PBS listed generic brands of these products) under the PBS (as discussed below at section 4.42 and following);

(2) Purchasers of pharmaceutical products for the treatment of mantle cell lymphoma including hospitals, pharmacies and wholesalers and Private Health Insurers who offer coverage for pharmaceutical products for the treatment of mantle cell lymphoma. For such purchasers, there will be increased choice in manufacturers and suppliers of pharmaceutical products for the treatment of mantle cell lymphoma in Australia; and

(3) Patients being treated for multiple myeloma, myelodysplastic syndromes or mantle cell lymphoma. These patients will gain access to a wider choice of treatments and supplier options.

4. Market information and concentration

4.1 Describe the products and/or services, and the geographic areas, supplied by the applicants. Identify all products and services in which two or more parties to the proposed conduct overlap (compete with each other) or have a vertical relationship (e.g. supplier-customer).

Relevant markets - The national market for the supply of products indicated for the treatment of multiple myeloma and mantle cell lymphoma

4.2 In the pharmaceutical context, the availability of multiple products for an indication means that a relevant market is often defined, for competition law purposes, with reference to a medicine's therapeutic use or indication.[8]

4.3 There are two overlapping product indications relevant to the Proposed Conduct. Celgene and Juno both currently supply products for the treatment of multiple myeloma and mantle cell lymphoma. Juno does not currently supply products in Australia for myelodysplastic syndromes.

4.4 Celgene has the following products which can be prescribed in Australia for the treatment of multiple myeloma and mantle cell lymphoma:

(a) Revlimid® is the brand name under which Celgene markets products registered on the ARTG for the treatment of patients with multiple myeloma and relapsed and/or refractory mantle cell lymphoma.[9] In respect of mantle cell lymphoma, Revlimid® is not commercially available in Australia with the product only available through Celgene's compassionate access program;[10] and

(b) Pomalyst® is the brand name under which Celgene markets products registered on the ARTG for the treatment of patients with relapsed and refractory multiple myeloma.

[8] See generally M. Howard Morse, Product Market Definition in the Pharmaceutical Industry, 71 Antitrust L.J. 633, 676 & n.203 (2003).
[9] Revlimid® is also registered on the ARTG for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
[10] See the following link for general TGA description of the program: https://www.tga.gov.au/special-access-scheme-guidance-health-practitioners-and-sponsors

4.5 Juno currently has two products in Australia that are registered on the ARTG and listed for multiple myeloma and mantle cell lymphoma under the brands *Bortezomib JN* and *Bortezomib Juno*. However, Juno only supplies *Bortezomib Juno* in the market, which is listed on the PBS for the treatment of multiple myeloma. Bortezomib Juno is also registered on the ARTG for the treatment of mantle cell lymphoma and, though not PBS listed, is available to be supplied in Australia

4.6 Bortezomib, lenalidomide and pomalidomide are each 'separate and distinct therapeutic goods' under the *Therapeutic Goods Act 1989* (Cth) (**TG Act**).

4.7 There are other available alternate products and suppliers of pharmaceutical products registered on the ARTG for the treatment of multiple myeloma and mantle cell lymphoma:

(a) **Table 1 below** identifies products that are supplied in Australia for the treatment of multiple myeloma, including: lenalidomide, pomalidomide, bortezomib, carfilzomib and daratumumab;

(b) paragraph 4.14(b) below, identifies products that are supplied in Australia for the treatment of mantle cell lymphoma including lenalidomide, bortezomib, bendamustine, acalabrutinib, brexucabtagene autoleucel and ibrutinib.

4.8 Accordingly, for the purposes of this Application, the Proposed Conduct should be assessed in the context of the national markets for:

(a) the supply of pharmaceutical products for the treatment of multiple myeloma; and

(b) the supply of pharmaceutical products for the treatment of mantle cell lymphoma,

(the **relevant markets**).

4.9 Absent the Agreement, whilst Celgene and Juno both supply products in the relevant markets, Juno is currently unable to supply the Generic Products (with the active ingredients lenalidomide and pomalidomide) for the treatment of multiple myeloma and mantle cell lymphoma without exposure to potential liability associated with an 'at risk' launch (unless and until Juno and Natco succeed in challenging the validity of the Celgene Patents, or the Celgene Patents expire).

4.10 Bortezomib is not a generic version of Revlimid® or Pomalyst®, therefore the *Bortezomib Juno* product has not triggered the movement of lenalidomide or pomalidomide from the F1 formulary to the F2 formulary as described in paragraphs (as described in 4.35 – 4.39 below).

4.11 The Proposed Conduct allows Natco and Juno to offer and supply a broader range of multiple myeloma and mantle cell lymphoma treatments by supplying the Generic Products . The Agreement also allows Juno to supply products approved for a wider range of indications namely: myelodysplastic syndromes and refractory multiple myeloma. The Agreement provides Natco and Juno with a non-exclusive licence under the Celgene Patents to manufacture, import or keep (in the case of Natco and its affiliates) and to keep, use or dispose of (including, but not limited to, selling) or offer to dispose of (in the Case of Juno and its affiliates), the Generic Products (i.e. generic versions of Revlimid (lenalidomide) and Pomalyst (pomalidomide))[11] in Australia from the relevant Authorised Launch Date. The effect of the Agreement is that Juno would be permitted to supply lenalidomide and pomalidomide Generic Products in Australia for the treatment of multiple myeloma.

[11] Bortezomib is not considered a Generic Product for this purpose.

4.12 There is no existing relevant vertical relationship from a supplier / customer perspective between the Applicants in the relevant markets for consideration in connection with entry into the Agreement.

4.13 In respect of the overlapping products and/or services identified, provide estimated market shares for each of the parties where readily available.

4.14 The market share estimates provided in **Table 1 below** are based on the most recent Australian Government's Department of Health figures available at the date of this application of prescriptions dispensed for the supply of PBS approved multiple myeloma pharmaceutical items, covering the period since Bortezomib Juno has been available in the relevant market. These figures have been adjusted to represent the standard services provided for monthly treatments to take into account differences in method of delivery (specifically, oral and intravenous delivery, and dosage levels).

(a) **Table 1** – products / suppliers and shares of pharmaceutical products supplied in Australia for the treatment of multiple myeloma

Product	Supplier	Services provided June-August 2021 apportioned for monthly treatments	% of total service
Revlimid	Celgene	10,169	59%
Pomalyst		1,073	6%
Thalidomide		228	1%
Velcade	Jannsen	379	2%
Darzalex		1,034	6%
Bortezomib Juno	Juno	3,497	20%
Kyprolis	Amgen	983	6%

(b) products / suppliers and shares of pharmaceutical products supplied in Australia for the treatment of mantle cell lymphoma

Mantle cell lymphoma is a rare subtype of Non Hodgkin Lymphoma. Celgene estimates that only between 286 and 572 patients are diagnosed with mantle cell lymphoma in Australia each year. Even within this small relevant market Celgene and Juno have limited involvement:

i. Celgene estimates it would provide Revlimid® for mantel cell lymphoma treatment to [redacted] patients per year though only through its compassionate access program (i.e. Revlimid® is not commercially available in Australia for the treatment of mantle cell lymphoma);

ii. Bortezomib Juno is not listed on the PBS. It is possible to obtain private scripts for the treatment of mantle cell lymphoma but Juno considers that such scripts are minimal if non-existent in practice. Because Bortezomib Juno is not listed on the PBS for the treatment of mantle cell lymphoma Juno does not have specific figures available for this indication;

iii. Other products indicated for the treatment of mantle cell lymphoma include acalabrutinib, brexucabtagene, autoleucel, bendamustine and ibrutinib. Data for all

of these pharmaceutical products is not available to the parties as the majority of these products are not listed on the PBS – meaning no public data is available.

Describe the relevant industry or industries. Where relevant, describe the sales process, the supply chains of any products or services involved, and the manufacturing process.

Australian pharmaceutical industry

4.15 The Australian pharmaceutical industry is comprised of three primary supply chain components:

(a) manufacturing or importation of overseas manufactured product;

(b) distribution and wholesaling within Australia; and

(c) retailing / dispensing of product.

4.16 Each of these above primary supply chain components are discussed in turn below, together with detail on the relevant regulatory regimes that govern the approval of pharmaceutical products supplied in the Australian market and the overlay of the Commonwealth funded reimbursement regime for prescriptions.

Manufacturing / import distribution

4.17 Manufacturers produce one or more of the following main categories of pharmaceutical products:

(1) **prescription products**, which are products that may only be made available to a patient by a pharmacist on the written instruction (prescription) of an authorised medical practitioner (either privately or in a hospital);

(2) **over the counter (OTC) products**, which are products that may be purchased for self-treatment from pharmacies and other retailers without a prescription. Some OTC products are classified as pharmacy only / pharmacist only products[12]; and

(3) **consumer healthcare products**, which are health focused products that do not have to be sold in pharmacies (and are also available without a prescription), such as vitamins, supplements and alternative medicines,

(together, **pharmaceutical products**).

4.18 Pharmaceutical products intended for the Australian market may be manufactured onshore (i.e. within Australia), or manufactured offshore and imported into Australia for distribution to wholesalers.

Australian Register of Therapeutic Goods

4.19 The TG Act requires that a product (as with any therapeutic good) must be registered on the ARTG before it can legally be imported to, exported from, manufactured in or supplied in Australia (unless specifically exempt from that regulatory requirement).

4.20 An essential requirement before a pharmaceutical product can be launched in Australia is to obtain regulatory approval from the Therapeutic Goods Administration (**TGA**), the

[12] Pharmacy only medicines may be purchased for self-treatment but are only available from pharmacies, whereas pharmacist only medicines must be purchased after a pharmacist has determined it is appropriate to sell them. There are rules regarding where such medicines may be located in retail pharmacies.

Commonwealth agency (within the Australian Government's Department of Heath) responsible for administering the TG Act and regulating Australian 'therapeutic goods'.

Prescription pharmaceuticals, originators and bioequivalent generics

4.21 Typically cancer treatment pharmaceutical products are supplied on prescription.

4.22 Prescription products are typically characterised as either:

(1) a branded product, which term is used to refer to the first commercially available brand of a particular product (for the purposes of this Application, these products are referred to as **originator** products). Celgene's Revlimid® and Pomalyst® are originator products; or

(2) a **generic** medicine, which term is used to refer to the second or subsequent brand of a particular product, that is approved by the TGA by reference to the approval of the applicable originator product, and upon establishing to the satisfaction of the TGA that the generic product is bioequivalent to the originator product.

Launch

4.23 Suppliers of generic products seeking to supply a generic form of the originator's product risk a claim to significant damages in the event that they supply a generic product that infringes a patent. In circumstances where a generic supplier wishes to supply a product that may infringe a patent, the generic supplier may seek to clear the way for the launch of its product by challenging the validity of the originator's patent. However, there is no guarantee that the generic supplier's claims of invalidity will be upheld by the Court and also typically, a generic manufacturer seeking to challenge the validity of a patent will be met with a cross-claim for threatened infringement of the originator's patent. In any event, suppliers will typically only commence supplying a product once it has been listed on the PBS for the reasons explained below. Alternatively, product may be supplied on a private prescription basis as is the case in relation pharmaceutical products for the treatment of mantle cell lymphoma.

Pharmaceutical Benefits Scheme

4.24 The Pharmaceutical Benefits Scheme (**PBS**) is a scheme established by the Commonwealth Government for the subsidisation of certain products.

4.25 A product must be registered on the ARTG before it can be listed on the PBS. While products cannot be supplied in Australia without being approved by the TGA, products can theoretically be supplied in Australia without being approved for reimbursement through the PBS (such as on a private prescription basis). However, the (unsubsidised) cost of many products is such that many patients would not be able to afford them unless and until they are eligible for a PBS reimbursement, which is given effect by the product being included in the Schedule of Pharmaceutical Benefits (**PBS Schedule**).

4.26 As such, it is common practice for a supplier to apply for PBS listing before supplying a product in Australia.

4.27 A new product (as distinct from a new brand, form or manner of administration of an existing PBS-listed medicine), or a new biosimilar, can only be listed on the PBS by the Minister for Health (**Minister**) if it has been the subject of a positive recommendation by the Pharmaceutical Benefits Advisory Committee (**PBAC**), which gives consideration to the cost and effectiveness of any new proposed therapy.[13] In contrast, an application seeking PBS listing of a new brand of an existing PBS-listed medicine, such as a first or subsequent generic, will typically be approved by the Department of Health on a cost-minimisation basis.

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[13] Section 101 NHA.

Pricing under the PBS

4.28 The 'dispensed price' of any PBS-listed pharmaceutical item, being the price paid by the Commonwealth Government directly to any person who dispenses the pharmaceutical item (e.g. a community pharmacy), is specified in the PBS Schedule.

4.29 The 'dispensed price' comprises:

(1) the cost to pharmacist, made up of the approved ex-manufacturer price (**AEMP**) and a set mark up for the wholesaler; plus

(2) a set mark up for the pharmacist; plus

(3) a dispensing fee per script.

4.30 The wholesaler, pharmacist mark ups and the dispensing fee referred to above are set by the Commonwealth Government by agreement with the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia.

4.31 The AEMP (previously, 'approved price to pharmacists' or 'AP2P') for a pharmaceutical item is the price agreed by the Minister and the 'responsible person' (also known as the 'sponsor') as the maximum price to be charged by wholesalers or manufacturers for sales of that product to approved pharmacists.

4.32 The AEMP may change due to statutory price reductions (discussed at sections 4.42 to 4.45 below), or if the Minister and the responsible person for a pharmaceutical item negotiate and agree to a change.

4.33 The AEMP is the *maximum* price the supplier can charge, however, the supplier can elect to sell to wholesalers or pharmacists at a price *lower* than the AEMP at any time, at their discretion. Discounting may take many forms, from a simple price reduction through to arrangements that include provision of 'bonus' stock (e.g. two for one deals) or volume-based rebates to the wholesaler or pharmacist.

4.34 The amount paid by a patient for any PBS-listed pharmaceutical medicine product (the **patient co-payment**) is set by the National Health Act 1953 (Cth) (**NHA**), and is adjusted annually in accordance with CPI. The patient co-payment differs for concession cardholders (social welfare recipients, pensioners, and the unemployed) and non-concessional users (other members of the public). In some circumstances, a patient may also be required to pay a brand price premium in addition to the patient co-payment. The patient co-payment received by a pharmacy for dispensing a pharmaceutical product is deducted from the dispensed price payable by the Commonwealth for that supply.

Allocation of PBS-listed products to 'F1' and 'F2' formularies

4.35 A PBS-listed product is allocated to one of two formularies, identified as F1 and F2, each with different pricing implications.

4.36 Pharmaceutical items for which there is only a single brand listed under the PBS are generally included in F1. This typically includes patented products, and off-patent products that are not substitutable with other products or brands.

4.37 Pharmaceutical items listed in the F1 formulary are presently subject to mandatory anniversary price reductions on the fifth, tenth, and fifteenth anniversary of their PBS listing (reductions of 5%, 10% and 5% respectively). The schedule of anniversary reduction dates is published on the PBS website.[14]

[14] Available here: https://www.pbs.gov.au/info/industry/pricing/anniversary-price-reductions.

4.38 The listing of the first generic or biosimilar brand of a pharmaceutical item already listed on the PBS triggers the movement of the originator brands(s) of the pharmaceutical item from F1 to F2. Thus, F2 only includes pharmaceutical items for which there are multiple brands listed under the PBS, which are approved as interchangeable.

4.39 The movement of a pharmaceutical item from F1 to F2 triggers a number of consequences, including statutory price reductions and price disclosure associated price reductions. In addition, all suppliers of a pharmaceutical item newly listed in F2 are required to comply with the guarantee of supply provisions in Part VII, Division 3C of the NHA.

Statutory price reductions

4.40 Upon the listing of the first generic product of an existing PBS-listed pharmaceutical item for which the generic's product is bioequivalent, the originator brand's AEMP is automatically reduced by at least 25%[15] (with the price of the generic brand/s also set at the reduced AEMP).[16]

4.41 The Minister has the discretion to reduce or not apply a mandatory price reduction in some circumstances such as when the originator's price has previously already been reduced.[17] Alternatively, the Minister may determine, by legislative instrument, that a product is an 'exempt item' (if the product satisfies the criteria set out in section 84AH of the NHA) and is excluded from one or more of the statutory price reductions and/or price disclosure price reductions.[18]

Price disclosure-related price reductions

4.42 The responsible person for PBS-listed pharmaceutical items included in the F2 formulary are also required to comply with the price disclosure requirements.[19] The information disclosed is used to calculate a Weighted Average Disclosed Price (**WADP**) for each pharmaceutical item.

4.43 The WADP is calculated by a formula that takes into account:

(1) the volume of sales of the pharmaceutical item; and

(2) the extent to which the responsible persons of those brands offer discounts and other incentives which result in the price *actually* paid by pharmacists being less than the AEMP plus the applicable wholesale mark-up.

4.44 The WADP is used to adjust (i.e. reduce) the dispensed price of the pharmaceutical item so that it more accurately reflects the *actual market price* of the medicine. Specifically, if the calculated WADP is more than 10% below the current AEMP, the AEMP will be reduced too in accordance with a pre-determined formula.[20]

4.45 The first data collection period commences on the date of listing of the first generic brand of a pharmaceutical item (i.e. the date upon which the pharmaceutical item moves from F1 to F2). Data collection cycles are 1 April to 30 September and 1 October to 31 March, with two corresponding price reduction days six months after the end of the data collection period, namely 1 April and 1 October, and continues on a rolling basis. The PBS calculates the WADP within a three-month period following the data collection period and subsequently announces the new WADP adjusted dispensed price to the market to be applied after a

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[15] This reduction increased from 12.5% to 16% on 1 February 2011, then again from 16% to 25% on 1 October 2018.
[16] Under section 99ACF of the NHA.
[17] Under sections 99ACB, 99ACD NHA.
[18] A list of the pharmaceutical items which are currently exempt under the NHA is published on the PBS website, see here: https://www.pbs.gov.au/info/industry/pricing/pbs-items/items-exempt-price-reductions.
[19] As set out in Division 3B of Part VII of the NHA and Part 7, Division 2 of the National Health (Pharmaceutical Benefits) Regulations 2017 (**NH Regulations**).
[20] Regulation 37C, NH Regulations.

further notice period. The first WADP price adjustment comes into effect up to 18 months after the date the PBS approves the new generic product.

Other aspects of the PBS-listing regime

4.46 Other obligations imposed on responsible persons following a listing of a pharmaceutical item on the PBS are:

(1) guarantee of supply[21]: the responsible person is required to guarantee supply of the relevant pharmaceutical item for a specified period and to notify the Minister if it expects to fail or be unable to supply, or has failed or been unable to supply, the pharmaceutical item for the required period; and

(2) assurance of supply: applicants for a PBS listing of a *new brand* of a product are required to provide 'assurance of supply' in the documentation submitted to obtain a PBS listing. This requirement is distinct and separate from the supply guarantee requirement in that it is a purely administrative requirement imposed by the Department of Health. As a matter of practicality, however, the applicants for a PBS listing are required to provide written assurance that sufficient stock of their brand will be available from the proposed PBS listing date to meet anticipated demand.

Distribution and wholesaling

4.47 Pharmaceutical wholesalers are responsible for the distribution of products that have been manufactured in, or imported into, Australia to community pharmacies. Typically, stock is initially held by a 'pre-wholesaler', which effectively operates as a large storage facility. Stock is then transferred to a wholesaler on an as needs basis, determined by ordering quantities of end customers.

4.48 Practically speaking, upon a wholesaler receiving an order from the end customer:

(1) the wholesaler will place an order on the supplier/manufacturer; and

(2) the supplier will direct their nominated pre-wholesaler to release product to the wholesaler, which the wholesaler will then resupply to the end customer.

4.49 However, negotiation concerning the terms of supply typically occurs between the supplier of the product (which could be the manufacturer, the sponsor of the product for TGA regulatory purposes (if not the manufacturer) or an appointed sales agent) and the end customer (that is, the wholesaler does not typically negotiate terms with the end customer, but acts only as a physical distributor).

Retailing

4.50 Depending on the nature of the product, and whether or not there are multiple brands of the product available, sales may be made by way of:

(1) direct negotiation with individual customers, typically directed to agreeing a formal supply contract;

(2) direct negotiation with state or territory procurement agencies or tender boards, which most commonly arises for a "sole supplier" product (that is, an originator with no generic competition), typically directed to reaching an agreed pricing arrangement; or

(3) a competitive tender process administered by a state or territory procurement agency or tender board (often conducted in respect of a number of different products

[21] Under division 3C, Part VII NHA.

simultaneously), which most commonly arises where is one or more generic brand available in addition to the originator, typically directed to a tender agreement.

4.51 In particular when engaged in a competitive tender process, pricing is typically framed by reference to a specific discount the supplier is willing to offer from the PBS list price. Alternatively, if there is no tender process, the supplier simply negotiates direct terms of supply with the customer.

4.52 In respect of the overlapping products and/or services identified, provide estimated market shares for each of the parties where readily available.

4.53 The Applicants note that market share estimates are provided above in section 4.13 above.

4.54 In assessing an application for authorisation, the ACCC takes into account competition faced by the parties to the proposed conduct. Describe the factors that would limit or prevent any ability for the parties involved to raise prices, reduce quality or choice, reduce innovation, or coordinate rather than compete vigorously. For example, describe existing competitors, likely entry by new competitors, any countervailing power of customers and/or suppliers; and any other relevant factors.

4.55 See section 6 (**Public Detriments**) below. In the Applicants' view, there are no Publc Detriments to the Proposed Conduct.

5. Public benefits

5.1 Describe the benefits to the public that are likely to result from the proposed conduct. Provide information, data, documents or other evidence relevant to the ACCC's assessment of the public benefits.

5.2 Public benefit is not defined in the CCA, but the Australian Competition Tribunal has said it should be given the widest possible meaning including: *"anything of value to the community generally, any contribution to the aims pursued by the society including as one of its principal elements (in the context of trade practices legislation) the achievement of the economic goals of efficiency and progress)"*.[22]

5.3 The Proposed Conduct will give rise to a number of compelling public benefits, including:

(1) certain and early launch of competing Generic Product for the treatment of multiple myeloma and mantle cell lymphoma;

(2) increased competition in the relevant markets;

(3) greater supply-side security of pharmaceutical items for the treatment of multiple myeloma and mantle cell lymphoma;

(4) PBS price reductions, with resultant cost savings to the Commonwealth;

(5) introduction of alternate supply of pharmaceutical items for the treatment of myelodysplastic syndrome patients; and

(6) facilitating the orderly and expeditious settlement of the Proceedings and Cross-Claim, with a resultant benefit in minimising the incursion on scarce judicial resources.

5.4 Each of these aspects are explained in further detail below.

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[22] Re 7-Eleven (1994), ATPR 41-357 at [42,677].

Certain and early launch of the Generic Products

5.5 The Proposed Conduct will generate substantial public benefits by giving certainty as to the early launch of the Generic Products in Australia.

5.6 Granting authorisation for the Proposed Conduct will result in a public benefit of ensuring certainty of the early supply of the Generic Products in Australia in a more timely manner than would otherwise be available to Juno / Natco. In fact, the Proposed Conduct will facilitate supply of the Generic Products earlier than in any other scenario that would enable Natco/Juno to launch the Generic Products free from the risk of being exposed to substantial damages.

5.7 The logical consequence of the entry into the Agreement is the certainty of the Generic Products entering and competing with Revlimid® and Pomalyst®. This benefit and the associated benefits from increased competition to the public are discussed further below.

Increased competition in the relevant markets

5.8 In effect, by authorising the Proposed Conduct and ensuring the certainty of an early launch of the Generic Products in Australia, increased competition in the relevant markets is guaranteed, including by reason of competitive pricing pressures as well as the presence of additional products.

5.9 Increasing competition in a particular market is inherently beneficial and a priority consideration for the ACCC in assessing and making a determination in relation to market activity and transactions. The specific benefits of increasing competition in the relevant markets are better outcomes for customers (including hospitals and pharmacists) and patients in terms of availability of medicine, alternative suppliers and price. These factors are discussed further below.

Greater supply-side security

5.10 The launch of the Generic Products in the relevant markets has the public benefit of ensuring certainty of additional sources of supply of pharmaceutical products in Australia for the treatment of multiple myeloma and mantle cell lymphoma, thereby increasing security of domestic supply and availability of these cancer products.

5.11 Security of supply of product is critical for mitigating supply shortages and ensuring hospitals and pharmacists (and therefore patients) have access to a reliable source of those products. The need for security of supply is arguably heightened in the current environment in which supply chains are exposed to exogenous shocks caused by the COVID-19 pandemic. These include international border closures impacting manufacturing volumes and the timeliness of delivery of imports and exports, which can impact the ability of an individual manufacturer, supplier or distributor to access inputs or achieve desired stock levels.

5.12 Granting authorisation in relation to the Proposed Conduct would create certainty of additional sources of supply of product for the treatment of multiple myeloma and mantle cell lymphoma in Australia and provide greater security to patients to whom existing products are being administered.

PBS price reduction

5.13 The Proposed Conduct will enable Natco and Juno to launch the Generic Products prior to the Celgene Patents ceasing to be on foot with certainty and without the risks associated with an 'at risk' launch. Accordingly, this will bring forward the price drops from the first entry of generics described above resulting in considerable savings to the Commonwealth Government, including benefiting third party payers such as Medicare. In particular, the launch of the Generic Products in Australia will trigger immediate, and automatic, statutory PBS price reductions which will, in turn, result in cost savings to the Commonwealth Government by way of reduced reimbursement. In addition, Juno's supply of the Generic

Products would lead to discount offers to customers and pharmacists, which, in turn, will generate further PBS price reductions (and savings to the Commonwealth Government) over time.

5.14 As set out in paragraphs 4.42 to 4.45 above, when the first generic brand of an originator PBS listed product is listed on the PBS, this will trigger the movement of originator brand product from the F1 to F2 formulary.

5.15 The first relevant impact of this move is an immediate price reduction applied to the AEMP (**First New Brand Statutory Price Reduction**). The revised AEMP applies to the originator brand and the generic. The First New Brand Statutory Price Reduction is presently 25% unless there are reductions as discussed in 4.41.

5.16 As the AEMP is one component of the dispensed price (and therefore the price paid by the Commonwealth Government directly to a pharmacist who dispenses the product), the First New Brand Statutory Price Reduction results in a reduction in the dispensed price and therefore the amount of the Commonwealth Government subsidy which applies to generic pharmaceutical products. Accordingly, the launch of the Generic Products will have the result of immediate and significant cost savings to the Commonwealth Government.

5.17 Secondly, the launch of the Generic Products and the subsequent activities of Juno / Natco to encourage uptake of the Generic Products will result in increased competitive supply, including by way of price discounts to customers and pharmacists, which will trigger further price reductions.

5.18 Following the launch of the Generic Products, Juno / Natco will be required to disclose, on an ongoing basis, all sales volumes, actual sales prices and the value of incentives (including rebates and any bonus stock deals) of its Generic Products. This data is submitted at the expiration of the initial 12-month cycle (being 12 months after the initial one-month non-disclosure period). The launch of the Generic Products will result in competitive responses including further price discounting and incentive offers to customers (e.g. to encourage pharmacists to stock Celgene branded product), this will, depending on the level of discounting, likely lead to a further reduction in the AEMP in accordance with a prescribed statutory formula.[23]

Facilitation of orderly and expeditious settlement of the Proceedings

5.19 There is also a public benefit from the Applicants entering into, and giving effect to, the terms of the Agreement, by which the Applicants agree to discontinue and withdraw their respective litigation claims, namely the Proceedings and the Cross Claim. Patent settlements (or avoiding litigation in the first instance) provide clear and recognisable benefits by reducing litigation costs and burdens on the courts.

5.20 There is a public interest in having the Proceedings and Cross-Claim discontinued and settled in an orderly manner. The foreseeable outcome of this is that the Applicants will save considerable costs that would otherwise be expended on conducting the Proceedings and the Cross Claim and instead have those funds available to allocate for the development, manufacture and distribution of products that provide significant public benefit. In general, the cost of litigating includes:

(1) direct litigation cost: The Proposed Conduct will result in the Applicants avoiding future litigation costs associated with the Proceedings, Cross-Claim and the Re-Examination Requests. These cost savings are a public benefit which can (and should) be taken into account. As recognised by the ACCC in its guidance: "*cost savings accruing to one or few firms arising from increases in productive efficiency*

[23] As set out in regulation 37C, NH Regulations.

can constitute public benefits and it is not necessary for the savings to be passed on to end consumers in the form of lower prices";[24] and

(2) indirect costs: in addition to direct costs, the Proposed Conduct will result in indirect cost savings such as internal resources. This includes on-going work to provide instructions to legal advisers (and, where required, direct assistance) in respect of the conduct of the litigation including in relation to the overall strategy, preparation of pleadings, evidence and submissions, and undertaking discovery, distracting them from the operation of the business. Economists model the cost of litigation using the concepts of "risk aversion" and "risk premiums." As a result, both brand name and generic manufacturers would accept lower expected profits under a settlement, rather than risk the uncertainty of litigation. Accordingly, even where parties recognise the validity of a patent, avoiding the enormous direct and indirect costs is attractive to the parties who would rather allocate their constrained and limited resources efficiently for their commercial benefit and for the general societal benefit.

5.21 Further, there are additional costs from litigation (even between private parties) to society as a whole, including increased congestion of the court system and the allocation of corporate resources towards dispute resolution as opposed to innovation and production activities.[25]

5.22 Settlement of the Applicants' claims also reduces the burden on scarce Court resources.

Future without the Proposed Conduct

5.23 Without the Agreement, if Celgene succeeds in the Proceedings and Cross-Claim and obtains a permanent injunction (which is typically granted for patent infringement), Natco and Juno will likely be prevented from supplying the Generic Products until each of the respective Celgene Patents expire. Thus the Agreement facilitates early entry and expanded competition, it allows the market the significant other Public Benefits arising from the Proposed Conduct (as set out in this Application).

5.24 In the absence of the Agreement, the only options available to Juno / Natco to supply the Generic Products prior to the expiry of the Celgene Patents, would be:

(a) to launch at risk of litigation, which is only an option subject to the possibility of Celgene obtaining an interlocutory injunction enforcing its patents and preventing supply or

(b) revert to pursue their Proceedings.

5.25 As noted at section 5.20 above, this would be conducted at a significant cost to each of the Applicants, in terms of money and time expended, and to the public, in terms of the opportunity cost of allocating money and time toward protracted litigation and use of scarce Court resources, and without certainty of outcome.

5.26 If the Proceedings and Cross Claim are not decided in favour of Juno / Natco, Juno / Natco will, in the absence of the Agreement, only be able to supply Generic Products upon expiry of each of the Celgene Patents.

5.27 Accordingly, in a future without the Proposed Conduct, there is no certainty that Juno / Natco would be able to launch the Generic Products, within the time frame permitted by the Agreement. Therefore, the Agreement brings forward the Public Benefits for Australian consumers earlier than is the case without the Proposed Conduct. Until the listing on the PBS of the Generic Products, the automatic statutory PBS price reductions of up to 25% that would be triggered by the launch of the Generic Products in the relevant markets (assuming it is the

[24] ACCC Guidelines for Authorisation of Conduct (Non-Merger) at [8.8].
[25] See, e.g., Carl Shapiro, *Antitrust Limits to Patent Settlements*, 43 RAND J. of Econ., 391, 392 (2003) at 394.

first generic brand listing) (and any cost savings to the Commonwealth Government resulting from a lower reimbursement prices) will not occur.

5.28 With the Proposed Conduct, launch of the Generic Products will not be delayed until the expiry of the Celgene Patents and such early launch will increase competition in the relevant markets. Juno has provided an expanded description of the counterfactual in **Confidential Attachment E**.

[redacted]

5.31 The Applicants submit that the Proposed Conduct (as given effect by the Agreement) has clear and substantial public benefits compared to any other counterfactual. Natco/Juno will be permitted to enter the market on [redacted]. This is significantly earlier than the expiry dates for the Celgene Patents being: 13 April 2023, 16 May 2023 and 2 August 2027.

5.32 In addition, the launch of the Natco/Juno's Generic Products (assuming they are the first generic brands to market), will trigger an automatic, immediate and substantial (c.25%) reduction in the price of branded Revlimid® and Pomalyst® under the PBS as well as follow on price reductions (see sections 5.13 – 5.18 above).

6. Public detriment (including likely competitive effects)

6.1 Describe any detriments to the public likely to result from the proposed conduct, including those likely to result from any lessening of competition. Provide information, data, documents, or other evidence relevant to the ACCC's assessment of the detriments.

6.2 In the Applicants' view, there are no Public Detriments arising from the Proposed Conduct.

7. Contact details of relevant market participants

7.1 Identify and/or provide names and, where possible, contact details (phone number and email address) for likely interested parties such as actual or potential competitors, key customers and suppliers, trade or industry associations and regulators.

7.2 These are provided in Attachment B (which includes both confidential and non-confidential information).

8. Additional information

8.1 Provide any other information or documents you consider relevant to the ACCC's assessment of the application

8.2 Relevant information and documents have been provided in other sections where relevant.

9. Declaration by Applicants

9.1 The undersigned declare that, to the best of their knowledge and belief, the information given in response to questions in this form is true, correct and complete, that complete copies of documents required by this form have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere.

9.2 The undersigned undertake(s) to advise the ACCC immediately of any material change in circumstances relating to the application.

9.3 The undersigned are aware the giving false or misleading information is a serious offence and are aware of the provisions of sections 137.1 and 149.1 of the Criminal Code (Cth).

……

MinterEllison

Geoff Carter

for and on behalf of Juno and Natco

This 3rd day of December 2021

……

Celgene Corporation

Patrick Elsevier – SVP Litigation, Government Investigations and HR Law

for and on behalf of Celgene Corporation

This 2nd day of December 2021

……

Celgene Pty Ltd

Neil MacGregor – Managing Director Aust/NZ

and

……

Celgene Pty Ltd

Bud Glogovac – Finance Director Aust/NZ

for and on behalf of Celgene Pty Ltd

This 3rd day of December 2021

Attachment A – the Agreement

[redacted]

Attachment B

Other interested parties

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Attachment C – Celgene Patents

No.	Australian Patent Number (and Title)	Type of patent	Compound / Treatment	Patent relevant to licence for	Expiry Date of Patent
1.	2003234626 (Methods and compositions using immunomodulatory compounds for treatment and management of cancers and other diseases)	Method of treatment	lenalidomide / multiple myeloma	Generic version of Revlimid®	16 May 2023
2.	2012254881 (Methods and compositions using immunomodulatory compounds for treatment and management of cancers and other diseases)	Method of treatment	lenalidomide and pomalidomide / multiple myeloma	Generic version of Revlimid® Generic version of Pomalyst®	16 May 2023
3.	2013263799 (Methods and compositions using immunomodulatory compounds for treatment and management of cancers and other diseases)	Method of treatment	lenalidomide / multiple myeloma	Generic version of Revlimid®	16 May 2023
4.	2006202316 (Methods and compositions using immunomodulatory compounds for treatment and management of cancers and other diseases)	Method of treatment	lenalidomide / multiple myeloma and mantle cell lymphoma	Generic version of Revlimid®	16 May 2023
5.	2010201484 (Methods and compositions using immunomodulatory compounds for treatment and management of cancers and other diseases)	Method of treatment	pomalidomide / multiple myeloma	Generic version of Pomalyst®	16 May 2023
6.	715779 (Substituted 2(2,6- dioxopiperidin-3-yl)phthalimides and -1-oxoisoindolines and method of reducing TNF-alpha levels)	Compound	lenalidomide	Generic version of Revlimid®	24 July 2022
7.	2003228508 (Methods of using and compositions comprising immunomodulatory compounds for the treatment and management of myelodysplastic syndromes)	Method of treatment	lenalidomide / myelodysplastic syndromes	Generic version of Revlimid®	13 April 2023
8.	2012201727 (Methods of using and compositions comprising immunomodulatory compounds for the treatment and management of myelodysplastic syndromes)	Method of treatment	lenalidomide / myelodysplastic syndromes	Generic version of Revlimid®	13 April 2023

No.	Australian Patent Number (and Title)	Type of patent	Compound / Treatment	Patent relevant to licence for	Expiry Date of Patent
9.	2007282027 (Use of 3- (4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the treatment of mantle cell lymphomas)	Method of treatment	lenalidomide / mantle cell lymphoma	Generic version of Revlimid®	2 August 2027

Attachment D – Juno ARTG Listings

Table 1: Lenalidomide ARTG Listings

ARTG ID	Registration Date	Sponsor	Product Name	Description
338517	23/07/2021	Juno	LENALIDOMIDE JUNO	Lenalidomide 2.5 mg capsules blister pack
338523	23/07/2021	Juno	LENALIDOMIDE JUNO	Lenalidomide 5 mg capsules blister pack
338530	23/07/2021	Juno	LENALIDOMIDE JUNO	Lenalidomide 7.5 mg capsules blister pack
338519	23/07/2021	Juno	LENALIDOMIDE JUNO	Lenalidomide 10 mg capsules blister pack
338514	23/07/2021	Juno	LENALIDOMIDE JUNO	Lenalidomide 15 mg capsules blister pack
338524	23/07/2021	Juno	LENALIDOMIDE JUNO	Lenalidomide 20 mg capsules blister pack
338511	23/07/2021	Juno	LENALIDOMIDE JUNO	Lenalidomide 25 mg capsules blister pack
338528	23/07/2021	Juno	LENALEX	Lenalidomide 2.5 mg capsules blister pack
338516	23/07/2021	Juno	LENALEX	Lenalidomide 5 mg capsules blister pack
338512	23/07/2021	Juno	LENALEX	Lenalidomide 7.5 mg capsules blister pack
338513	23/07/2021	Juno	LENALEX	Lenalidomide 10 mg capsules blister pack
338525	23/07/2021	Juno	LENALEX	Lenalidomide 15 mg capsules blister pack
338529	23/07/2021	Juno	LENALEX	Lenalidomide 20 mg capsules blister pack

ARTG ID	Registration Date	Sponsor	Product Name	Description
338510	23/07/2021	Juno	LENALEX	Lenalidomide 25 mg capsules blister pack
338520	23/07/2021	Juno	LENALIDE	Lenalidomide 2.5 mg capsules blister pack
338518	23/07/2021	Juno	LENALIDE	Lenalidomide 5 mg capsules blister pack
338521	23/07/2021	Juno	LENALIDE	Lenalidomide 7.5 mg capsules blister pack
338515	23/07/2021	Juno	LENALIDE	Lenalidomide 10 mg capsules blister pack
338526	23/07/2021	Juno	LENALIDE	Lenalidomide 15 mg capsules blister pack
338522	23/07/2021	Juno	LENALIDE	Lenalidomide 20 mg capsules blister pack
338527	23/07/2021	Juno	LENALIDE	Lenalidomide 25 mg capsules blister pack

Table 2: Pomalidomide ARTG Listings

ARTG ID	Registration Date	Sponsor	Product Name	Description
335276	18/05/2021	Juno	POMALIDOMIDE JUNO	Pomalidomide 1 mg hard gelatin capsule blister pack
335275	18/05/2021	Juno	POMALIDOMIDE JUNO	Pomalidomide 2 mg hard gelatin capsule blister pack
335281	18/05/2021	Juno	POMALIDOMIDE JUNO	Pomalidomide 3 mg hard gelatin capsule blister pack

ARTG ID	Registration Date	Sponsor	Product Name	Description
335272	18/05/2021	Juno	POMALIDOMIDE JUNO	Pomalidomide 4 mg hard gelatin capsule blister pack
335277	18/05/2021	Juno	POMOLIDE	Pomalidomide 1 mg hard gelatin capsule blister pack
335279	18/05/2021	Juno	POMOLIDE	Pomalidomide 2 mg hard gelatin capsule blister pack
335280	18/05/2021	Juno	POMOLIDE	Pomalidomide 3 mg hard gelatin capsule blister pack
335274	18/05/2021	Juno	POMOLIDE	Pomalidomide 4 mg hard gelatin capsule blister pack
335278	18/05/2021	Juno	POMALIDOMIDE JN	Pomalidomide 1 mg hard gelatin capsule blister pack
335271	18/05/2021	Juno	POMALIDOMIDE JN	Pomalidomide 2 mg hard gelatin capsule blister pack
335273	18/05/2021	Juno	POMALIDOMIDE JN	Pomalidomide 3 mg hard gelatin capsule blister pack
335270	18/05/2021	Juno	POMALIDOMIDE JN	Pomalidomide 4 mg hard gelatin capsule blister pack

Attachment E – Juno counterfactual description

[redacted]

Annexure E – Confidential counterfactual analysis

[redacted]

1.2 Absent the Agreement, the parties identified possible counterfactual scenarios available to Juno / Natco to supply the Generic Products prior to the expiry of the Celgene Patents in paragraph 5.24, including the following options:

(a) Juno / Natco to launch at risk, which is only possible if Celgene does not obtain an interlocutory injunction preventing supply of the Generic Products pending the final determination of the Proceedings and Cross Claim; or

(b) pursue their contested litigation strategy, which will only enable launch of the Generic Products during the term of the Celgene Patents if the Proceedings and Cross Claim are decided in favour of Juno / Natco before patent expiry.

[redacted]

[redacted]

[redacted]

[redacted]

Table 2 – Summary of proceedings to date

Date	Event
9 November 2020	Federal Court proceeding VID718/2020 commenced by Juno and Natco seeking revocation of AU715779 (lenalidomide compound patent)
8 December 2020	Celgene files defence
28 January 2021	Juno/Natco file validity evidence in support of revocation of AU715779
29 January 2021	Celgene files cross-claim alleging infringement of Australian Patents 715779, 2003228508, 2012201727, 2003234626, 2006202316, 2012254881, 2013263799, and 2007282027 (lenalidomide compound patent, plus 6 method of treatment patents relating to the use of lenalidomide to treat multiple myeloma, myelodysplastic disorders and mantle cell lymphoma (MOT patents))
11 February 2021	Juno/Natco file application to strike out cross-claim
15 March 2021	Interlocutory hearing of strike out application, and orders sought for expedition of case in respect of lenalidomide compound patent
19 March 2021	Court dismisses strike out application and orders an expedited trial in respect of lenalidomide compound patent. Orders record undertaking given by Juno/Natco.
01 April 2021	Lenalidomide compound patent case set down for hearing commencing on 16 August 2021
12 April 2021	Juno/Natco file defence to cross claim
28 May 2021	Juno/Natco file application seeking leave to file amended statement of claim to seek revocation of the MOT Patents and Australian Patent 2010201484 (method of treatment patent for use of pomalidomide for multiple myeloma).
30 May 2021	Celgene files evidence in answer on revocation of lenalidomide compound patent
3 June 2021	Juno/Natco granted leave to file amended statement of claim to seek revocation of the MOT Patents and Australian Patent 2010201484
24 June 2021	Juno/Natco file amended statement of claim seeking revocation of MOT Patents and Australian Patent 2010201484
09 July 2021	Celgene files amended statement of cross claim alleging infringement of Australian Patent 2010201484 and additional claims of 2012254881 relating to use of pomalidomide [note that Juno/Natco notified Celgene on 13 May 2021 that TGA approval and entry in the ARTG for Juno's pomalidomide products was imminent]
16 - 27 August 2021	Hearing of revocation action in respect of AU715779 (lenalidomide compound patent) (Juno/Natco admitting patent would be infringed if valid)
22 October 2021	Deadline for filing validity evidence in support of revocation of the MOT Patents Settlement agreement signed

[redacted]

25 October 2021	Orders made staying the revocation and infringement claim insofar as they relate to the lenalidomide and pomalidomide method of treatment patents (AU, 2003228508, 2012201727, 2003234626, 2006202316, 2012254881, 2010201484 2013263799, and 2007282027)
27 October 2021	Revocation and infringement claim in respect of AU715779 (lenalidomide compound patent) discontinued by consent

[redacted]