Draft Determination

Application for authorisation AA1000592
lodged by
Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd and Celgene Corporation and Celgene Pty Ltd,
in respect of
giving effect to a Settlement and Licence Agreement in relation to pharmaceutical products
Authorisation number: AA1000592

Date: 23 March 2022

Commissioners:	Keogh
	Rickard
	Brakey
	Carver
	Crone
	Ridgeway

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Executive Summary

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

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

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

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

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

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

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

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

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

[redacted]

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

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

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

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

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

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

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

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

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

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

1. The application for authorisation

1.1. On 3 December 2021, Juno Pharmaceuticals Pty Ltd (**Juno**), Natco Pharma Ltd (**Natco**), Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) (the **Applicants**) lodged an application for authorisation (AA1000592) with the Australian Competition and Consumer Commission (the **ACCC**). The Applicants are seeking authorisation to enter into, and give effect to, specific operative provisions of a settlement and licence agreement (the **Agreement**) that would resolve pending legal proceedings between the Applicants regarding patents held by Celgene in relation to the cancer treatment drugs Revlimid® and Pomalyst® (the **Proceedings**). The Agreement grants licences to Juno/Natco to bring to market generic versions of Revlimid® and Pomalyst® (**Generic Products**) from a specified launch date for each drug. The Applicants seek authorisation until 2 August 2027, when the last of Celgene's patents expires.

1.2. The Applicants seek authorisation on behalf of:

a) 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.

1.3. The application for authorisation AA1000592 was made under subsection 88(1) of the *Competition and Consumer Act 2010* (Cth) (the **Act**) for conduct that may make or give effect to a contract, arrangement or understanding that may contain a cartel provision within the meaning of sections 45AF, 45AJ, 45AG and 45AK of the Act.

1.4. The ACCC may grant authorisation, which provides businesses with protection from legal action under the competition provisions in Part IV of the Act for arrangements that may otherwise risk breaching those provisions in the Act, but are not harmful to competition and/or are likely to result in overall public benefits.

The Applicants

Juno and Natco

1.5. Juno is a Victorian-based supplier of marketing and distribution services to pharmaceutical manufacturers and specialises in post-patent pharmaceuticals (i.e. generic products). Juno distributes generic pharmaceutical products obtained from

third party manufacturers pursuant to supply arrangements. It does not manufacture pharmaceutical products itself.

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

Celgene

1.7. Celgene is a Swiss-based global biopharmaceutical company that develops and manufactures pharmaceutical products, with a particular focus on cancer and immunology-related diseases. Celgene Pty Ltd is a wholly owned subsidiary of Celgene Corporation which is a wholly owned subsidiary of Bristol-Myers Squibb.

1.8. Celgene is the manufacturer of Revlimid® (active ingredient lenalidomide) and Pomalyst® (active ingredient pomalidomide) which are immunomodulatory drugs indicated for the treatment of some blood cancers. Celgene owns several patents in relation to Revlimid® and Pomalyst® (the **Celgene Patents**).[1]

The Proposed Conduct

1.9. The Applicants seek authorisation to enter into, and give effect to, specific operative provisions of the Agreement that would enable the Applicants to engage in the following conduct:

a) Celgene will grant a non-exclusive, non-sublicensable, non-transferable, [redacted] licence to Juno/Natco under the Celgene Patents to manufacture, import and distribute the Generic Products from the relevant specified launch dates for each drug;

b) Natco will be permitted to submit applications for the listing of the Generic Products on the Pharmaceutical Benefits Scheme (**PBS**), provided that such listings do not take effect until the relevant specified launch dates for each drug;

c) Celgene will not bring or participate in legal proceedings in Australia against Juno/Natco (or their suppliers, distributors, importers, wholesalers, or customers) in respect of the Generic Products after the relevant specified launch dates for each drug;

d) Juno/Natco will not manufacture, import or distribute the Generic Products in Australia or export the Generic Products prior to the relevant specified launch dates for each drug;

e) Juno/Natco will not bring or participate in legal proceedings in Australia against Celgene alleging invalidity of the Celgene Patents;

f) Juno will not assign or transfer any registration on the Australian Register of Therapeutic Goods 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;

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[1] Australian Patent Nos. 715779, 2003228508, 2012201727, 2003234626, 2006202316, 2012254881, 2013263799, 2007282027, 2010201484.

g) the Applicants will each irrevocably and unconditionally release each other from all legal proceedings in Australia relating to the Celgene Patents; and

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

(the **Proposed Conduct**).

1.10. The Proposed Conduct will enable the supply of the Generic Products prior to the expiry of the Celgene Patents. The Applicants state the specified launch dates for the Generic Products is at least 2 months earlier than under any scenario involving Juno/Natco launching the products.[2] Juno/Natco will be permitted to supply pomalidomide from [redacted] and lenalidomide from [redacted]

Rationale for the Proposed Conduct

1.11. The Applicants submit that the rationale for the Proposed Conduct is to:

a) enable Juno/Natco to sell the Generic Products, without incurring the legal risk of liability and damages from infringing the Celgene Patents, earlier than they could otherwise while the Celgene Patents are on foot;

b) avoid further unnecessary costs, business disruption and uncertainty associated with continuing patent litigation; and

c) allow the Applicants to invest the costs and time that would be directed towards the Proceedings to other business-as-usual functions.

1.12. The Applicants believe that the Agreement is a fair compromise of their respective litigation positions.[3] [redacted]

1.13. Celgene submits that the Agreement will provide them with greater certainty over the launch date of the Generic Products than if Juno/Natco were to launch 'at risk' or if Juno/Natco were to obtain a favourable judgment in the Federal Court. Accordingly, the certainty afforded by the Agreement allows Celgene to better plan and prepare for generic entry, including having regard to the 25% first brand statutory price reduction under the PBS.[5]

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2 Applicants, Applicant's response to ACCC request for information, 13 December 2021, paragraph 2.1.

3 Applicants, Application Received, 3 December 2021, paragraph 3.14.

4 [redacted]

5 Applicants, Celgene's response to ACCC request for information, 11 February 2022, paragraph 1.3.

2. Background

Celgene patents and products

Celgene Patents

2.1. Celgene supplies and holds patents in relation to two cancer drugs in Australia; Revlimid® and Pomalyst®. Revlimid® is used in the treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma. Pomalyst® is used in the treatment of multiple myeloma.

2.2. Multiple myeloma is a type of blood cancer that develops from plasma cells in the bone marrow, affecting multiple areas of the body. Cancer Australia and the Australian Institute of Health and Welfare estimate that 2,423 new cases of multiple myeloma were diagnosed in Australia in 2021, representing about 1.6% of all new cancer cases diagnosed for that year.[6] In the 2020-21 financial year, there were 38,779 prescriptions of Revlimid® dispensed in Australia for the treatment of multiple myeloma and 4,267 prescriptions of Pomalyst® dispensed in Australia for the same indication.[7]

2.3. Lenalidomide and pomalidomide are listed on the PBS Highly Specialised Drugs Program,[8] which provides access to medicines for the treatment of chronic conditions which, because of their clinical use, have restrictions on where they can be prescribed and supplied.[9]

2.4. With regard to Revlimid®, Celgene was granted Australian Patent No. 715779 with an expiry date of 23 July 2022 (**Compound Patent**). In addition, Celgene holds the following seven method of treatment patents[10] in relation to lenalidomide:

a) 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;

b) 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;

c) 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; and

d) 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

(collectively, the **Lenalidomide Method of Treatment Patents**).

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6 Cancer Australia, Multiple myeloma in Australia statistics, 3 January 2022, accessed 23 February 2022; Australian Institute of Health and Welfare, Cancer data in Australia, 8 June 2021, accessed 23 February 2022.

7 Australian Government Department of Health, PBS data from the Department of Health, 11 February 2022.

8 Highly Specialised Drugs are administered under section 100 of the National Health Act 1953.

9 Pharmaceutical Benefits Scheme, Section 100 – Highly Specialised Drugs Program, 1 September 2019, Accessed 25 February 2022.

10 Method of treatment patents are patents that protect 'methods or processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the human body is involved' per Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) 50 FCR 1.

2.5. Celgene submits that if a pharmaceutical company sought to supply lenalidomide in Australia prior to 24 July 2022, this would infringe the Compound Patent. Additionally, a pharmaceutical company seeking to supply lenalidomide for the treatments below would infringe one or more of the Lenalidomide Method of Treatment Patents:

a) for myelodysplastic syndromes prior to 14 April 2023;

b) for multiple myeloma prior to 17 May 2023; and

c) for mantle cell lymphoma prior to 3 August 2027.[11]

2.6. With regard to Pomalyst®, Celgene was granted Australian Patent Nos. 2012254881 and 2010201484 claiming inter alia the administration of pomalidomide for the treatment of multiple myeloma (**Pomalidomide Method of Treatment Patents**). These patents both expire on 16 May 2023.

2.7. Celgene submits that if a pharmaceutical company sought to supply pomalidomide in Australia for the treatment of multiple myeloma prior to 17 May 2023 this would infringe the Pomalidomide Method of Treatment Patents.[12]

2.8. Together, the Compound Patent, Lenalidomide Method of Treatment Patents and Pomalidomide Method of Treatment Patents are referred to as the '**Celgene Patents**'.

2.9. Between 18 November 2020 and 23 December 2020, JH Corporate Services Pty Ltd, acting as agent for Juno/Natco, filed requests with IP Australia for re-examination of certain Celgene Patents,[13] meaning IP Australia will reconsider the validity of the patent and as a result some of the Celgene Patents may have their scope of protection altered or revoked, either partially or fully.[14] IP Australia advises that re-examination of the Celgene Patents was paused while the Proceedings between the Applicants were pending, and that re-examination will recommence once the Proceedings cease.[15] In the event that the re-examination request is withdrawn by the requestor, the Commissioner of Patents has the authority to undertake re-examination. Celgene and Juno/Natco submit that this does not imply some likelihood that the scope of protection of the Celgene Patents would be varied notwithstanding withdrawal of the re-examination requests.[16] Celgene notes the right to appeal re-examination decisions, and that any re-examination processes would not conclude prior to the specified launch dates or the expiry of the relevant Celgene Patents.[17]

Celgene litigation and the licensing agreement

2.10. On 9 November 2020, Juno/Natco commenced proceedings against Celgene in the Federal Court of Australia, wherein Juno/Natco sought for the Compound Patent to be invalidated. On 29 January 2021, Celgene filed a cross claim against Juno/Natco for threatened infringement of the Celgene Patents.

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11 Applicants, Application Received, 3 December 2021, paragraphs 2.6, 2.8.

12 Applicants, Application Received, 3 December 2021, paragraph 2.13.

13 Australian Patent Nos 2003234626, 2013263799, 2012254881, 2010201484 and 2006202316 – Applicants, Celgene's response to ACCC request for information, 11 February 2022, paragraph 1.3.

14 IP Australia, Submission to the ACCC, 14 January 2022.

15 IP Australia, Submission to the ACCC 14 January 2022.

16 Applicants, Juno/Natco's response to IP submissions, 4 March 2022, paragraph 2.5; Applicants, Celgene's response to interested party submissions, 8 March 2022, paragraph 7.3.

17 Applicants, Celgene's response to interested party submissions, 8 March 2022, paragraph 7.5.

2.11. Both the claim (insofar as it relates to the Compound Patent) and cross claim (insofar as it relates to the Compound Patent and alleged breaches of the Australian Consumer Law) were discontinued by the parties by consent on 27 October 2021, [redacted] However, the claims insofar as they relate to the Lenalidomide Method of Treatment Patents and Pomalidomide Method of Treatment Patents are stayed, not discontinued.[18]

2.12. Separately, on 17 November 2021, Celgene instituted proceedings against another generic manufacturer, Dr Reddy's Laboratories Australia Pty Ltd, alleging infringement of the Compound Patent and Lenalidomide Method of Treatment Patents. On 24 February 2022, Celgene discontinued these proceedings.[19]

'At risk' generic launch

2.13. An 'at risk' generic launch occurs when a manufacturer launches a generic pharmaceutical product prior to the expiry of the relevant patents for that product, without the approval of the patent holder.

2.14. Juno/Natco submit that pharmaceutical companies in the position of Juno/Natco in assessing the potential success of an 'at risk' launch would consider the likelihood of defeating an interlocutory injunction or succeeding at trial. Juno/Natco also submit that a generic manufacturer may consider a number of factors when deciding whether to launch 'at risk' including (but not limited to) the likelihood of infringement, the likelihood of a patentee commencing infringement proceedings, the strength of the relevant patents, and the magnitude of potential damages if the generic company is being found to infringe one or more relevant patents.[20]

2.15. It is also possible for manufacturers to launch generic pharmaceutical products for fewer indications than are PBS-listed for the compound to mitigate potential patent infringement. For instance, excluding certain indications that remain under a method of treatment patent while targeting indications that do not. Where this occurs, there is less likely to be patent infringement for a method of treatment patent that covers a small proportion of prescriptions and where there could be significant non-infringing use.[21] For example, with lenalidomide, the last patent to expire on 1 August 2027 (Australian Patent No. 2007282027) covers a method of treatment relating to mantle cell lymphoma, a rare subtype of Non Hodgkin Lymphoma for which Celgene provides Revlimid® to [redacted] patients per year. Therefore, it is possible for manufacturers to supply lenalidomide for the other two indications (multiple myeloma and myelodysplastic syndromes) when the relevant patents expire, possibly without infringing the last patent.

Licencing agreements

2.16. Licensing agreements involving originator and generic pharmaceutical manufacturers can arise as part of a settlement of patent litigation.

2.17. If a generic manufacturer enters the market 'at risk', that is, without the licence of the patent holder or without the patent(s) being held to be invalid by a court, the generic

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18 Applicants, Application Received, 3 December 2021, paragraph 2.20.

19 Lawyerly, Celgene drops patent suit against Dr Reddy's over Revlimid® generic, 25 February 2022, accessed 2 February 2022.

20 Applicants, Applicant's response to ACCC request for information, 18 January 2022, paragraphs 2.2, 2.48.

21 F. Hoffman-La Roche AG v Sandoz Pty Ltd [2018] FCA 874.

manufacturer risks proceedings being brought against it by the patent holder for a patent infringement. In bringing patent infringement proceedings, the patent holder can seek an interlocutory injunction to prevent the generic manufacturer from supplying or taking steps to supply (such as importing product or approaching customers) its medicine until after the final hearing. However, there are risks to both the generic manufacturer and the patent holder from patent litigation, and patent litigation often requires significant time and legal costs before it is resolved.

2.18. If a generic manufacturer is unsuccessful in litigation, that is, the relevant patents are upheld, the generic manufacturer may not be able to enter the market and may be liable for damages if it has launched 'at risk'. On the other hand, if the patent is found invalid or not infringed, then new entry by a number of generic manufacturers may take place. Further, if the patent holder had obtained an interlocutory injunction preventing the generic manufacturer from entering while litigation was on foot, the patent holder may be liable to pay significant damages to third parties, including the Australian Government. The Australian Government may seek to claim an entitlement to compensation pursuant to the "usual undertaking as to damages", to recover savings in PBS expenditure forgone as a result of the delayed listing of generic medicines on the PBS following the unsuccessful patent proceedings brought by the patent holder.[22]

2.19. Given the risks and time involved in patent litigation, parties may settle proceedings by entering into a licence agreement that allows the generic manufacturer to commence supply, subject to various conditions. The effect of such a settlement may accelerate market entry of the generic medicine (compared to a status quo in which the patent remains in place until its expiry, assuming it is not successfully challenged in court) and avoid long and uncertain litigation. On the other hand, if a court would have decided that the patent is invalid, an agreed launch date in a licence agreement may cause a delay or restriction in the planned market launch of the generic medicine (compared to the date when one or more generic products would have launched, after the patent was invalided). The ACCC notes that the expiry date of patents the subject of any patent litigation (or of any licence agreement) is relevant to the extent to which a licence agreement may accelerate market entry.

2.20. In a number of international jurisdictions, such settlements have attracted scrutiny from competition regulators, particularly in cases where the licensing agreement can be characterised as a pay-for-delay agreement.[23] Pay-for-delay generally refers to a practice whereby patent holding companies (i.e. originator companies) pay or incentivise generic companies to keep their products off the market beyond the scope of a patent.

Industry overview – Australian pharmaceutical industry

Australian Register of Therapeutic Goods

2.21. An essential requirement before a pharmaceutical product can be launched in Australia is to obtain regulatory approval from the Therapeutic Goods Administration

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[22] Before the Federal Court will grant an interlocutory injunction, the party seeking the order will almost always be required to give to the Court the "usual undertaking as to damages", that is, to compensate any person (including a third party) affected by the operation of the order. – Federal Court of Australia, Usual Undertaking as to Damages Practice Note (GPN-UNDR), 25 October 2016, accessed 9 March 2022.

[23] See e.g. In the United States: Federal Trade Commission v. Actavis, Inc. 17 June 2013 570 U.S. 136, Impax Laboratories Inc v. Federal Trade Commission, 13 April 2021 5th U.S. Circuit Court of Appeals, No. 19-60394. In Europe: Lundbeck v Commission 25 March 2021 C-591/16, Generics (UK) Ltd and Others v Competition and Markets Authority Case 22 January 2020 C-307/18.

(**TGA**), the Commonwealth Agency responsible for administering the *Therapeutic Goods Act 1989* (Cth) (**Therapeutic Goods Act**).

2.22. The Therapeutic Goods Act requires that a pharmaceutical product classified as a 'therapeutic good' must be registered on the Australian Register of Therapeutic Goods before it can legally be imported to, exported from, manufactured in, or supplied in Australia (unless specifically exempt from that regulatory requirement). The TGA also requires that sponsors of products containing lenalidomide and pomalidomide provide a risk management plan as a condition for registration on the Australian Register of Therapeutic Goods. The risk management plan will provide a description of a specifically designed risk management system to screen all patients prior to administration of lenalidomide or pomalidomide by a specialist.[24]

2.23. There are currently 6 sponsors who have registered products containing lenalidomide on the Australian Register of Therapeutic Goods and 2 sponsors for pomalidomide (as shown in Table 1 below). Obtaining registration on the Australian Register of Therapeutic Goods is a necessary step in the pre-launch process for a manufacturer to supply a pharmaceutical product in Australia. However, as discussed at 2.29 and 4.33, registration on the Australian Register of Therapeutic Goods alone is not necessarily indicative of a generic manufacturer's intention to launch their product in Australia.

Table 1: Australian Register of Therapeutic Goods registrations for lenalidomide and pomalidomide

	Sponsor	**Registration date**
lenalidomide	Sandoz Pty Ltd	30 November 2021
	Juno	23 July 2021
	Dr Reddy's Laboratories (Australia Pty Ltd)	10 July 2021
	Teva Pharma Australia Pty Ltd	16 June 2021
	Cipla Australia Pty Ltd	8 October 2019
	Celgene	20 December 2007
pomalidomide	Juno	18 May 2021
	Celgene	1 July 2014

Prescription pharmaceuticals, originators, and bioequivalent generics

2.24. Pharmaceutical products indicated for the treatment of cancers are typically supplied on prescription.

2.25. Prescription products are generally characterised as either:

a) an originator product, which is used to refer to the first commercially available brand of a particular product. These pharmaceutical products are typically patent-protected and identified by their brand name. Celgene's Revlimid® and Pomalyst® are originator products; or

[24] Applicants, Applicant's response to ACCC request for information,18 January 2022, paragraph 2.52; Therapeutic Goods Administration, Risk management plans for medicines and biologicals, 29 March 2019, accessed 25 February 2022.

b) a generic product, which 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.

Supply of prescription pharmaceuticals in Australia

2.26. The prescription pharmaceutical supply chain in Australia operates across 3 levels:

a) Manufacturing: manufacturers produce the pharmaceutical products for supply in Australia. Manufacturers use wholesalers to distribute the pharmaceutical products to pharmacies and hospitals (there is limited direct distribution from manufacturers, but only to hospitals).

b) Wholesaling: pharmaceutical wholesalers are responsible for the distribution of products that have been manufactured in, or imported into, Australia to pharmacies and hospitals.

c) Retailing: sales of pharmaceutical products occur between the supplier and the end customer (i.e. pharmacies and hospitals) and may be made by way of direct negotiation with individual customers, direct negotiation with state/territory procurement agencies or via a competitive tender process administered by state/territory procurement agencies.

Pharmaceutical Benefits Scheme

2.27. The PBS is a scheme established by the Australian Government for the subsidisation of certain pharmaceutical products.

2.28. A product must be registered on the Australian Register of Therapeutic Goods before it can be listed on the PBS.

2.29. While products cannot be supplied in Australia without being approved by the TGA, products can be supplied in Australia without being approved for reimbursement through the PBS. However, the unsubsidised cost of many products is such that many patients would not be able to afford them unless they are subsidised under the PBS.

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

Pricing under the PBS

2.31. The ‘dispensed price’ is the price paid by the Australian Government directly to any person who dispenses the pharmaceutical item (i.e. pharmacies or hospitals).

2.32. The ‘dispensed price’ comprises:

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

b) a set mark up for the pharmacist; plus

c) a dispensing fee per script.[25]

[25] The wholesaler and pharmacist mark ups and the dispensing fee are set by the Australian Government by agreement with the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia.

2.33. A PBS-listed item is allocated to one of two formularies (lists), identified as F1 and F2.

2.34. The listing of the first generic or biosimilar brand of a PBS-listed item triggers the movement of the originator product from F1 to F2.

2.35. Pharmaceutical items in F2 are subject to an automatic statutory price reduction of up to 25%[26] and price disclosure-related price reductions.

Revlimid® and Pomalyst® PBS Data

2.36. Revlimid® and Pomalyst® are currently the only brands containing lenalidomide and pomalidomide listed on the PBS. Lenalidomide is listed for the treatment of multiple myeloma and myelodysplastic syndromes. Pomalidomide is listed for the treatment of multiple myeloma.

2.37. Lenalidomide and pomalidomide are both very high-cost drugs for the PBS. Based on PBS data for 2020-21 (see Tables 1 and 2), the average price per prescription was $5,479 for Lenalidomide and $10,286 for Pomalidomide. In total, Lenalidomide cost the PBS $216 million in 2020-21 and was the 8th most expensive drug (and 3rd most expensive cancer drug) of the 906 drugs listed on the PBS. Pomalidomide cost the PBS $43.8 million in 2020-21 and was the 24th most expensive cancer drug listed on the PBS.

Table 1: Total PBS cost of Lenalidomide (2018-19 to 2020-21)[27]

Financial year	PBS Subsidised Prescriptions	Government Cost ($'000)	Patient Contribution ($'000)	Average Price ($)
2018-19	23,780	144,816	369.7	6,105
2019-20	28,133	165,780	457.1	5,909
2020-21	39,622	216,334	747.0	5,479

Table 1: Total PBS cost of Pomalidomide (2018-19 to 2020-21)[28]

Financial year	PBS Subsidised Prescriptions	Government Cost ($'000)	Patient Contribution ($'000)	Average Price ($)
2018-19	2,363	24,801	34.5	10,510
2019-20	3,541	37,062	52.3	10,481
2020-21	4,267	43,824	64.7	10,286

2.38. In addition to being high-cost drugs, the number of lenalidomide and pomalidomide PBS subsidised prescriptions has increased substantially for the 5 years since 2015-16 (Figure 1). The annual number of lenalidomide prescriptions increased by 208%

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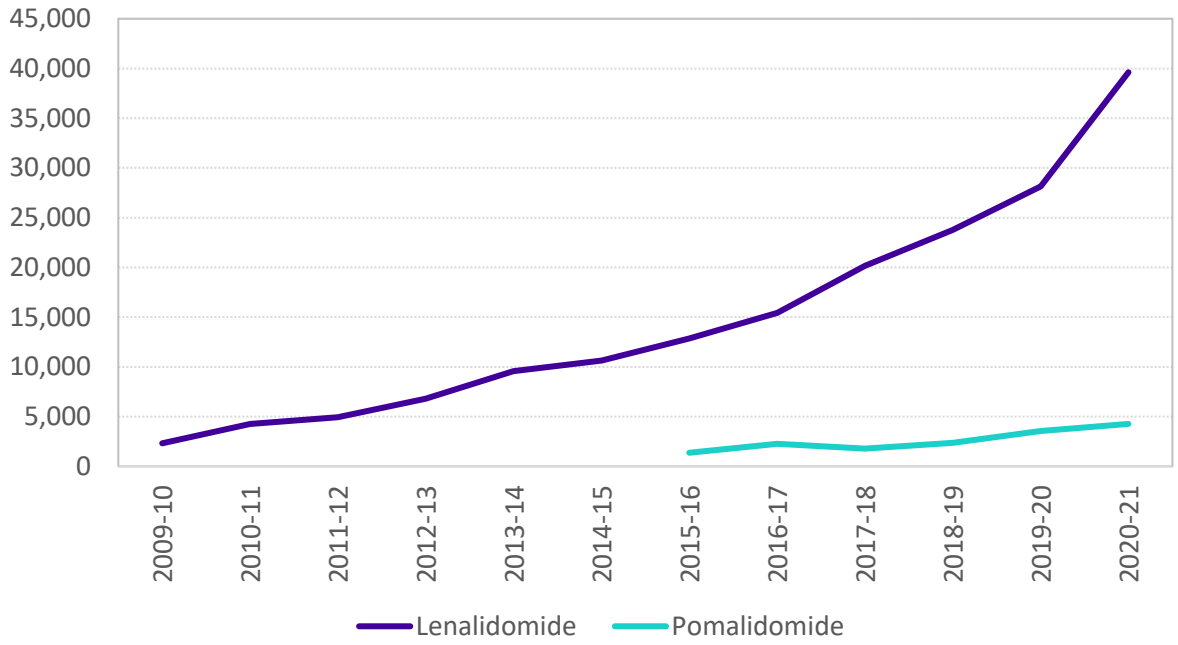
[26] The Minister has the discretion to reduce or not apply a mandatory price reduction in some circumstances such as when the originator's price has previously already been reduced. The Minister may also exempt items from statutory price reductions or price disclosure price reductions.

[27] Pharmaceutical Benefits Scheme, PBS Expenditure and Prescriptions Report 1 July 2020 to 30 June 2021 and PBS Expenditure and Prescriptions Report 1 July 2019 to 30 June 2020.

[28] Pharmaceutical Benefits Scheme, PBS Expenditure and Prescriptions Report 1 July 2020 to 30 June 2021 and PBS Expenditure and Prescriptions Report 1 July 2019 to 30 June 2020.

between 2015-16 and 2020-21 and 140% for pomalidomide prescriptions between 2017-18 and 2020-21. This increase in prescriptions is reflected in increasing PBS costs. Lenalidomide had the 5th biggest increase in PBS expenditure between 2019-20 and 2020-21 of all PBS listed drugs.[29]

Figure 1: Total PBS subsidised prescriptions for Lenalidomide and Pomalidomide[30]



3. Consultation

3.1. A public consultation process informs the ACCC's assessment of the likely public benefits and detriments from the Proposed Conduct.

3.2. The ACCC invited submissions from a range of potentially interested parties including pharmaceutical manufacturers, state and territory government health departments, relevant regulatory bodies, medical organisations, hospitals and pharmacies.[31]

3.3. The ACCC received submissions from Myeloma Australia, IP Australia and the Australian Government Department of Health. The ACCC spoke with a further 5 interested parties to assist its understanding of topics such as hospital and pharmacy procurement processes, prescribing practices and treatments for multiple myeloma and the impact of generic entry on the supply and acquisition of pharmaceutical products. The ACCC received no submissions from pharmaceutical manufacturers. Issues raised in submissions and calls with interested parties are discussed where relevant throughout this draft determination.

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29 Pharmaceutical Benefits Scheme, PBS Expenditure and Prescriptions Report 1 July 2020 to 30 June 2021, Table 9(a).

30 Australian Government Department of Health, PBS data from the Department of Health, 11 February 2022.

31 A list of the parties consulted and the public submissions received is available from the ACCC's Authorisations public register.

3.4. Public submissions by interested parties (including summaries of calls) are on the ACCC's Authorisations public register.

3.5. The Applicants provided responses to submissions from interested parties, in which they point out that in general, interested parties do not oppose the application for authorisation and acknowledge the public benefits that are likely to arise . More specific comments raised by the Applicants in response to interested party submissions are discussed where relevant throughout this draft determination.

3.6. Shortly after the application for authorisation was lodged, the ACCC requested further information from each of Celgene and Juno/Natco seeking further detail on such topics as their commercial strategies, the rationale for and the future without the Proposed Conduct, relevant agreements entered into in other jurisdictions, and the claimed savings to the PBS as a result of the Proposed Conduct. The ACCC requested internal documents to support the Applicants' responses.

3.7. The Applicants provided the ACCC with few documents to support the submissions in their application, and in response to the ACCC's information request. In addition, the Applicants requested exclusion for large parts of their responses on the basis that they contained commercially sensitive information.

3.8. In light of the Applicants' confidentiality claims, this draft determination contains substantial amounts of redacted text, including parts of the analysis and conclusions. ACCC determinations typically do not contain redacted information, and where they do this would usually be very limited.

3.9. The authorisation process is a public, transparent process. Under the Act, the ACCC is required to keep a public register for each application for authorisation containing the application, any documents furnished to the ACCC in relation to the application (including by the applicant and interested persons) and particulars of oral submissions. This is intended to allow the ACCC to publicly test the information received in relation to an application such that it can be satisfied that the public benefits of conduct that would otherwise breach the competition provisions in part IV of the Act would outweigh any public detriments.

3.10. The Act permits the applicant or interested persons to request that the ACCC exclude information from the public register by reason of the confidential nature of the information. The ACCC appreciates the commercially sensitive nature of some information held by pharmaceutical companies (which may include their commercial strategies regarding market entry and litigation), and that the authorisation process provides for parties to seek exclusion of such information. However, the ACCC's ability to test information in the public domain is important to the ACCC's assessment of applications for authorisation and whether the net public benefit test is satisfied.

3.11. The public versions of the Applicants' responses to the ACCC's requests for information and the Applicants' responses to submissions from interested parties are on the ACCC's Authorisations public register.

4. ACCC assessment

4.1. The ACCC's assessment of the Proposed Conduct is carried out in accordance with the relevant authorisation test contained in the Act.

4.2. The Applicants have sought authorisation for Proposed Conduct that would or might constitute a cartel provision within the meaning of sections 45AF, 45AJ, 45AG and 45AK of the Act. Consistent with subsections 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied, in all the circumstances, that the conduct would result or be likely to result in a benefit to the public, and the benefit would outweigh the detriment to the public that would be likely to result (authorisation test).

Relevant areas of Competition

4.3. To assess the likely effect of the Proposed Conduct, the ACCC identifies the relevant areas of competition likely to be impacted.

4.4. The Applicants submit that the Proposed Conduct should be assessed in the context of separate national markets for the supply of pharmaceutical products for the treatment of multiple myeloma and for the supply of pharmaceutical products for the treatment of mantle cell lymphoma. This is because Celgene and Juno overlap in the supply of products for these indications (Juno does not currently supply products indicated for the treatment of myelodysplastic syndromes). The Applicants refer to previous literature that suggests that the availability of multiple pharmaceutical products for an indication means that a relevant market is often defined with reference to a medicine's therapeutic use or indication.[32]

4.5. The Applicants submit that the geographic scope of the relevant product markets should be national, by reference to the products they supply in Australia for the treatment of multiple myeloma and mantle cell lymphoma.

4.6. The ACCC considers that the relevant areas of competition are likely to be markets for:

a) the supply and acquisition of lenalidomide; and

b) the supply and acquisition of pomalidomide.

4.7. The ACCC has considered whether consumers view different drugs as close substitutes, on account of factors such as the drug's characteristics, prices and intended use. While the ACCC is aware of other medicines that are indicated for the treatment of multiple myeloma, mantle cell lymphoma and myelodysplastic syndromes, information from interested parties suggests that when prescribing these drugs, clinicians take into account each patient's specific circumstances, for example the stages of relapse, the patient's prior treatment and comorbidities.[33]

4.8. The ACCC notes that patients with multiple myeloma, mantle cell lymphoma or myelodysplastic syndromes generally do not decide what drugs they are prescribed and often will not be able to choose between the generic or originator brand. In this context, it is prescribers and those responsible for drug procurement in the public and private hospital systems that make decisions around which drugs are procured and ultimately given to patients. As discussed in the Public benefits section starting at paragraph 4.41, the ACCC considers the Proposed Conduct will have limited impact on a patient's access to lenalidomide or pomalidomide, particularly in terms of the cost they incur.

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[32] Applicants, Application Received, 3 December 2021, paragraph 4.2.

[33] ACCC, File note of meeting with Dr Nick Murphy, 11 February 2022; Medical Scientific Advisory Group to Myeloma Australia, Clinical Practice Guideline – Multiple Myeloma, October 2019, accessed 10 March 2022.

4.9. The ACCC notes that the relevant markets in relation to the Proposed Conduct will include, when available to prescribers, both originator and generic pharmaceutical products. The ACCC understands that pharmacies typically stock the originator and, once available, generic versions of each prescription pharmaceutical product (with the same active ingredient), or may decide to stock one or the other. Information from interested parties indicated that generally, prescribers and pharmacists (particularly in the public hospital setting) have little reluctance to switch patients from originator to generic drugs unless there are clinical or administrative concerns associated with switching.[34]

4.10. For the purposes of assessing the Proposed Conduct, the ACCC considers it appropriate to define separate markets for each active ingredient, rather than a market for a broader group of different active ingredients that may be used to treat multiple myeloma, myelodysplastic syndromes or mantle cell lymphoma.

4.11. The information gathered from market inquiries focused primarily on drugs indicated for the treatment of multiple myeloma, as this is the more prevalent disease relative to myelodysplastic syndromes and mantle cell lymphoma and where interested parties tended to have the most expertise. Notwithstanding the complexities of these diseases and the patients requiring such treatments, the ACCC considers that the information gathered in relation to multiple myeloma for the purpose of determining the relevant areas of competition is likely to also be applicable in respect of myelodysplastic syndromes and mantle cell lymphoma.

4.12. Market inquiries indicated that treatments containing different active ingredients (such as bortezomib or carfilzomib) are not close substitutes for lenalidomide or pomalidomide, nor are lenalidomide or pomalidomide substitutable for each other, for the following reasons:[35]

a) Lenalidomide is a commonly used first line treatment for multiple myeloma. In some cases, lenalidomide would not be prescribed in the first instance for specific reasons such as in patients with impaired renal function. As such, lenalidomide (as with other treatments) is prescribed to patients after careful assessment and based on specific patient criteria.

b) Pomalidomide is generally used as a second, third or later line treatment and is typically prescribed after lenalidomide has stopped being effective in multiple myeloma patients.

c) While lenalidomide may be used in combination with other active ingredients in specific circumstances, it would not be used in substitution of them. Similarly, while pomalidomide may be used in combination with other active ingredients, it is not used in substitution of them.

4.13. In addition, the ACCC's review of the proposed merger of Mylan N.V. and Pfizer's Upjohn Inc. division made the following relevant observations:[36]

a) Pharmacies and hospitals purchase pharmaceutical products on the basis of the active ingredient rather than a product's indication.

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[34] ACCC, File note of meeting with the Society of Hospital Pharmacists of Australia, 16 February 2022; ACCC, File note of meeting with Dr Nick Murphy, 11 February 2022; ACCC, File note of meeting with the Tasmanian Department of Health, 21 February 2022.

[35] ACCC, File note of meeting with Dr Nick Murphy, 11 February 2022.

[36] ACCC, Mylan-Upjohn – Public Competition Assessment, 4 December 2020.

b) Pharmacies cannot substitute prescriptions from one active ingredient to another active ingredient with the same indication without the patient obtaining a new prescription from their prescribing doctor.

4.14. The ACCC considers that in the pharmaceutical context, the supply of products is typically subject to national regulatory regimes, and pricing policies and marketing strategies employed by pharmaceutical companies are likely national in scope. Further, the Applicants submit that the Proposed Conduct should be assessed in the context of national markets. However, the ACCC understands that pharmaceutical contracts tend to be entered into on a state-wide basis, rather than nationally.

4.15. The ACCC considers the relevant areas of competition to be the supply and acquisition of lenalidomide and pomalidomide to, and by, hospitals and relevant buying groups. The ACCC does not consider that a definitive view needs to be reached regarding the geographic scope of the relevant areas of competition in order to assess the application for authorisation.

Future with and without the Proposed Conduct

4.16. In applying the authorisation test, the ACCC compares the likely future with the Proposed Conduct that is the subject of the authorisation to the likely future in which the Proposed Conduct does not occur (that is, the counterfactual).

4.17. The Applicants submit that the Proposed Conduct has clear and substantial benefits compared to any other counterfactual because in the future without the Proposed Conduct, it is unlikely that Juno/Natco would be able to launch the Generic Products before expiry of the Celgene Patents. The Applicants submit that the specified launch dates for the Generic Products are at least 2 months earlier than under any counterfactual involving Juno/Natco launching the Generic Products.[37]

4.18. In the absence of the Proposed Conduct, Celgene has indicated that it would expect to succeed in the Proceedings and therefore obtain a permanent injunction against Juno/Natco. As such, absent the Proposed Conduct, the Applicants submit that the only options available to Juno/Natco to supply the Generic Products prior to the expiry of the Celgene Patents would be to launch 'at risk' of litigation (and face the possibility of an interlocutory injunction preventing supply) or revert to pursuing the Proceedings at significant cost to each of the Applicants.

4.19. Celgene submits that [redacted] The ACCC has not received any documents from Celgene which relate to its strategy if the Agreement does not come into effect.

4.20. Juno/Natco submit that [redacted] The ACCC has not received any documents from Juno/Natco which relate to its strategy if the Agreement does not come into effect.

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37 Applicants, Applicant's response to ACCC request for information, 13 December 2021, paragraph 2.1.

38 [redacted]

39 [redacted]

4.21. [redacted]

4.22. [redacted]

4.23. [redacted]

4.24. [redacted]

4.25. [redacted]

a) [redacted]

b) [redacted]

4.26. In a future without the Proposed Conduct, the Applicants submit that there is no certainty that Juno/Natco would be able to launch the Generic Products 'at risk' within the timeframe permitted by the Proposed Conduct.

4.27. On 11 February 2022, Celgene provided the following information: [44]

4.28. [redacted]

40 [redacted]

41 [redacted]

42 [redacted]

43 [redacted]

44 [redacted]

4.29. [redacted]

4.30. [redacted]

4.31. [redacted]

ACCC view

4.32. The ACCC notes that it has received submissions on a confidential basis from the Applicants on the potential counterfactual scenarios. However, to date, the ACCC has received no evidence to substantiate the submissions.

4.33. The ACCC considers there are several potential counterfactual scenarios that may apply to the Proposed Conduct, including the Proceedings (whether it continues and the likely outcome of litigation) and the expiry dates of the relevant Celgene patents. The ACCC also notes that the Australian Government may seek to claim an entitlement to compensation to recover savings in PBS expenditure forgone as a result of the delayed listing of generic medicines on the PBS following the unsuccessful patent proceedings brought by the patent holder. The ACCC is not in a position to form views on the validity of the Celgene Patents, or the likely outcome of the Proceedings, as that is the role of the Federal Court of Australia or what action the Australian Government may undertake.

4.34. The Applicants contend for a counterfactual which assumes that the Agreement represents the only terms on which the Applicants would be prepared to settle the Proceedings. This appears to be a questionable premise, as the information provided by the Applicants does not establish that the Applicants would refuse to settle based on alternative terms (e.g. removing some or all of the provisions in respect of which authorisation is sought).

4.35. With and without the Proposed Conduct, the lenalidomide compound patent will expire on 24 July 2022 and all but one of Celgene's method of treatment patents will expire in April and May 2023. The ACCC considers that without the Proposed Conduct, the least speculative scenario is one in which Juno/Natco seeks to enter the market with the generic lenalidomide and pomalidomide products after May 2023, at least for indications relating to multiple myeloma and myelodysplastic syndromes.

4.36. In any event, however, the ACCC considers that the appropriate counterfactual for the purposes of this application should not be focused solely on the potential alternative conduct of the Applicants. Instead, it should consider the broader markets in which the relevant products are sold, including the potential conduct of other generic manufacturers.

4.37. As noted at paragraph 2.23, several generic manufacturers have sought registration on the Australian Register of Therapeutic Goods for lenalidomide and pomalidomide products. The ACCC understands that registration on the Australian Register of Therapeutic Goods does not necessarily confirm that a generic manufacturer is

intending to enter the market with its own generic product, rather it is a step in the pre-launch process for manufacturers who may be considering supplying a product.

4.38. The ACCC has not received any submissions from generic manufacturers on the application for authorisation, and therefore their respective intentions regarding the supply of generic lenalidomide or pomalidomide products are unclear.

4.39. In the future without the Proposed Conduct the ACCC considers that it is likely that [redacted]

4.40. The ACCC recognises it is exceptional and unusual for the full details of the relevant counterfactual to be unable to be made public, to allow interested third parties to make fully-informed submissions on it. This is due to the confidentiality claims of the Applicants, and it has compromised the ACCC's ability to test the Applicants' submissions, which in turn has influenced the ACCC's conclusions in assessing the application under the public benefit test.

Public benefits

4.41. The Act does not define what constitutes a public benefit. The ACCC adopts a broad approach. This is consistent with the Australian Competition Tribunal (the **Tribunal**) which has stated that the term should be given its widest possible meaning, and includes:

> *…we would not wish to rule out of consideration any argument coming within the widest possible conception of public benefit. This we see as anything of value to the community generally, any contribution to the aims pursued by society including as one of its principal elements … the achievement of the economic goals of efficiency and progress.*[45]

4.42. The Applicants submit that the Proposed Conduct will give rise to the following public benefits: [46]

a) certain and early launch of competing Generic Products for the treatment of multiple myeloma and mantle cell lymphoma;

b) increased competition in the relevant markets;

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

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

e) Introduction of alternate supply of pharmaceutical items for the treatment of myelodysplastic syndrome patients; and

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

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[45] Queensland Co-operative Milling Association Ltd (1976) ATPR 40-012 at 17,242; cited with approval in Re 7-Eleven Stores (1994) ATPR 41-357 at 42,677.

[46] Applicants, Application Received, 3 December 2021, paragraph 5.3.

4.43. The ACCC considers that the public benefit claims relevant to its assessment of the Proposed Conduct fall within the following categories:

a) Early launch of Generic Products leading to increased competition in the relevant markets and resulting in:

   i. PBS price reductions, with resultant cost savings to the Australian Government

   ii. Greater supply security of pharmaceutical items for the treatment of multiple myeloma and mantle cell lymphoma

b) Facilitating the orderly and expeditious settlement of the Proceedings, with resultant benefit in minimising the burden on scarce judicial resources.

4.44. Submissions on public benefits from the Applicants and, where relevant, interested parties are discussed below.

PBS price reductions, with resultant cost savings to the Australian Government

4.45. The Applicants submit that the Proposed Conduct will increase competition in the relevant markets by bringing forward the first entry of generic versions of lenalidomide and pomalidomide, which will result in better outcomes for customers and patients. They submit that the Proposed Conduct will result in considerable savings to the Australian Government, particularly because of the automatic 25% PBS price reduction triggered by the launch of the Generic Products (i.e. the First New Brand Statutory Price Reduction). The Applicants also submit that 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 Australian Government over time.

4.46. In response to the ACCC's request for information, Juno provided estimates of the likely savings to the Australian Government as a result of the First New Brand Statutory Price Reduction for the first generic versions of lenalidomide and pomalidomide. Juno's estimates are based on assumptions of different special pricing arrangements of 0%, 35% and 50% (Juno notes that Juno/Natco do not know the value of the special pricing arrangements for Celgene).[47] Based on a special pricing arrangement of 35%, Juno estimates the monthly costs savings to the Australian Government from the specified launch dates until the likely entry of other generics to be approximately $4.8 million per month for lenalidomide and $933,591 per month for pomalidomide.[48]

4.47. [redacted] As discussed in

[47] Special pricing arrangements are arrangements put in place between the Australian Government and suppliers of pharmaceutical products whereby the PBS can recover a percentage of expenditure on a listed product (through a rebate) at the listed price to reflect the price recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) as cost-effective. This enables Australians to have access to medicines at cost-effective prices where, due to international reference pricing or various other commercial reasons, sponsors are not able to supply the medicine at a particular publicly available price. The content of individual arrangements is confidential and commercially privileged information.

[48] Applicants, Applicant's response to ACCC request for information (PBS savings), 18 January 2022. Juno's estimates are based on a number of key assumptions, including the actions of other market participants that are independent of Juno/Natco.

[49] [redacted]

paragraphs 2.37 and 2.38, the Australian Government incurs significant costs subsidising lenalidomide and, to a lesser extent, pomalidomide prescriptions. In the 2020-2021 financial year, lenalidomide had a total cost to the PBS of $216.3 million (with an average price per prescription of $5,479) and was the 8th most expensive drug and 3rd most expensive oncology drug in terms of total cost to the Australian Government. In the same year, pomalidomide had a total cost to the PBS of $43.8 million (with an average price per prescription of $10,286). Pomalidomide is outside the top 50 most expensive drugs but is the 24th most expensive oncology drug in terms of total cost to the Australian Government.

4.48. Although the ACCC requested information regarding this claimed public benefit, Celgene has not provided its own estimates of the cost savings to the Australian Government that it considers will be the result of the Proposed Conduct.[50] [redacted] While the ACCC accepts that PBS cost savings to the Australian Government as a result of the early launch of generic products could theoretically constitute a public benefit for consideration, in the absence of sufficient information, the PBS cost savings are uncertain. [redacted]

4.49. The ACCC does not have any evidence to confirm the Applicants' claims that Juno's supply of the Generic Products will result in further PBS savings over time as a result of competitive responses including further price discounting and incentive offers to customers. Some interested parties consider it unlikely that significant price competition will occur with the entry of one generic manufacturer, particularly given the high cost of these drugs. For example, the Pharmacy Guild of Australia stated that higher cost drugs typically take longer to reduce in price as result of discounting and price competition, because there is a limited volume of patients and thus manufacturers cannot take advantage of economies of scale.[52] In response, Juno/Natco submits that this observation is not applicable in all high cost drug scenarios.[53] Celgene submits that even a smaller relative discount to a higher cost drug would result in a high overall reduction in price and accordingly is a significant public benefit. Celgene further points out the price disclosure regime that applies following generic PBS listing which progressively reduces the price for PBS medicines as competitive supply increases, including by way of price discounts and incentives to customers and pharmacists.[54]

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50 ACCC, ACCC to Celgene re request for information, 16 December 2021, paragraph 1.3.

51 [redacted]

52 ACCC, File note of meeting with The Pharmacy Guild of Australia, 14 February 2022; ACCC, File note of meeting with Myeloma Australia, 10 February 2022.

53 Applicants, Juno/Natco's response to interested party submissions, 4 March 2022, paragraph 2.28.

54 Applicants, Celgene's response to interested party submissions, 8 March 2022, paragraphs 6.2 and 6.3.

4.50. The Proposed Conduct is unlikely to give rise to public benefits in the form of cost savings for patients, given that the relatively high cost of lenalidomide and pomalidomide far exceeds the patient co-payment under the PBS.[55]

4.51. In the event that the Proceedings are recommenced absent the Proposed Conduct and they resulted in a favourable outcome for Juno/Natco, it is still open to the Australian Government to seek compensation for losses arising from an interlocutory injunction restraining the launch of a generic drug in order to recover the savings it would have derived in PBS expenditure from generic competition. This may be relevant to the ACCC's assessment of the claimed public benefit in relation to the PBS cost savings.

4.52. [redacted]

Greater supply security of pharmaceutical items for the treatment of multiple myeloma and mantle cell lymphoma

4.53. The Applicants submit that the launch of the Generic Products by Juno/Natco will ensure 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. The Applicants submit that the need for security of supply is heightened due to issues caused by the COVID-19 pandemic. The Applicants submit that the Proposed Conduct will lead to better outcomes for customers (including hospitals and pharmacists) and patients in terms of availability of medicine and alternative suppliers (in addition to price).

4.54. Information from interested parties suggests that no supply issues have arisen in the context of lenalidomide and pomalidomide in the past.

4.55. In contradiction to the Applicants' submission that generic entry will improve pharmaceutical availability, one interested party raised concerns about the potential for supply issues resulting from the Proposed Conduct, based on previous experiences whereby an originator brand of an oncology drug withdrew from the market upon entry of generic versions of its product, leading to problematic supply shortages.[56] In response, Juno/Natco submit that there is no basis to consider that such a situation would arise in the circumstances, and [redacted]

4.56. Further, some interested parties noted that the introduction of generic versions of lenalidomide and pomalidomide could broaden patient access to these drugs for indications that are not listed on the PBS, which may give rise to public benefits. This generally occurs where generic entry lowers the cost of drugs and leads to a broader range of indications approved for use by the PBS or improved access to the drugs. For example, one interested party advised that there are multiple indications for lenalidomide and pomalidomide that are not subsidised by the PBS but as the price of

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55 A co-payment is a charge levied on patients whenever a prescription for a PBS listed item is dispensed. The patient co-payment is set by the *National health Act* 1953 and is adjusted annually in accordance with CPI. From 1 January 2022, the general patient co-payment for lenalidomide and pomalidomide is $42.50.

56 ACCC, File note of meeting with the Tasmanian Department of Health, 21 February 2022.

57 [redacted]

58 [redacted]

these drugs falls over time, they may be added to the PBS or hospitals may be able to self-fund them more easily. However, it was noted that these drugs are particularly expensive and as such it may be unlikely that price reductions as a result of Juno/Natco's entry would be significant enough to improve patient access.[59] In response, Juno/Natco submit that while the quantum of public benefit by way of price reduction will depend on the outcome of competitive processes, it is a material benefit to have broader access to the drugs from earlier potential for price competition.[60] Celgene submits that if PBS-listed indications for lenalidomide and pomalidomide products were expanded as a result of the Proposed Conduct, this would allow clinicians to prescribe the drugs in new combinations, thereby improving patient access to them and representing a public benefit. Celgene also notes that the expected reduction in the price of lenalidomide and pomalidomide products would also benefit self-funded patients.[61] Celgene has not provided details of how many self-funded patients take the drugs in Australia.

4.57. The ACCC does not have sufficient evidence to be satisfied that Juno/Natco's entry with the Generic Products is likely to improve or broaden patient access to lenalidomide and pomalidomide.

4.58. The ACCC considers that an additional source of supply does not necessarily result in greater security of supply in the circumstances, as the ACCC does not have evidence of any supply issues in the past and the patient cohort being treated with these products is unlikely to change significantly in the foreseeable future.

4.59. [redacted]

4.60. In all the circumstances and based on the current information, the ACCC is unable to be satisfied that a public benefit is likely to result from the Proposed Conduct in the form of greater supply security.

Facilitation of orderly and expeditious settlement of the Proceedings

4.61. The Applicants submit that the Proposed Conduct will facilitate the orderly and expeditious settlement of the Proceedings, with a resultant benefit in minimising the incursion on scarce judicial resources. The Applicants claim that public benefits will arise as a result of direct and indirect litigation cost savings that will make funds available to allocate to the development, manufacture and distribution of products. The Applicants also submit that congestion of the court system and allocation of corporate resources towards dispute resolution as opposed to innovation and production activities has costs on society as a whole.

4.62. As noted at paragraph 2.11 the claim (insofar as it relates to the Compound Patent) and cross claim (insofar as it relates to the Compound Patent and alleged breaches of the Australian Consumer Law) were discontinued by the parties by consent on 27 October 2021. However, the claims insofar as they relate to the Lenalidomide Method of Treatment Patents and Pomalidomide Method of Treatment Patents are stayed, not discontinued.

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[59] ACCC, File note of meeting with Myeloma Australia, 10 February 2022; ACCC, File note of meeting with Dr Nick Murphy, 11 February 2022; ACCC, File note of meeting with the Tasmanian Department of Health, 21 February 2022; ACCC, File note of meeting with the Society of Hospital Pharmacists of Australia, 16 February 2022.

[60] Applicants, Juno/Natco's response to interested party submissions, 4 March 2022, paragraph 2.18.

[61] Applicants, Celgene's response to interested party submissions, 8 March 2022, paragraph 2.4.

4.63. The ACCC considers that the resolution of the Proceedings caused by the Proposed Conduct may have savings from two different perspectives: the legal costs that the Applicants may save by ending the Proceedings, and the potential savings for the court system as a result of the Proceedings not continuing.

4.64. In relation to the former perspective on any legal cost savings, the ACCC acknowledges that the Applicants may incur litigation cost savings specifically in relation to these Proceedings as a result of the Proposed Conduct. The ACCC notes that Celgene has not provided information in relation to its litigation costs. Juno/Natco estimated their legal costs [redacted] The ACCC notes that cost savings accruing to one or more firms which result in increases in productive efficiency can constitute a public benefit and it is not necessary for the savings to be passed onto consumers. However, the ACCC will give more weight to benefits which flow through to the broader community and are sustained over time.

4.65. In relation to the latter perspective on any legal cost savings, the ACCC recognises that resolving litigation without final judicial determination will lessen the burden on the court system. The size of these benefits is uncertain and the ACCC has not been provided with the information necessary to estimate their size.

4.66. The ACCC notes that given the timing of when the Celgene Patents expire and the length of time it could take for the Proceedings to be finalised, it is possible the Proceedings could be discontinued or not pursued further without the Proposed Conduct. [redacted] In that event, there would not be any litigation cost savings accrued in the future with compared to a future without the Proposed Conduct.

4.67. In all the circumstances and based on the information currently available, the ACCC is unable to be satisfied that litigation cost savings claimed to arise from the Proposed Conduct are likely to result in a public benefit.

ACCC conclusion on public benefit

4.68. The ACCC considers that the extent of any public benefit likely to arise due to possible PBS savings to the Australian Government as a result of the Proposed Conduct is uncertain. Based on the information currently available, [redacted]

4.69. Further, the possible continuation and outcome of the Proceedings between the Applicants, and consequently any potential compensation claim made against Celgene by the Australian Government to recover PBS expenditure, is relevant to the extent of the public benefit likely to arise as a result of the Proposed Conduct.

4.70. [redacted]

4.71. The ACCC considers that an additional source of supply does not necessarily result in greater security of supply in the circumstances, as the ACCC does not have evidence of any supply issues in the past and the patient cohort being treated with these products is unlikely to change significantly in the foreseeable future.

4.72. [redacted]

4.73. The ACCC does not consider the Proposed Conduct is likely to lead to greater security of supply and is therefore unable to be satisfied that this public benefit would likely result.

4.74. Based on the information currently available, in particular the timing of when the Celgene patents expire as noted in paragraph 4.66, it appears to the ACCC that it is possible that the litigation will be discontinued or not pursued further without the Proposed Conduct. In that event, there would not be any litigation cost savings accrued in the future with the Proposed Conduct compared to a future without the Proposed Conduct. In addition, the Applicants did not provide sufficient information to satisfy the ACCC that the litigation would proceed without the Proposed Conduct. Therefore, in all the circumstances, the ACCC is not satisfied that litigation cost savings would result in a public benefit.

4.75. For these reasons, the ACCC considers that public benefits arising from the Proposed Conduct are uncertain, minimal or unlikely to arise at all.

Public detriments

4.76. The Act does not define what constitutes a public detriment. The ACCC adopts a broad approach. This is consistent with the Tribunal which has defined it as:

> *…any impairment to the community generally, any harm or damage to the aims pursued by the society including as one of its principal elements the achievement of the goal of economic efficiency*.[62]

4.77. The Applicants submit there are no public detriments arising from the Proposed Conduct.

4.78. None of the eight interested parties, including regulatory bodies, medical organisations, hospitals and pharmacies who provided submissions or spoke to the ACCC raised concerns relating to public detriments likely to arise from the Proposed Conduct. The ACCC did not receive submissions from any generic manufacturers.

4.79. The ACCC considers the following detriments are relevant to its assessment of the Proposed Conduct:

a) Reduced competitive tension in relation to generic entry in the supply of lenalidomide and pomalidomide; and

b) Pre-launch activities undertaken by Juno/Natco.

4.80. Given the lack of information received from interested parties (in particular, competing generic manufacturers) on the competitive implications of the Proposed Conduct, and the extent of confidential information under consideration that could not be tested through consultation, the nature and extent of such detriments is unclear. [redacted]

[62] Re 7-Eleven Stores (1994) ATPR 41-357 at 42,683.

[redacted] the ACCC is uncertain of the nature of generic competition that may occur with or without the Proposed Conduct.

The Proposed Conduct reduces competitive tension in relation to generic entry in the supply of lenalidomide and pomalidomide products

4.81. The ACCC considers the Proposed Conduct gives Celgene greater control and certainty over the timing of generic entry by Juno/Natco, seeks to confer on Juno/Natco a 'first mover advantage' may deter generic entry, and [redacted] The Proposed Conduct replaces the competitive tension among current or future generic manufacturers of lenalidomide and pomalidomide which are looking to enter the market, by seeking to establish Juno/Natco as the first generic manufacturer and distributor in Australia for these products. It also affects Celgene's response to generic entry by removing elements of commercial risk, which, in the absence of the Proposed Conduct, might generate a more competitive response to the actions of generic manufacturers. There is a risk that affecting the structure of the relevant markets for the supply of lenalidomide and pomalidomide in this way will result in public detriment. The ACCC considers the nature and extent of this public detriment is unclear.

4.82. The ACCC has considered whether the Proposed Conduct changes the dynamics in the relevant areas of competition and whether other generic manufacturers may have a reduced incentive or ability to enter 'at risk' (i.e. before the relevant patents expire, and potentially before the specified launch dates). This would ultimately impact the wider community, including patients, hospitals and buying groups, and the Australian Government.

4.83. Without the Proposed Conduct, the ACCC considers that generic manufacturers (including Juno/Natco) could seek to launch lenalidomide or pomalidomide products 'at risk', that is, enter before the relevant patents expire, which could be before the specified launch dates. The ACCC considers the threat of generic entry occurring, including the possibility of 'at risk' entry and any response to entry, can be a key driver of competition in the supply of products and is likely to exert pressure on Celgene. The ACCC is concerned that the Proposed Conduct compromises this competitive threat and could affect the way in which Celgene responds to generic entry, which may not be in the interests of competition.

4.84. The ACCC cannot comment on the likelihood of success of any generics seeking to launch 'at risk'. As noted above at paragraph 2.15, when the majority of patents expire,[63] generic entry for certain indications of lenalidomide is possible from 17 May 2023 and generic entry for pomalidomide is possible from 17 May 2023. Any generic entry prior to these dates will be considered 'at risk' as prior to these dates it is possible for Celgene to institute legal proceedings against any party that seeks to supply generic versions of lenalidomide or pomalidomide respectively.

4.85. Celgene may file for injunctive relief against a generic manufacturer seeking to enter 'at risk' with or without the Proposed Conduct. [redacted]

[63] Australian Patent No. 2007282027 covers the administration of lenalidomide for the treatment of mantle cell lymphoma and expires on 2 August 2027. For reasons stated above, the ACCC considers it likely that after 16 May 2023, generics are able to enter for indications of multiple myeloma and myelodysplastic syndrome without breaching this patent.

[redacted] Therefore, the ACCC considers that, to the extent the Proposed Conduct reduces the threat associated with generic entry [redacted] this may result in public detriment compared to the situation without the Proposed Conduct.

4.86. [redacted]

4.87. Juno/Natco submit [redacted]

4.88. The Applicants have not sought authorisation for [redacted] of the Agreement. However, in the factual scenario for which the Applicants contend (i.e. the scenario in which the Proposed Conduct occurs) all of the provisions contained within the Agreement will be implemented. Accordingly, in considering what is likely to result from the Proposed Conduct in all the circumstances, the ACCC has considered the likely result of [redacted] The ACCC considers that [redacted] and as such is an example of how the Proposed Conduct could distort the competitive process when compared to the counterfactual.

4.89. Celgene submits that the Proposed Conduct will give it greater certainty over the timing of Juno/Natco's entry than if Juno/Natco were to launch 'at risk'. Celgene submits that if Juno/Natco were to obtain a favourable judgement in the Proceedings and subsequently launch the Generic Products, which would then not be 'at risk' entry, it would involve uncertainty as to the launch date given it is impossible to predict the timing of a judgment.[65] The ACCC considers that Celgene having certainty over when Juno/Natco enters, [redacted] along with the potential for reduced 'at risk' generic entry prior to the specified launch dates, reduces Celgene's commercial risk and provides it with the ability to better plan and take

64 [redacted]

65 Applicants, Celgene's response to ACCC request for information, 11 February 2022, paragraph 1.3.

strategic actions which may affect competition in the relevant markets. However, as noted above, the ACCC considers these elements of commercial risk for Celgene exert competitive pressure on it, and the removal of this discipline could diminish future competition in the markets for the supply and acquisition of lenalidomide and pomalidomide.

4.90. Under the Proposed Conduct, Juno/Natco has a non-exclusive licence to launch the Generic Products from the specified launch dates. [redacted] In effect, the Agreement appears intended to make Juno/Natco the first supplier of generic lenalidomide and pomalidomide in the relevant markets and the only generic supplier for a period until other generic manufacturers enter (whether through 'at risk' entry or after the relevant patents expire). The Agreement appears to allow Juno/Natco to achieve a, potentially very lucrative, first mover advantage. The ACCC makes no comment on whether Juno/Natco would be more or less competitive than any other generic that may seek to enter the market. However, the ACCC notes that a competitive process determining the outcome of who obtains that first mover advantage can be beneficial for competition, for example if the first to enter achieves that lead *because* it is a more innovative or vigorous competitor than its rivals.

4.91. The extent of the first mover advantage depends on a number of factors including how long the first mover is in the market before subsequent entrants follow, the nature of the pharmaceutical products and the length of contracts with relevant customers. The ACCC notes that lenalidomide and pomalidomide are high risk drugs which are subject to additional regulatory requirements that a new entrant must satisfy (for example, establishing a risk management program). This may extend the first mover advantage beyond the short term where relevant buying groups consider it unsafe or costly to switch products. Without information from other generic manufacturers, it is uncertain what benefit the first mover advantage is likely to provide to Juno/Natco, and how sustained that advantage is likely to be. The ACCC considers any first mover advantage obtained by Juno/Natco may affect the investment decisions of other generic manufactures which may deter or delay their entry into the market. Any successful deterrence of entry in this context would benefit the Applicants at the cost of potential competition.

4.92. Absent the Proposed Conduct, the first mover advantage could be determined by a competitive process in which generic manufacturers must make an independent decision on when to enter once the relevant Celgene Patents expire or whether to launch 'at risk' in order to obtain this first mover advantage. The Proposed Conduct seems likely to distort the competitive process among generic manufacturers, by seeking to determine which competitor is able to establish the first mover advantage in the relevant markets. It also allows Celgene as the incumbent to negotiate the first mover advantage with Juno/Natco and conditions of entry, including the timing of entry, which in turn may dampen competition between Celgene and Juno/Natco.

4.93. The ACCC is concerned that the Proposed Conduct seeks to provide Juno/Natco with a pre-determined first mover advantage, provides Celgene with greater certainty as to the timing of Juno/Natco's entry, may deter generic entry [redacted]

[redacted] The ACCC considers there is a risk that affecting the structure of the relevant markets for the supply of lenalidomide and pomalidomide in this manner will result in public detriment by potentially diminishing competition compared to a future without the Proposed Conduct. Absent information relevant to the counterfactual, the nature and extent of detriments is unclear.

Pre-launch activities undertaken by Juno/Natco

4.94. Under the Proposed Conduct, Juno/Natco is permitted to submit applications for the listing of the Generic Products on the PBS, provided that such listing is not to take effect until the relevant specified launch dates. [redacted]

4.95. Juno/Natco stated that it has the capabilities to launch the Generic Products on the specified launch dates on the basis that it has the manufacturing resources, the necessary regulatory approval from the TGA and the capabilities to import and distribute the Generic Products in Australia.[66]

4.96. Juno/Natco submit that the pre-launch activities that they will undertake (or have already undertaken) to launch the Generic Products include[67]:

a) Obtaining registration on the Australian Register of Therapeutic Goods: Juno has obtained registrations for each Generic Product.

b) Establishing a Risk Management System: This is a requirement of selling the Generic Products imposed by the TGA. Juno states it will have completed building this system for each respective product prior to the specified launch dates.

c) Applying for PBS listing: Juno states it will need to apply to the Commonwealth Department of Health to obtain PBS listing. In order to obtain a PBS listing, Juno/Natco is required to 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 the wholesaler or pharmacist within a reasonable period of such a request. In order to fulfil this requirement, 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. Juno would need to place purchase orders with Natco, and Natco would need to confirm such purchase orders and schedule manufacturing. The finished product needs to be transported to Australia. Once the stock is cleared by customs, it is held in pre-wholesale, and then shipped to full line wholesalers, based on the demand of prescribers. Due to the effects of the COVID-19 pandemic, the timelines for freight have significantly increased, with shipping estimated to take 10-12 weeks.

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66 Applicants, Applicant's response to ACCC request for information, 18 January 2022, paragraph 2.52.

67 Applicants, Applicant's response to ACCC request for information, 18 January 2022, paragraph 2.54.

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

4.97. The ACCC understands that taking steps to list a generic product on the PBS would not ordinarily infringe a patent, as applying for PBS listing is not an 'offer to supply'.[68] As such, it is unclear whether, under the Proposed Conduct, [redacted] The ACCC seeks submissions as to whether public detriment is likely to arise in this regard. Based on the information provided by Juno/Natco, it is not clear which of the pre-launch activities Juno/Natco has already undertaken and which are dependent on the ACCC granting authorisation for the Proposed Conduct. Given the [redacted] and that the Applicants have not commenced giving effect to any of the Proposed Conduct, it is [redacted]

4.98. The ACCC notes that its findings in relation to this issue will likely impact on its assessment of the Applicants' public benefit claims in relation to early launch of generic products.

ACCC conclusion on public detriment

4.99. The ACCC is concerned that the Proposed Conduct seeks to confer on Juno/Natco a pre-determined first mover advantage, provides Celgene with greater certainty as to the timing of Juno/Natco's entry, may deter other generic entry [redacted] There is a risk that affecting the structure of the relevant markets for the supply of lenalidomide and pomalidomide in this way will result in public detriment by potentially diminishing competition in the relevant markets, compared to a future without the Proposed Conduct.

4.100. The ACCC considers the threat of generic entry, including the possibility of 'at risk' entry and any response to entry, is a key driver of competition and is likely to exert pressure on Celgene. The ACCC is concerned that the Proposed Conduct compromises this threat and could impact the way in which Celgene responds to generic entry, which may not be in the interests of competition. Absent sufficient information, the nature and extent of any detriments is unclear.

4.101. The ACCC also considers that the Proposed Conduct has the potential to result in public detriment by [redacted]

4.102. The ACCC seeks further submissions as to the nature and extent of any public detriments likely to arise from the Proposed Conduct.

[68] Apotex Pty Ltd v Warner-Lambert Company LLC (No 3) [2017] FCA 94 (15 February 2017)

Balance of public benefit and detriment

4.103. In order for the ACCC to grant authorisation, the Act requires the ACCC to be satisfied in all the circumstances that the net public benefit test is met. For the reasons outlined in this draft determination, the ACCC is not satisfied, in all the circumstances, that the Proposed Conduct is likely to result in a public benefit that would outweigh any likely detriment to the public from the Proposed Conduct.

4.104. The ACCC considers that the existence and extent of public benefits arising from the Proposed Conduct, in the form of PBS cost savings to the Australian Government, is uncertain. [redacted]

4.105. The ACCC is not satisfied that the Proposed Conduct will result in greater security for the supply of lenalidomide and pomalidomide, as it has no evidence that supply issues have arisen for lenalidomide or pomalidomide in the past or could be expected in the future. The ACCC is also unable to be satisfied that Juno/Natco's entry with the Generic Products is likely to give rise to a public benefit [redacted]

4.106. The ACCC is not satisfied that the litigation would proceed without the agreement, and therefore cannot be satisfied that there would be litigation cost savings which would result in a public benefit.

4.107. The ACCC considers the Proposed Conduct is likely to result in public detriment by reducing competitive tension in relation to generic entry in the supply of lenalidomide and pomalidomide. The ACCC considers the Proposed Conduct seeks to provide Celgene with greater control and commercial certainty over the timing of generic entry by Juno/Natco, seeks to confer on Juno/Natco a 'first mover advantage', may deter generic entry [redacted] The Proposed Conduct replaces the competitive tension among generic manufacturers of lenalidomide and pomalidomide that are looking to enter the market by seeking to establish Juno/Natco as the first generic to market. It also affects Celgene's response to generic entry by removing elements of commercial risk, which, in the absence of the Proposed Conduct, might generate a more competitive response to competitive actions of generic manufacturers. There is a risk that affecting the structure of the relevant markets in this way will result in a public detriment. Given the lack of information received from interested parties on the competitive implications of the Proposed Conduct and the extent of confidential information under consideration that could not be tested through consultation, the nature and extent of such detriments is unclear.

4.108. The ACCC also considers that the Proposed Conduct has the potential to result in a public detriment by [redacted]

4.109. Accordingly, given the public benefits are uncertain, minimal or unlikely to arise at all, and that the ACCC cannot be satisfied of the extent and significance of the public detriments arising from the Proposed Conduct, the ACCC is not satisfied in all the

circumstances that the net public benefit test is met.[69] As the Act specifies that the ACCC must not grant authorisation unless it is satisfied that the likely public benefit will outweigh the likely public detriment, the ACCC proposes to deny authorisation.

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

5. Draft determination

The application

5.1. On 3 December 2021, the Applicants lodged application AA1000592 with the ACCC, seeking authorisation under subsection 88(1) of the Act.

5.2. Subsection 90A(1) of the Act requires that before determining an application for authorisation, the ACCC shall prepare a draft determination.

The authorisation test

5.3. Under subsections 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied in all the circumstances that the Proposed Conduct is likely to result in a benefit to the public and the benefit would outweigh the detriment to the public that would be likely to result from the Proposed Conduct.

5.4. For the reasons outlined in this draft determination, the ACCC is not satisfied, in all the circumstances, that the Proposed Conduct would be likely to result in a benefit to the public and the benefit to the public would outweigh the detriment to the public that would result or be likely to result from the Proposed Conduct, including any lessening of competition.

5.5. Accordingly, the ACCC proposes to deny authorisation.

5.6. The draft determination is made on 23 March 2022.

6. Next steps

6.1. The ACCC now invites submissions in response to this draft determination, by 6 April 2022. In addition, consistent with section 90A of the Act, the Applicants or an interested party may request that the ACCC hold a conference to discuss the draft determination.

[69] Application by Port of Newcastle Operation Pty Ltd (No 2) [2022] ACompT 1