MinterEllison.

18 January 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

Additional information - 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 Thank you for the ACCC's information and document request dated 16 December 2021 with respect to the application for authorisation dated 3 December 2021 (the **Application**).

1.3 This letter comprises Juno / Natco's response to the information requested. Defined terms in this letter have the same meaning as set out in the Application.

1.4 This letter is accompanied by an electronic copy of documents requested. An index of these documents is attached at **Annexure A**.

2. Juno / Natco's response

2.1 Question 1: Rationale / Industry Background Information

Generic products

1.1 Explain Natco and/or Juno's strategy in relation to actions taken by patent holders or their licensees in response to Natco or Juno's proposed launch of any generic products that will compete with originating products, either generally in relation to any originator's products or in relation to Celgene specifically, and either in Australia or in locations including Australia.

2.2 Pharmaceutical companies in the position of Natco and Juno typically undertake substantial investigations prior to any proposed launch of a generic pharmaceutical product. Specifically, they will (at their own substantial cost) typically engage patent attorneys and/or specialist patent lawyers to undertake a thorough investigation of the relevant patent "landscape", that would identify all patents potentially relevant to the proposed generic product. Subsequently, advice would be sought in respect of:

(a) The relevance of those patents to the proposed generic product; that is, the likelihood that the generic product could potentially infringe the patent and the basis upon which such a generic product could be said to relevantly differ from the claims of the relevant patents;

(b) The strength of those patents; that is, the extent to which those patents might be susceptible to a revocation action alleging that they are invalid;

(c) The practical likelihood that the patentee of any potentially relevant patent might commence infringement proceedings against the generic company; and

(d) The financial exposure that may result if the generic company is allowed to launch its product, by defeating a preliminary injunction application if applied for by the patentee or one not being sought by the patentee, but subsequently being found to infringe one or more relevant patent after launch in a patent infringement main action.

2.3 The consequences of any such investigations will depend upon the particular circumstances and nature of the proposed generic product, and the strength of the potentially relevant patent(s). Further, the information relevant to consideration of whether or not to proceed with an "at risk" launch will necessarily be the subject of confidential and privileged legal advice on the merits and a review of the risk of exposure to any significant damages if the litigation ultimately fails.

1.2 Identify all Generic Products, and for each product identify the indications, that Natco and Juno intend to apply for on the PBS.

2.4 Juno intend to apply for PBS listing in relation to the products in **Table 1** and **Table 2** below. Juno intends to launch Lenalide and Pomolide brands only. It is not uncommon for generic companies to register multiple MAs at submission to allow for flexibility around launch strategies (and it is the same cost for one or many) and to do so after the initial MA is approved incurs additional costs and time (around 6 months). Also note, not all approved presentations, i.e. stock-keeping units (SKUs), are necessarily approved for funding and listed on the PBS (i.e. they are not currently all listed for the brands of lenalidomide and pomalidomide). Finally, in terms of the indications that Juno intend to list with the PBS these will be same PBS funded indications as the brand, which for lenalidomide is multiple myeloma and myelodysplastic syndrome and for pomalidomide it is relapsed or refractory multiple myeloma.

Table 1: Lenalidomide ARTG Listings – intention to apply for PBS listing

ARTG ID	Registration Date	Sponsor	Product Name	Description
338518	23/07/2021	Juno	LENALIDE	Lenalidomide 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
338527	23/07/2021	Juno	LENALIDE	Lenalidomide 25 mg capsules blister pack

Table 2: Pomalidomide ARTG Listings – intention to apply for PBS listing

ARTG ID	Registration Date	Sponsor	Product Name	Description
335280	18/05/2021	Juno	POMOLIDE	Pomalidomide 3 mg hard gelatin capsule blister pack

ARTG ID	Registration Date	Sponsor	Product Name	Description
335274	18/05/2021	Juno	POMOLIDE	Pomalidomide 4 mg hard gelatin capsule blister pack

1.3 For each Generic Product and indication identified in response to 1.2, provide the following:

(a) projected sales volumes for the first 3 financial years under the Agreement;

(b) projected revenue for the first 3 financial years under the Agreement.

Please provide Documents to support the response to this question.

2.5 Please see accompanying confidential spreadsheets (20211221_pomalidomide and 20211221_lenalidomide) which model the projected sales volume and projected revenue for pomalidomide and lenalidomide for a 5 year period. Please note;

(a) the modelling includes key assumptions outlined on the first sheet ('Overview'); and

(b) the models involves a number of key assumptions about future matters and the actual outcomes may vary materially from the model including among other reasons because outcomes will depend on actions of other market participants that are independent of Juno and Natco.

1.4 For each patent associated with Revlimid®, as identified in Attachment C of the application, identify the patents for which a licence is required to enable Natco and Juno to produce and supply a generic version of Revlimid® and describe why each licence is required.

2.6 Please see attached Annexure B which identifies the patents for which a licence is required to enable Juno / Natco to make and supply in Australia a generic version of Revlimid® and describes why each licence is required.

1.5 For each patent associated with Pomalyst®, as identified in Attachment C of the application, identify the patents for which a licence is required for Natco and Juno to produce and supply a generic version of Pomalyst® and describe why each licence is required.

2.7 Please see attached Annexure C which identifies the patents for which a licence is required to enable Juno / Natco to make and supply in Australia a generic version of Pomalyst® and describes why each licence is required.

The agreement

1.6 Explain the rationale, including the benefits and disadvantages, for entering into the Agreement. Please provide Documents to support the response to this question.

2.8 The rationale for entering into the Agreement is to enable Juno / Natco to sell the Generic Products earlier than they could otherwise with the Celgene Patents at issue without the risk of liability for infringing the Celgene Patents. In summary, the Agreement:

(a) offered certainty of a launch earlier that Juno / Natco could achieve via litigation;

(b) eliminated future legal costs associated with continued litigation; and

(c) removed the risk of an adverse costs order.

[redacted]

2.10 At trial of the validity of the lenalidomide compound patent, the case rested heavily upon the interpretation of the key references by each sides' respective expert witnesses. [redacted]

[redacted]

2.14 Therefore, settlement offered certainty, eliminated future legal costs and removed the risk of exposure to an adverse costs order. In addition, it also brought forward market entry for Juno / Natco's generic lenalidomide and pomalidomide products. The Agreement allows Juno / Natco to sell the Generic Products earlier than they could otherwise with the Celgene Patents on foot.

1.7 Provide the following information in relation to the Agreement and provide any Documents which support the responses to the following requested information:

(a) any business case and cost-benefit analysis undertaken to assess whether to enter into the Agreement;

[redacted]

2.15 Juno / Natco repeat their answer to question 1.6 above. In summary, Juno / Natco considered it beneficial to enter into the Agreement for the following reasons:

(a) The Agreement provided certainty of launch, allowing Juno / Natco to sell the Generic Products earlier than they could otherwise with the Celgene Patents on foot, without the risk of liability for infringing the Celgene Patents.

(b) Continued litigation would be conducted at a significant cost to Juno / Natco.

(c) The Agreement also removed the risk of an adverse costs order.

(b) quantify the financial value of the Agreement for Natco and Juno;

2.16 Please see accompanying confidential spreadsheets (20211221_pomalidomide and 20211221_lenalidomide) which provide a basis for quantifying the financial value of the Agreement for Natco and Juno. Please note:

(a) The profit shares for Natco and Juno are outlined on the second sheet of each spreadsheet ('Output') in row 10 and 11 respectively.

(b) IP/legal costs are not specifically included in the model. This sum will be paid out of profits before Juno and Natco receive the profit shares. [redacted] Therefore, the financial value of the Agreement is the profit share Juno and Natco each receive once legal costs have been deducted.

(c) As any additional margin Natco may make on supply at the floor prices is considered immaterial compared to the amounts in their profits share, this has not been factored into the financial value of the agreement to Natco.

(c) quantify the financial value for Natco and Juno of supplying the Generic Products by the Authorised Launch Dates.

2.17 Juno / Natco repeat their answer to question 1.7(b) above.

2.18 **Question 2: Impact on Competition**

Potential entrants

2.1 What impact will the Agreement have or be likely to have on or in relation to parties who enter or seek to enter with their own generic version of the Celgene Products before the Celgene Patents expire?

2.19 The Agreement will not have any specific impact on third parties who enter or seek to enter the market with their own generic version of the Celgene Products before the Celgene Patents expire. The position of these parties remain the same, regardless of the Agreement. That is, those parties would be faced with the decision of whether to (a) seek to launch at risk, which is only possible if Celgene does not obtain an interlocutory injunction preventing supply of those generic versions, (b) seek a licence from Celgene, or (c) refraining from seeking to launch until expiry of all relevant patents.

2.2 What other parties is Natco or Juno aware of who may consider or may have considered an 'at risk' launch of the generic version of the Celgene Products? Please outline what monitoring Natco or Juno has undertaken with regard to third parties' 'at risk' launch of generic versions of the Celgene Products and, to the extent available, provide as much detail of the parties, proposed launch date(s), products, indications, PBS listings, patent licences, and pending or anticipated litigation in relation to each launch.

2.20 Juno / Natco are not aware of whether or not any other parties may consider an 'at risk' launch. At the time Juno and Natco signed the Agreement, the parties were only aware of the other publicly listed ARTG registrations and had no specific knowledge of other generic company having taken steps to launch or being involved in litigation with Celgene in relation to the Celgene Products.

Subsequent to signing the Agreement, Juno and Natco have become aware that Dr Reddy's Laboratories is involved in some form of litigation with Celgene involving the Celgene Products.

2.3 To the extent known, other than Natco and Juno, what parties may or are likely to enter the market in the next 10 years with a generic version of the Celgene Products or a substitute of the Celgene Products. For each of these parties, please state when entry is likely to occur if known.

2.21 Juno considers that there are potentially multiple sources of lenalidomide generic dossiers available and, to a lesser, extent pomalidomide that can be in-licensed from a number of contract manufacturing organisations (CMOs) globally.

2.22 Juno do not know how many Australian companies currently have plans to in-license such generic version of lenalidomide and pomalidomide products to seek approval on the ARTG nor which companies are in the process of obtaining ARTG registration as such discussions are confidential. The TGA does not publish any records of pending ARTG approvals. Juno are only aware of those product approved on the ARTG. Juno do monitor the ARTG on a daily basis for all generic approvals as a means for establishing which competitors have which products approved and adjusting commercial strategies.

2.4 Having regard to the Proposed Conduct, please explain the rationale for including each of clauses 3.2-3.7, 4.5 and 4.6 of the Agreement. Please respond from the perspective of Natco and Juno, as well as the perspective of Celgene if known.

[redacted]

2.5 Explain whether Natco and Juno would be able to assign or transfer any ARTG registration without the Agreement (per paragraph 3.7(5) of the application)?

[redacted]

2.28 In the absence of the Agreement, Juno would be able to transfer to any third party any ARTG registration under the processes provided for in the *Therapeutic Goods Act 1989* (the **Act**), the *Therapeutic Goods Regulation 1990* (the **Regulations**), and pursuant to Australian contract law generally.

2.29 Under the Regulations, a 'sponsor' of a therapeutic good (i.e. Juno in this case) , can transfer or assign, in whole or in part:

(a) the business to which the therapeutic goods relate; or

(b) that person's interest in those therapeutic goods; and

in such circumstances, can agree to transfer or assign the registration or listing of the therapeutic goods on the ARTG.[2]

2.30 The new sponsor resulting from such a transfer or assignment becomes responsible for the therapeutic goods the subject of that ARTG entry, and must notify the TGA of the transfer or assignment.

2.31 **Question 3: Counterfactual**

3.1 Outline Natco and Juno's strategy and proposed steps for the Generic Products if ACCC authorisation is not granted and the Agreement does not come into effect. Please provide Documents to support the response to this question.

2.32 If the ACCC authorisation is not granted, Juno / Natco would be faced with the following options:

(a) 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;

(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; or

(c) wait until the expiry of the Celgene Patents to launch the Generic Products.

[redacted]

[2] *Therapeutic Goods Regulation 1990*, reg 10AB(5).

[redacted]

[redacted]

3.2 Provide the following information in relation to an 'at risk' launch of the Generic Products for each indication, if ACCC authorisation is not granted and the Agreement does not come into effect, and provide Documents to support the responses:

(a) What are the risks associated with an 'at risk' launch for Natco and Juno for each of the Generic Products?

[redacted]

[4] [redacted]

[redacted]

(b) What is the anticipated or proposed 'at risk' launch date for each of the Generic Products?

[redacted]

(c) What is the likelihood of Natco and Juno executing an 'at risk' launch for each of the Generic Products?

[redacted] As discussed above, Juno believe that Celgene would likely seek an interlocutory injunction to prevent launch of the Generic Products (and, in effect, preclude Juno / Natco from applying for PBS listing of the Generic Products). Juno repeats the answer to question 3.2(a) above.

(d) How would Natco and Juno measure or assess the success or failure of an 'at risk' launch for each of the Generic Products, and the likelihood of a successful 'at risk' launch at this time?

2.48 In general, the potential success of an 'at risk' launch is contingent on the likelihood of (a) defeating an interlocutory injunction and (b) succeeding at trial in circumstances where a failure to succeed at trial exposes Juno / Natco to a potentially substantial damages exposure. Juno repeats the answer to question 3.2(a) above.

(e) What are the likely indications for the Generic Products under an 'at risk' launch (if they differ from the indication listed in response to 1.2 above).

2.49 Juno repeats the answer to question 3.2(a) above.

3.3 Explain the practical and commercial steps required for Natco and Juno to pursue an 'at risk' launch of the Generic Products for each indication and provide a timeline of any anticipated or potential launch (i) with the Agreement and (ii) without the Agreement. In relation to (ii) please identify which steps Natco and Juno have taken to date, and which steps they intend to take irrespective of the Agreement. Please provide Documents to support the response to this question.

2.50 Juno and Natco repeat the answer to question 3 above.

2.51 **Question 4: Public Benefit Claims**

[5] [redacted]

4.1 Please outline Natco and Juno's plans to launch the Generic Products in Australia if the Agreement is executed, including:

(a) Natco and Juno's capabilities to launch the Generic Products for each indication on the Authorised Launch Dates under the Agreement;

2.52 Juno / Natco have the following capabilities to launch the Generic Products on the Authorised Launch Date under the Agreement:

(a) First, Juno has an agreement with Natco to distribute and market the Generic Products in Australia and New Zealand. In turn, Natco has the manufacturing resources to make the products.

(b) Secondly, Juno has the necessary regulatory approval from the Therapeutic Goods Administration (**TGA**). One condition of regulatory approval for the Generic Products is the creation of a specifically designed risk management system (**RMS**) to screen all patients prior to administration of those products by a specialist. Juno will have completed creating this system for each respective product prior to the Authorised Launch Date.

(c) Thirdly, Juno has the capabilities to import and distribute the Generic Products in Australia. This commences with supply chain management (wholesaling and distribution), and Juno further has a sales team within Australia to engage in promotional and distribution activities with specialist/prescribers and prescribers respectively.

(b) the pre-launch activities involved in launching the Generic Products for each indication including any regulatory and commercial steps;

[redacted]

2.54 In practice, the pre-launch activities that Juno / Natco will undertake (or have already undertaken) to launch the Generic Products include:

(a) Obtaining ARTG listing: Juno has obtained ARTG listing for each Generic Product. In the course of obtaining such regulatory approval, Juno is required to submit a regulatory dossier that provides sufficient evidence to support that regulatory approval. Such a dossier has been obtained by Juno.

(b) Establishing a RMS: This is a requirement of selling the Generic Products imposed by the TGA. Juno will have completed building this system for each respective product prior to the Authorised Launch Date.

(c) Applying for PBS listing: Juno will then need to apply to the Commonwealth Department of Health to obtain PBS listing. In order to obtain a PBS listing, Juno / Natco is required have a proper basis to give the assurance of supply declaration required when applying to list a new brand of an existing pharmaceutical item on the PBS, and as a consequence of the PBS listing, Juno / Natco must, from the listing date, be in a position to supply requested amounts of the products to a wholesaler or pharmacist within a reasonable period of such a request ('guarantee of supply' provisions). In order to fulfil the above requirements, Juno will need to arrange for the Generic Products to be imported into Australia and available for supply prior to the PBS listing date.

(d) Ordering stock: The Generic Products are manufactured internationally. The finished dose product comes from [redacted], however a number of its components are sourced from other

countries. Juno would need to place purchase orders with Natco, and Natco would need to confirm such purchase orders and schedule manufacturing consistent with the requirements of those purchase orders. [redacted] In addition, the finished product needs to be transported (by sea or air freight) to Australia. Once the stock is cleared by customs, it is held in pre-wholesale, and then shipped to full line wholesalers, based on demand from prescribers. Due to the effects of the COVID-19 pandemic, the time lines for freight have significantly increased, with shipping estimated to take 10-12 weeks.

(e) Undertaking sales and marketing activities: Sales and marketing activities will commence at a time agreed between Juno / Natco and Celgene in accordance with the terms of Agreement.

(c) the volumes of Generic Products for each indication to be manufactured and distributed at launch.

2.55 Please note that Juno / Natco do not intend to launch all approved SKUs for all indications. As such, this response outlines the volumes for each of the Generic Products (pomalidomide and lenalidomide) that Juno do intend to launch.

2.56 Juno is currently assessing volumes of stock to order for the launch of pomalidomide pending approval of the Agreement with Celgene [redacted] Until the end of 2021 there was only 2 strengths of pomalidomide funded by the PBS and they were 3mg and 4mg. Additionally funding was only for treatment protocols in combination with dexamethasone requiring 21 capsules per pack for a course. [redacted]

2.57 For lenalidomide a similar process will be followed in placing opening orders. [redacted]

Please provide Documents to support the response to this question.

Please contact us if the ACCC requires further information.

Yours faithfully

MinterEllison

Contact: Alice Waterston T: [redacted]

Partner: Geoff Carter T: [redacted]

Annexure A – Index of relevant documents

	Document description	Document date	Relevant question(s)	Document ID
1.	20211221_pomalidomide (confidential forecasts for pomalidomide)	21 December 2021	1.3 and 1.7	JUN.5000.0001.0071
2.	20211221_lenalidomide (confidential forecasts for lenalidomide)	21 December 2021	1.3 and 1.7	JUN.5000.0001.0070
3.	Natco and Juno – Licence and Supply Agreement (lenalidomide)	8 May 2020	4.1	JUN.5000.0001.0023
4.	Natco and Juno – Licence and Supply Amendment (lenalidomide)	1 July 2021	4.1	JUN.5000.0001.0061
5.	Natco and Juno – Licence and Supply Agreement (pomalidomide)	7 May 2020	4.1	JUN.5000.0001.0001
6.	Natco and Juno – Licence and Supply Amendment (pomalidomide)	1 July 2021	4.1	JUN.5000.0001.0021
7.	Natco and Juno – Licence and Supply Prices (lenalidomide and pomalidomide)	7 October 2020	4.1	JUN.5000.0001.0063

Annexure B – Patents associated with Revlimid®

No. (as numbered in Attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
6	715779 (Substituted 2(2,6-dioxopiperidin-3-yl)phthalimides and -1-oxoisoindolines and method of reducing TNF-alpha levels) (**Compound Patent** as defined in Application for Authorisation)	Compound	lenalidomide	Revlimid®	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. Celgene alleged in its Cross Claim in the proceedings that Natco/Juno have threatened to infringe certain claims of the Compound Patent. Natco/Juno admitted in their Defence that their lenalidomide Generic Products contain lenalidomide as the active ingredient. Natco/Juno admitted that their lenalidomide Generic Products fall within the scope of certain claims of the Compound Patent to the extent that such claims are valid. Natco/Juno say that the claims in suit of the Compound Patent are invalid. Celgene's position is that a pharmaceutical	24 July 2022

No. (as numbered in Attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
					company seeking to supply lenalidomide in Australia prior to 24 July 2022 would infringe the Compound Patent absent a licence from Celgene. A finding of patent infringement would entitle Celgene to seek remedies against Natco/Juno including a permanent injunction, damages and costs. If Celgene's Cross Claim were successful, Natco/Juno would be prevented from marketing their lenalidomide Generic Products until expiry of the Compound Patent. Because the Authorised Launch Date for lenalidomide under the licence contained in the Agreement is after expiry of the Compound Patent, Natco/Juno will not require a licence of the Compound Patent at that date. As part of the Agreement, Celgene has withdrawn its infringement claim in respect of the Compound Patent and Natco/Juno have withdrawn their invalidity claim in respect of that patent (but only as part of the compromise reached between	

No. (as numbered in Attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
					the parties for the reasons specified in Recital I of the Agreement).	
1	2003234626 (Methods and compositions using immunomodulatory compounds for treatment and management of cancers and other diseases)	Method of treatment	lenalidomide/ multiple myeloma	Revlimid®	Under the Lenalidomide Method of Treatment Patent Claims (patents 1, 2, 3, 4, 7, 8 and 9 of Attachment C), Celgene has the exclusive right to supply lenalidomide for the treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma according to the methods claimed (and authorise others to do so). Celgene alleges in its Cross Claim in the proceedings that Natco/Juno have threatened to infringe at least one claim of each of the patents comprising the Lenalidomide Method of Treatment Patent Claims. Natco/Juno admitted in their Defence that their lenalidomide Generic Products contain lenalidomide as the active ingredient and will be supplied with product information for the treatment of multiple myeloma. Natco/Juno admitted that the supply of their lenalidomide Generic Products for multiple myeloma	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	Revlimid®		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	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	Revlimid®		16 May 2023
7	2003228508 (Methods of using and compositions comprising immunomodulatory compounds for the treatment and management of myelodysplastic syndromes)	Method of treatment	lenalidomide/ myelodysplastic syndromes	Revlimid®		13 April 2023

No. (as numbered in Attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
8	2012201727 (Methods of using and compositions comprising immunomodulatory compounds for the treatment and management of myelodysplastic syndromes)	Method of treatment	lenalidomide/ myelodysplastic syndromes	Revlimid®	would fall within the scope of at least one claim of the following Lenalidomide Method of Treatment Claims to the extent that they are valid: 626 Patent, 316 Patent, 881 Patent, 799 Patent. Natco/Juno's lenalidomide Generic Products are currently registered on the ARTG for the treatment of multiple myeloma, certain conditions due to myelodysplastic syndrome and mantle cell lymphoma. Juno has made an application to the TGA to remove the following indications from the label of their lenalidomide Generic Products: certain conditions due to myelodysplastic syndrome, mantle cell lymphoma. Juno/Natco deny infringement of the Lenalidomide Method of Treatment Patent Claims that relate to myelodysplastic syndromes or mantle cell lymphoma (508 Patent, 727 Patent, 027 Patent, 316 Patent). However Celgene has maintained its infringement claims in respect of these	13 April 2023
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	Revlimid®		2 August 2027

No. (as numbered in Attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
					patents notwithstanding Juno's application to the TGA to remove indications certain conditions due to myelodysplastic syndrome, mantle cell lymphoma Natco/Juno say that the claims in suit of <u>all</u> the Lenalidomide Method of Treatment Patent Claims are invalid. Celgene's position is that a pharmaceutical company seeking to supply lenalidomide in Australia for the treatments and by the methods claimed in the Lenalidomide Method of Treatment Patent Claims, during the term of those patents, would infringe those patents 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 permanent injunction, damages and costs. If Celgene's Cross Claim were successful, Natco/Juno would be prevented from marketing their lenalidomide Generic Products until expiry of the Lenalidomide Method of	

No. (as numbered in Attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
					Treatment Patent Claims. The Agreement, including the licence granted to Juno/Natco, will allow Juno/Natco to sell the lenalidomide Generic Products earlier than they otherwise could without the risk of liability from infringing the Lenalidomide Method of Treatment Patent Claims, and will avoid further unnecessary costs, business disruption and uncertainty of lengthy and complex patent litigation	

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Annexure C – Patents associated with Pomalyst®

No. (as numbered in attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
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	Pomalyst®	Under the Pomalidomide Method of Treatment Patent Claims, Celgene has the exclusive right to supply pomalidomide in the treatment multiple myeloma according to the methods claimed (and authorise others to do so). Celgene alleged in its Cross Claim in the proceedings that Natco/Juno have threatened to infringe certain claims of each of the patents comprising the Pomalidomide Method of Treatment Patent Claims. Natco/Juno admitted in their Defence that their pomalidomide Generic Products contain pomalidomide and are indicated for multiple myeloma. However Natco/Juno say that the claims in suit of the Pomalidomide Method of Treatment Patent Claims are invalid. Celgene's position is that a pharmaceutical company seeking to supply pomalidomide in Australia for the treatment of multiple myeloma by the methods claimed in the Pomalidomide Method of Treatment Patent Claims, during the term of those patents, would infringe	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	Pomalyst®		16 May 2023

No. (as numbered in attachment C)	Australian Patent Number (and Title)	Type of patent	Compound/ treatment	Patent licence required to enable Natco and Juno to produce and supply a generic version of:	Reason why patent licence is required	Expiry Date of Patent
					those patents 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 permanent injunction, damages and costs. If Celgene's Cross Claim were successful, Natco/Juno would be prevented from marketing its pomalidomide Generic Products until expiry of the Pomalidomide Method of Treatment Patent Claims. The Agreement, including the licence granted to Juno/Natco, will allow Juno/Natco to sell the pomalidomide Generic Products earlier than they otherwise could without the risk of liability from infringing the Pomalidomide Method of Treatment Patent Claims, and will avoid further unnecessary costs, business disruption and uncertainty of lengthy and complex patent litigation	