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6 April 2022

Re: Submission in relation to draft determination (AA1000592) Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd.

Dear Sir/Madam,

This submission supports the ACCC's draft determination to deny authorisation AA1000592. The proposed conduct raises distinct anticompetitive concerns relating to the settlement between a pharmaceutical brand company and a generic competitor that are exacerbated by the agreed early entry of Juno/Natco.

Anticompetitive concern relating to the proposed patent settlement

The proposed settlement displays features akin to so-called pay for delay or reverse payment settlements that have been considered as anticompetitive in Europe (C-591/16 P - Lundbeck v EU Commission) and the United States (see FTC v Actavis 133 S. Ct. 2223 (2013); also more recently Impax Inc v FTC No. 19-60394 (5th Cir. 2021)).

Although the parties propose an "early entry" resulting in supposed savings for Revlimid and Pomalyst, it must be highlighted that the date of generic entry following patent expiry cannot be regarded as a fixed date. It is rather a perception that reflects the generic competitor's willingness to enter the market "at risk".

Patents are generally probabilistic in nature. Brand drugs are protected by a myriad of different patents, ranging from compound patents protecting the active ingredient to process patents that are often applied at a later stage and are considered as potentially weaker patents (see, Lemley, Mark, A., and Carl Shapiro, *"Probabilistic Patents."* (2005) Journal of Economic Perspectives, 19 (2): 75-98.

Empirical evidence from the US further shows that the majority of pay for delay settlements in the US concern weaker process patents that have a higher likelihood of being challenged successfully (see C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386, 1387 (2013)).

Against this backdrop, it needs to be considered that the proposed conduct would not only see Juno/Natco withdraw its claims against the compound patent (Australian Patent No. 715779) but also prevents any challenge of the other Celgene patents including the mentioned process patents that have a higher probability of being challenged by generic competitors. Authorising the proposed settlement terms would therefore remove the probabilistic nature of the Celgene patents and turn them into 'iron clad' patents.

Although the proposed settlement terms only concern the involved parties, the remainder of this submission outlines how the proposed early entry agreement coupled with an authorised settlement

has the potential to extent the 'iron clad protection' beyond the parties to the agreement. This strategy could result in market foreclosure for subsequent generic entrants, leading to the same anticompetitive concerns triggered by pay for delay settlements in the United States and Europe.

It is important to note that a pay for delay strategy does not require a US-style regulatory bottleneck to be successful. This is highlighted by the European Commission enforcement efforts against Lundbeck. Recognising the lack of a regulatory bottleneck that would facilitate a pay for delay strategy, requires the focus to be placed on the field of potential future generic competitors and their ability/willingness to enter the relevant market (see, Sven Gallasch, "Activating Actavis in Europe – The Proposal of a "structured effects-based" approach to pay for delay settlements" (2016) 36 (4) Legal Studies 683-705).

Although the ACCC has already established the number of potential competitors in both relevant markets, their willingness to challenge especially the later patents or to enter 'at risk' is questionable as Juno/Natco's early entry and the associated first mover advantage are likely to have a significant impact on their market entry decision.

But for these potential generic entrants, the proposed settlement would de facto foreclose the market and create a duopoly in the relevant market until at least May 2023 and in some cases until August 2027.

Anticompetitive concerns regarding the early entry of Juno/Natco

The first mover advantage associated with the early entry can raise the barriers to entry for subsequent generic competitors with a potential negative impact of the long-run equilibrium of the relevant market due to delayed competition from subsequent entry and the brand company's potential control over the generic price (see, for example Hollis A, 'The importance of being first: evidence from Canadian generic pharmaceuticals' (2002) 11 Health Economics 723).

Empirical evidence has shown that prescribing inertia in relation to the switching from brand drugs to generic drugs is a contributing factor for the first-mover advantage and can raise barriers to entry. Doctors' and pharmacists' concern can range from the generic's efficacy to patients' resistance or confusion in relation to generic substitution. This situation can be further exacerbated by the availability of subsequent generic alternatives. (Toverud EL., et al., A Systematic Review of Physicians' and Pharmacists' Perspectives on Generic Drug Use: What are the Global Challenges? (2015) 13 Appl Health Econ Health Policy 35–45. Thus, the mere market presence of subsequent generic alternatives might not necessarily translate into the expected competitive pressure or only with delay.

Importantly, the empirical evidence is not consistent across relevant markets defined according to their therapeutic indications. It would therefore be difficult to make general predictions about subsequent generic entry and the competitive pressure that such entry could exert in the relevant market. Instead, the evidence suggests that the impact of a first mover advantage is specific to the relevant therapeutic class of drugs and should be considered on a case-by-case basis.

The early entry of a 'brand-approved' generic company also has an impact on subsequent generic companies' willingness to enter. Their willingness should be reduced, as it is a function of the likelihood of patent infringement litigation by the brand company due to the 'at risk' entry and the estimated profit following entry. Again, the estimated profit is likely to be dependent on the characteristics of the specific market as well as the first generic entrants' response to potential subsequent entry. For example, the 'brand approved' generic company could signal aggressive marketing changes as a potential strategic barrier to entry.

However, for the relevant market that is subject to this determination, the Pharmacy Guild of Australia (File note of meeting with The Pharmacy Guild of Australia, 14 February 2022) has already submitted that subsequent generic entry is unlikely due the limited economies of scale at the wholesale level in the market Highly Specialised Drugs (HSDs) such as Revlimid and Pomalyst.

The proposed conduct has thus the potential to extend the protection of all Celgene patents beyond the parties to the settlement and de facto make patent challenges by further generic companies economically unviable, reinforcing the "iron-clad" status of the relevant patents.

Lastly, it is also worth investigating the brand company's control over the generic competitor based on the terms of the settlement and its ability to keep the approved generic entrant as a 'pet competitor'. Yet, even without direct control over the output and price of the approved generic entrant, the brand company should be relatively confident about the generic company's response to subsequent generic entry as retaining duopoly profits for as long as possible is in the aligned interest for both companies.

Concluding remarks

Settlements between brand and generic companies that determine a generic entry date have raised competition law concerns in the United States and Europe for good reason. They are far from being benign or per se procompetitive. Instead, they represent a win-win situation for the parties. The brand company has the potential to share part of its monopoly profits with an approved 'pet competitor' in return for avoiding any patent challenges and the ability to influence and shape the competitive environment of the given market post patent expiry. These potential competition law concerns should always warrant scrutiny and any authorisation should be denied.

Sincerely,

Dr Sven Gallasch