RESPONSE TO ADDITIONAL INTERESTED PARTY SUBMISSIONS

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1. Introduction

1.1 This document sets out Celgene's response to the following additional interested party submissions:

(a) Commonwealth Department of Health and Aged Care's (**DOH's**) submission dated 15 July 2022 (**DOH Submission**); and

(b) RonaiPalombi's submission dated 7 July 2022 (**RP Submission**) (which to a large degree expands on matters set out in RonaiPalombi's submission dated 29 April 2022).

1.2 As a preliminary matter, Celgene notes that both of these submissions are extensive and were provided to the Applicants on 19 July 2022 only 10 days ahead of the ACCC's statutory deadline of 29 July 2022 for a final determination on the authorisation application. Given this, Celgene has not had sufficient time to respond to these submissions in detail and is presently only in a position to make relatively high-level comments.

1.3 To the extent this document does not comment on any specific part(s) or matters from these submissions, this must not be taken as indicating Celgene's agreement with or acceptance of those part(s) or matters. Further, Celgene reserves its right to further address these submissions in relation to the authorisation application or in any other forum.

1.4 Celgene also notes that Natco/Juno provided its response to the DOH Submission on 21 July 2022 (the **Natco/Juno's response**), reference to which is made below.

2. DOH Submission

2.1 The DOH Submission raises a number of matters regarding the modelling analysis presented by Mr O'Toole in his statutory declaration dated 29 April 2022 (**O'Toole declaration**). Celgene comments further on these matters below.

2.2 However, it is notable that even despite these matters, the DOH submission strongly supports the Applicants' position as to the public benefits that arise from the Proposed Conduct.

2.3 First, Celgene notes that the DOH Submission acknowledges that it is appropriate to quantify potential cost savings to the PBS using the percentages by which price is reduced. As the DOH Submission states, the higher the percentage of price reductions, the more the medicine is discounted and the greater the cost savings to the PBS.

2.4 Second, the DOH Submission confirms that there is a:

(a) *likely* association between the number of competing PBS brands and the occurrence of price disclosure reductions; and

(b) *likely* association between the number of competing PBS brands and the likely magnitude and timing of the first price disclosure reduction.[1]

2.5 Significantly, the DOH Submission also expressly accepts the statements made at paragraph [57] of the O'Toole declaration as noted in the paragraph below in further detail.

2.6 Mr O'Toole states that the greater the market density (that is, the more numerous the PBS listed generic brands of a pharmaceutical supplied), the greater the downward pressure on the PBS price arising from the price disclosure regime. This is accepted in the DOH Submission as follows:

> *"The Department agrees with the submissions made by Mr O'Toole at paragraph 57. In particular, the Department agrees that, all other things being equal, the greater the market density for a given pharmaceutical, the greater the expected downward pressure on the PBS price."* [2]

2.7 In addition, Mr O'Toole also states in paragraph [57] of his declaration that a pharmaceutical operating in a market with numerous PBS listed generic competitors is more likely to have its first price disclosure reduction occur earlier and also to experience price reductions in excess of the statutory discount threshold of 10% compared to pharmaceuticals with fewer PBS listed generic competitors.

2.8 The DOH Submission also accepts this proposition advanced by O'Toole, as follows:

> "*This downward pressure would be expected to be more pronounced when multiple generic brands are listed on the PBS at or about the same time. In the Department's experience, the first price disclosure price reduction is more likely to occur at an earlier stage and to generate price reductions in excess of the 10 percent statutory threshold in these circumstance*s."[3]

2.9 As stated in Natco/Juno's response the DOH Submission, [Confidential to Celgene].

2.10 The position adopted by the DOH Submission (consistent with the evidence of Mr O'Toole) makes good the Applicants' position that there is clear benefit to the public in PBS price reductions that will result by virtue of the increased market density arising from the Proposed Conduct.

2.11 Significantly, although the DOH Submission raises some "reservations" concerning the conclusion in paragraph [109] of the O'Toole declaration, Celgene notes that this relates to the specific conclusion reached by Mr O'Toole that when lenalidomide faces generic competition, the timing and extent of price reductions by operation of the price disclosure regime will approximate the curve for the median cumulative price disclosure reduction for pharmaceuticals with 7 or more listed brands identified by Mr O'Toole (which indicates the 1st price disclosure reduction will take place in cycle 1 and a cumulative percentage reduction in AEMP of 80% after 10 price disclosure cycles).

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[1] DOH Submission, response to Q7 regarding the O'Toole declaration.

[2] DOH Submission, response to Q3 regarding the O'Toole declaration.

[3] DOH Submission, response to Q3 regarding the O'Toole declaration.

2.12 That is whilst the DOH Submission may not endorse the position as to the precise estimated timing of the first price reduction in the first cycle and the percentage reduction in AEMP of 80% (magnitude of price reduction), as noted above, the DOH Submission **does accept that the Proposed Conduct will lead to the first price disclosure reduction occurring *earlier* and also accepts that there will be price reductions in *excess* of the statutory discount threshold of 10% compared to pharmaceuticals with fewer PBS listed generic competitors**.

2.13 In light of this, Celgene need not address "reservations" expressed by the DOH on the conclusion on precise timing and quantum of price reductions reached by Mr O'Toole. However, for completeness, Celgene notes that the reservations relate primarily to the DOH's view that Mr O'Toole's methodology does not take into account the differences between lenalidomide and the individual pharmaceuticals which comprise the group of drugs with 7 or more listed brands, which form the basis of Mr O'Toole's conclusions in paragraph [109]. It is important to note that there is of course no pharmaceutical that mirrors that of lenalidomide, and hence Mr O'Toole necessarily undertakes a modelling exercise. The DOH Submission clearly accepts the fact that a modelling exercise is required (and suggests further modelling exercises, including as noted below in paragraph 2.15).

2.14 With respect, Celgene submits that the DOH's position lacks substance in that it fails to recognise that the task of modelling the likely price reductions of a pharmaceutical by operation of the price disclosure regime will necessarily involve differences between the pharmaceutical being modelled and the pharmaceuticals which have had generic entry which are available to form the basis of that analysis.

2.15 Tellingly, even the DOH's suggested approach of analysing "*price disclosure reductions generated by generic drugs listed on the [Highly Specialised Drugs Program (HDSP) within the period adopted by Mr O'Toole*" would not eliminate such differences.

2.16 Furthermore, and significantly, Celgene submits that the fact that *despite their diversity*, all 11 pharmaceuticals which underpin the basis of the conclusion in paragraph [109] of the O'Toole declaration follow the same trajectory (i.e. median curve), which in fact demonstrates the strength of the analysis. That is, despite the differences, the same trends are observed, leading to a high degree of confidence that lenalidomide would exhibit the same trajectory (despite differences with each of the 11 pharmaceuticals).

2.17 The other key premise about which the DOH expresses reservations appears to be based on the assumption that "*if the proposed conduct is authorised by the ACCC, Juno would, on the available information, be the only generic authorised to enter the markets for lenalidomide and pomalidomide on the authorised launch dates*". [4] As stated in Natco/Juno's response, [Confidential to Celgene].

2.18 The DOH Submission also notes that to date, "*sales to public hospitals have been excluded from price disclosure data under the regime, adds to the difficulty compared the data*".[5] In fact, given the discounting observed in the public hospital tender system discussed in the evidence of Mr O'Toole at paragraph [35], the absence of such data is likely to mean that the AEMP price reductions predicted to occur by Mr O'Toole underestimate the position.

2.19 In any event, as noted in the evidence of Mr O'Toole at paragraph [35] and evidence of Mark Crotty at paragraph [106], even aside from PBS price reductions, under the competitive tender system, the Proposed Conduct will lead to price reductions that constitute a clear public benefit.

2.20 Finally, Celgene considers that the DOH's comment that "*differences between the PBS price any* [sic] *discounted price negotiated by private hospitals are more properly characterised as a*

[4] DOH Submission, response to Q9 regarding the O'Toole declaration.

[5] DOH Submission, response to Q4 regarding the O'Toole declaration.

private benefit"[6] mischaracterises these benefits. The savings which accrue to private hospitals from lower prices will necessarily provide value to the community generally, in terms of lowering the hospitals costs, and the associated benefits that will flow to patients. The Australian Competition Tribunal has previously held that "*[c]ost savings achieved by a firm in the course of providing goods or services to members of the public are a public benefit which can and should be taken into account, … where they result in pass through which reduces prices to final consumers, or in other benefits*"[7]. The principle enunciated in this case is equally applicable to third parties, albeit the weight attributed to specific benefits may vary depending on "*who takes advantage of them and the time period over which the benefits are received*".

2.21 As to the DOH's response to question 5 in response to the ACCC's additional questions dated 29 June 2022, the amendments the DOH Submission makes to paragraph 2.18 of the Draft Determination make clear that it ought not be taken as given that any savings in PBS expenditure will be forgone as a result of the interlocutory injunction delaying the listing of generic medicines on the PBS.

2.22 Further, as to the Commonwealth's purported entitlement to damages, Celgene reiterates its 23 March 2022 submission in response to the Draft Determination at paragraphs 5.18 to 5.30. Celgene also notes that while the Commonwealth is entitled to *pursue* further claims pursuant to the usual undertaking as to damages, that does not mean that the Commonwealth will succeed in such claims (and Celgene submits that it will not), and that no Australian Court has recognised such an entitlement.

2.23 In any case, the matter simply does not arise, as no undertaking as to damages has been given by Celgene in the Federal Court Proceeding.

3. RP Submission

3.1 Celgene does not propose to address the RP Submission in detail. It however notes a number of misstatements and errors in the RP Submission and considers that it and RonaiPalombi's first submission dated 29 April 2022 should be entirely rejected.

3.2 Contrary to the statements at page 2 of the RP Submission, Celgene does not *directly* receive a benefit from the Commonwealth for the supply of lenalidomide through the PBS. Rather, as has been explained, the PBS is a government reimbursement scheme that provides subsidised medicines to the Australian public.

3.3 The critique (indeed criticism) of the rights that Celgene has and continues to enjoy under the Celgene Patents is not relevant to the ACCC's assessment of the authorisation application. Those are statutory rights afforded to all patentees under the *Patents Act 1990* (Cth) (**Patents Act**), including in respect of extensions of patent term. Any monopoly which Celgene has by virtue of its patent is not a detriment to the Australian public but the intended and legitimate purpose of the patent system. The criticisms levelled at these rights afforded by the Commonwealth under the Patents Act are of no relevance to the ACCC's assessment of the authorisation application.

3.4 As to the use of the term "*evergreening*" in the RP Submission, such a term does not appear in the Patents Act, and is adopted in the RP Submission pejoratively to seek to undermine the value of the Celgene Patents. This should be rejected. Method of treatment patents represent a species of patent of equal value to all other patents, a fact acknowledged by the High Court of Australia in *Apotex Pty Ltd v Sanofi-Aventis* [2013] HCA 50 (the Court rejecting a challenge to method of treatment patents as unpatentable under Australian law).

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[6] DOH Submission, response to Q3 regarding additional ACCC questions.

[7] *Qantas Airways Limited* [2004] ACompT 9 at 189.

3.5 For completeness, Celgene notes that in the context of competition law, "evergreening" practices involve incremental reformulations of first-generation drugs, presented as innovations to preserve patent protection, typically through the launch of a second-generation product.[8] It is clear that the assertion that the Proposed Conduct constitutes evergreening as it has been understood in a competition context, including by the European Union and the Court of Justice of the European Union, is a manifest error.

3.6 The RP Submission also appears to proceed on the basis that the discontinuance of the Federal Court Proceeding is a substantial and real detriment to the public as it denies the public the benefit that would otherwise flow from removal of "invalid patents" from the Patent Register. This submission is misconceived. First, [Confidential Natco/Juno]. Second, any other party has been and remains at liberty to challenge the patents at any time (there being no standing requirement under Australian law). Third, the submission assumes that the patents are invalid. That is not the case.

3.7 Although section 20(1) of the Patents Act states that nothing done under the Act guarantees that a patent is valid, a person seeking to invalidate a granted patent bears the onus of proof in establishing invalidity. In the absence of a finding of invalidity, the patent remains enforceable and the patentee holds the exclusive right to exploit the invention the subject of the patent and to authorise others to do so, pursuant to section 13 of the Patents Act.

3.8 Further, Celgene does not agree with the submission by RP that the passages from the Federal Court cases it has referred to at paragraphs 4.17 – 4.18 of its response to the Draft Determination are *obiter dicta*. For example, as to *GenRx Pty Ltd v Sanofi-Aventis* (2007) 73 IPR 502, cited in paragraph 4.17, this is demonstrated by the headnote to the judgement which states as follows (emphasis added):

> *Held, the injunction should be granted provided that the undertaking for damages is adequately secured:*
>
> *…*
>
> *(iii) In Australia, the commissioner is charged with the responsibility of examining the validity of a patent before grant, including any relevant question of anticipation or lack of novelty.* ***This goes towards establishing a prima facie case for the validity of the patent: at [5], [6] and [12].***

3.9 As to *Samsung Electronics Co Ltd v Apple Inc* (2011) 217 FCR 238, referred to at paragraph 4.18 of Celgene's response to the Draft Determination, Celgene notes that the extract provided at paragraph 4.18 clearly indicates the Full Court's approval of the primary judge's summary of the applicable legal principles ("*These propositions are supported by*…"). The primary judge's reasons indicate that those principles formed part of the consideration of the patentee's *prima facie* case and therefore, are *ratio decidendi* (*Apple Inc v Samsung Electronics Co (*2011) 284 ALR 309, at [28]). The primary judge's decision was overturned on appeal but the Full Court did not disturb this part of the primary judge's decision.

3.10 In any event, a debate as to the characterization of these judicial pronouncements is a distraction. Even if (which Celgene does not accept), the statements are *obiter dicta*, they still reflect the position as enunciated by senior judges of the Federal Court of Australia. The ACCC ought give them significant weight, and certainly could not adopt a contrary approach.

3.11 In the RP Submission and in the earlier submission from RonaiPalombi dated 29 April 2022 at [10] – [18], it is suggested that the Commonwealth has some right at large to claim compensation to recoup "overpayment" by the PBS where an invalid patent has the effect of maintaining a monopoly over a medicine that is listed on the PBS in the F1 formulary. This

[8] Case T-321/05, *AstraZeneca v. Commission*, ECLI:EU:T:2010:266, These practices were also identified in the EC's Pharmaceutical Sector Inquiry. See EC Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report (8 July 2009), 3.2.6.

position is entirely without merit even if one assumes that the Celgene Patents will be held invalid (which Celgene says is not a legitimate position). No such right has been asserted by the Commonwealth. It has no precedent in Australian law.

3.12 The RP Submission incorrectly states that "*Celgene, from its submission, is clearly aware of the rationale for such a claim…*" This is false. Celgene categorically rejects that the Commonwealth has any such claw-back right.

3.13 RonaiPalombi can point to no legal authority to support its position. Recourse to a decision of the Israeli Supreme Court does not assist, and rather demonstrates that no such right exists under Australian law.

3.14 For completeness, Celgene notes that it understands that the RP submission refers to the decision of the Israeli Supreme Court in *Sanofi et al. vs. Unipharm Ltd*, to support its contention that the Commonwealth of Australia may be able to bring a claim for compensation based on the application of equitable principles. Celgene understands that the case referred to is case number 2167/16 (***Unipharm***). RonaiPalombi also refers to an extract from a paper by Prof Hacohen.

3.15 Based on this extract, Celgene says that there are two matters which demonstrate the inappropriateness of reliance on this case in the RP Submission. Firstly, Sanofi had been found (in the District Court below) to have provided misleading information to the Patent Registrar in its relevant patent application. This information was found to be crucial, because its proper disclosure to the Registrar could have affected the likelihood of the patent application being accepted, as well as the period of opposition. The District Court found that Unipharm was entitled to compensation under the principles of unjust enrichment, as the existence of the misleading patent application was the main reason for Unipharm having to delay the launch of its generic product into the market and for its increased costs of development. These findings were upheld on appeal in *Unipharm*. It is thus incorrect to characterise the decision as one in which the patentee was required to give compensation for evergreening practices, as RonaiPalombi appears to suggest. Secondly, neither RonaiPalombi nor the extract provide any basis for the contention that the finding of unjust enrichment, for which compensation was paid to Unipharm, a generic pharmaceutical company, would be applicable to the Commonwealth.

3.16 The RP Submission also proceeds on a number of significant misconceptions as to the operation of the agreement / Proposed Conduct, namely:

(a) the agreement does not create a duopoly;

(b) the agreement does not appoint Natco/Juno as a first mover (being the basis on which the RP Submission suggests that the agreement will "*snuff out*" other generic competition). Furthermore, the agreement does not deter other generics from entering the market (as set out in paragraphs 1.2(c) and 4.52 – 4.60 of Celgene's response to the Draft Determination dated 5 May 2022).

3.17 Even if the agreement did create a duopoly (which Celgene submits is clearly not the case), that would create competition as it provides for an alternative supplier and competitor which is in itself a clear public benefit.

3.18 Celgene agrees with the statement at page 4 of the RP Submission that the "*trigger*" for the 25% price reduction is the listing of the second brand of a medicine, i.e. the first generic. Whilst the reduction may be caused simultaneously by a number of generics, Celgene submits that significant PBS cost savings, in the form of price disclosure reductions following generic entry, are likely to arise even if another generic manufacturer enters at the same time as the launch of Natco/Juno's generic product (and occur earlier and be of greater magnitude if the Proposed Conduct is authorised). In support of its submissions, Celgene refers to the O'Toole declaration and its statements in section 2 above (as supported by the DOH).

3.19 In response to the reference to the Biogen case at page 7 of the RP Submission, Celgene considers that it would be successful in obtaining an interlocutory injunction to restrain any at-risk launch of a generic lenalidomide or pomalidomide product. The reference to the Biogen case is therefore misguided. The injunction was refused in that case in light of several factors that do not arise here, including the Court's finding as to the high likelihood that the patent term extension granted to Biogen was invalid.

4. Conclusion

4.1 Celgene notes that the DOH Submission raises a number of matters concerning particular aspects of the modelling analysis presented by Mr O'Toole but ultimately the DOH Submission strongly supports the Applicants' position as to the public benefit that arises from the Proposed Conduct.

4.2 The RP Submission contains a number of misstatements and errors and to the extent it does address the Proposed Conduct does so on the basis of several misconceptions. Celgene has addressed these misconceptions including that the agreement does not create a duopoly nor appoint Natco/Juno as a first mover.

4.3 The additional submissions do not affect the position that there are no detriments and substantial benefits to the public from the Proposed Conduct. As a result, the ACCC should be satisfied of the net public benefit test and should grant authorisation for the Proposed Conduct.