## MinterEllison.



9 December 2021

Danielle Staltari
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Australian Competition & Consumer Commission
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BY EMAIL: danielle.staltari@accc.gov.au

Dear Danielle

Additional information - Application for authorisation of conduct - Settlement and Licence Agreement between Celgene Corporation, Celgene Pty Ltd, Natco Pharma Limited and Juno Pharmaceuticals Pty Ltd

- 1. Introduction
- 1.1 Minter Ellison acts for Juno Pharmaceuticals Pty Ltd (Juno) and Natco Pharma Limited (Natco). Jones Day acts for Celgene Corporation and Celgene Pty Ltd (together, Celgene) (the Applicants).
- 1.2 Thank you for your request for further information dated 7 December 2021 with respect to the application for authorisation dated 3 December 2021, first submitted to the ACCC for prelodgement consultation on 2 November 2021<sup>1</sup> (the **Application**).
- 1.3 This letter comprises the Applicant's response to the issues raised. Defined terms in this letter have the same meaning as set out in the Application.
- 2. The Applicant's response

Question 1: Description of the Proposed Conduct - Paragraph 3.7 states

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

We note that section 45AM of the Act provides that sections 45AF and 45AJ do not apply in relation to the making of a contract that contains a cartel provision if:

 The contract is subject to a condition that the relevant provision(s) will not come into force unless and until the corporation is granted an authorisation to give effect to the provision(s) and

<sup>&</sup>lt;sup>1</sup> As recommended in paragraph 3.3 of the ACCC's Guidelines for Authorisation of Conduct (non-merger), March 2019.

MinterEllison. JONES DAY

The corporation applies for authorisation within the 14 days after the contract is made.

We note that the Agreement was made on 21 October 2021. Given the timing of when the Agreement was made, the ACCC is unable to grant authorisation for past conduct of entering into the Agreement. In light of this information, can you please consider what conduct the Applicants are seeking authorisation for.

Can you please confirm whether the Applicants are seeking authorisation for the Proposed Conduct which is outlined in paragraph 3.7(1) to (7)? If the Applicants are seeking authorisation for particular provisions of the Agreement we would ask that you identify the specific clauses of the Agreement for which the Applicants are applying authorisation for.

- 2.1 The Applicants confirm that they are not seeking authorisation for any past conduct.
- 2.2 Section 88(1) of the Competition and Consumer Act 2010 (Cth) (CCA) provides that '... the Commission may, on application by a person, grant an authorisation to a person to engage in conduct [emphasis added], specified in the authorisation, to which one or more provisions of Part IV specified in the authorisation would or might apply'. Section 4(2)(a) of the CCA further provides (inter alia) that '... a reference to engaging in conduct shall be read as a reference to doing, or refusing to do, any act, including the making of, or the giving effect to a provision of, a contract or arrangement...'. Section 88(6) provides that the Commission '... does not have power to grant an authorisation for conduct engaged in before the Commission decides the application for the authorisation'.

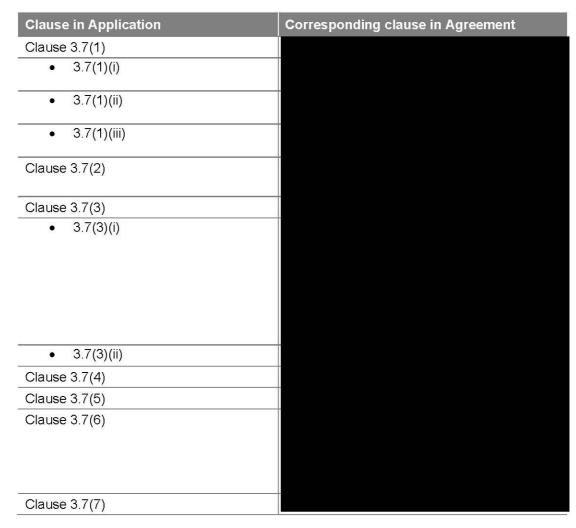
2.3	Clause of the Agreement expressly provides that '[s]ections will not come into effect (and the respective rights and obligations contained therein will not be binding on any Party to this Agreement) unless and until the ACCC Condition Precedent is satisfied'.
	.' The
	effect of clause of the Agreement is that no contract, or provisions of any contract, of the kind described in sections have as yet been made, entered into or been given effect by the Applicants.

- As set out in paragraph 3.7 of the Application, the parties have sought authorisation to 'engage in conduct' as required by section 88(1) of the CCA, namely to enter into and give effect to the provisions described in paragraph 3.7 of the Application (if the ACCC Condition were to be satisfied). Section 4(2) of the CCA makes it clear that 'engaging in conduct' can include exactly this type of conduct, namely making (or entering) into and giving effect to 'provisions of a contract'. The relevant 'provisions of a contract' in this case can only be made, entered into or given effect if and from the date on which authorisation is granted and the 'ACCC Condition' in the Agreement has been satisfied. This is conduct that can only occur at a date **after** the Commission decides to grant the application for authorisation. It is therefore also clear that section 88(6) of the CCA does not operate to prevent the Commission authorising the Applicants engaging in the relevant conduct.
- 2.5 The Applicants note that section 88(1) was amended in 2017 to broaden the Commission's authorisation power by referring to 'engaging in conduct' whereas the language of the section previously had referred to the Commission having power to grant an authorisation to a corporation 'to make a contract or arrangement, or arrive at an understanding, if a provision of the proposed contract, arrangement or understanding would be or might be, a cartel provision....'. The new formulation of the authorisation provision in section 88(1) is clearly broader than the previous formulation, and in the Applicants view, clearly contemplates and permits authorisation to engage in conduct of the very kind now sought.
- 2.6 The Applicants have described the relevant provisions in 3.7 of the Application without referring to clause numbers in the Agreement for the reason that a claim of confidentiality has been made in respect of the Agreement itself. However, to assist staff, we set out below in **Table 1** the corresponding provisions of the Agreement which are referred to in paragraph 3.7 of the

MinterEllison. JONES DAY

Application and which would be entered into and given effect if authorisation were granted and the ACCC Condition in the Agreement were to be satisfied.

**Table 1: Corresponding clauses** 



Question 2: Confidentiality claim over the authorised launch dates – We understand that the specific dates are commercially sensitive. However, it is difficult for interested parties to comment on the public benefits of the Proposed Conduct when there is no explanation of the meaning of 'significantly earlier than the expiry dates for the Celgene Patents'. The lack of public information may make it difficult for the ACCC to assess the public benefits claims.

 Is there an approach the Applicants can consider which provides a sense of how significant the earlier entry of the generic products will be?

- Would the parties allow the ACCC to disclose the exact dates with relevant government agencies, including the Department of Health, Pharmaceutical Benefits Scheme, Therapeutic Goods Administration and IP Australia?
- 2.8 The Applicants would have no objection to the ACCC disclosing the exact dates to the Department of Health (including the Pharmaceutical Benefits Scheme) on the basis they

MinterEllison. JONES DAY

undertake to keep this information strictly confidential. The Applicants do not agree to disclose the exact dates to any other party or agency.

Question 3: Confidentiality claim over the information in 3.9(2) – It is difficult for interested parties to comment on the scope of the Proposed Conduct given the current claim for confidentiality and this may impact the ability for the ACCC to consider this information in assessing the likely pubic benefits and public detriments to arise from the Proposed Conduct. Could you please consider the claim over this paragraph or if there is another approach to conveying the information.



Question 4: Confidentiality claim over Table 1 under paragraph 4.14 – this table appears to be based on information from the Department of Health. Why is this table confidential? If the market shares between Juno and Janssen are not publicly available, can this information be redacted from the table instead of all the information?

2.10 The Applicants do not press this claim for confidentiality.

Question 5: Attachment E - confidential to Juno/Natco - it appears that there may be information in this attachment which is public. For example, the information provided at Table 2, the information at paragraph 1.2 and paragraph 1.4? Can you please review the claim made over this attachment. We note that in considering requests to exclude information from the public register we are unlikely to grant exclusion for information which is public.

2.11 Juno / Natco do not press the claim for confidentiality in respect of paragraph 2 and Table 2. Juno / Natco do press the claim for confidentiality in relation to paragraph 1.4 as this is a highly commercially confidential analysis and conclusion with respect to Juno / Natco's commercial options in the counterfactual which should remain confidential from both Celgene and the public.

Please contact us if the ACCC requires further information.

Yours faithfully

MinterEllison	Jones Day
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Partner: Geoff Carter OUR REF: 1355471	Contact: Matthew Bull Ref: 501872 - 750001