RONAIPALOMBI
BIOTECH MEDICAL PHARMACEUTICAL

7 July 2022

Ms Danielle Staltari
Australian Competition & Consumer Commission
Level 17
2 Lonsdale Street
MELBOURNE VIC 3000

BY EMAIL: exemptions@accc.gov.au
cc: danielle.staltari@accc.gov.au; gavin.jones@accc.gov.au; lily.xiao@accc.gov.au

Dear Ms Staltari

Application by Juno / Natco (Authorisation number AA1000592-1) – Draft Determination dated 23 March 2022

We write in response to the submissions filed by Juno and Natco dated 27 April 2022 and Celgene dated 13 May 2022 subsequent to publication of the ACCC's Draft Determination (the Determination) proposing to deny authorisation of Application AA100592 from Juno Pharmaceuticals Pty Ltd & Ors.

The Applicants contend that their joint Application for Authorisation of an Agreement made between them on 21 December 2021 (the Agreement) should be approved because there are clear and substantial benefits to the public, with no detriments to the public.

We disagree.

The Proposed Conduct will provide no benefit whatsoever to the public. Whatever benefit it does provide will be exclusive to the Parties to the Agreement. Therefore, it does not constitute a "benefit to the public" under s.90(7) of the *Competition and Consumer Act, 2010*. However, the detriment to the public will be substantial, significant and real for the reasons outlined in this submission.

From the outset it must be appreciated that a patent, such as the patent over lenalidomide granted to Celgene due to expire on 24 July 2022, which we shall call the 'compound patent', is one example of the operation of the social contract that is made between an inventor and the State, the consideration of which is the public disclosure of an invention with sufficient particularity so that at the expiry of the patent, the invention, so disclosed and described, is capable of being reproduced by a person of ordinary skill in the art, without the need for undue experimentation. In return, the inventor is granted the right to the exclusive exploitation of the invention for a period of 20 years.[1] That right does not demand that the inventor do so, but it does enable the inventor to prevent unauthorised parties from doing so.

Accordingly, once Celgene's compound patent expires in a few weeks from now, it will no longer be able to prevent a third party from exploiting the compound 'lenalidomide' either by itself or as an ingredient in a medicine. In this respect it is relevant to note that the scope of the patent monopoly that Celgene was granted over the lenalidomide compound and through which it directly

[1] Except in the case of a patent over a new pharmaceutical substance which can be extended to a maximum period of 25 years.

obtained a financial benefit from the Commonwealth, with its medicines containing lenalidomide being included in the F1 PBS formulary, included the following:

> "***A pharmaceutical composition*** comprising ***a quantity of a compound according to claim 1*** sufficient upon administration in a single or multiple dose regimen to reduce levels of TNFα in a mammal in combination with a carrier." (Emphasis added)

In other words, Celgene has exercised its rights to a patent monopoly over the use of the compound 'lenalidomide' in a medicine in Australia from the time the patent application upon which it is based was open for public inspection. That occurred on 10 February 1998. The original term of the compound patent was for a period of 20 years and should have expired on 10 February 2018. However, Celgene applied for and was granted a patent term extension, applicable to new pharmaceutical substances, for a further 4 years 5 months 14 days, as a result of which it expires on 24 July 2022. Therefore, on expiry Celgene will have enjoyed exclusive patent monopoly rights over medicines containing lenalidomide for 24 years, 5 months and 14 days.

Not content with the benefits of such a lengthy patent monopoly, Celgene, which in 2009 listed its medicine containing lenalidomide in the F1 formulary of the PBS, subsequently applied for and was granted an additional six 'evergreening' patents that effectively extend its patent monopoly until August 2027 when the last of these evergreening patents expire, by which time Celgene will have held a patent monopoly over such medicines for a total period of 29 years. These secondary or tertiary patents are called 'evergreening' patents because they have the effect of extending the original patent monopoly term, which in this case is more than 24 years. It is a matter of public record that Celgene has been paid over $1 billion between 2009 and 2021 by the Commonwealth for the supply of medicines containing lenalidomide through the PBS.

There can be no other way of describing it than that Celgene has received a very valuable benefit in the form of a patent monopoly over the compound 'lenalidomide', the scope of which expressly includes "a pharmaceutical composition comprising a quantity of" lenalidomide.

This said, the scope of the patent monopoly that Celgene will enjoy after the expiry of the compound patent in a few weeks is, supposedly, more restricted in scope. Specifically, the six evergreening patents, generally referred to as 'method of treatment' patents, apply to the use of medicines containing lenalidomide in the treatment of specific indications. These indications are for multiple myeloma, myelodysplastic syndrome and mantel cell lymphoma.

However, IP Australia is not required by law to consider the impact of its actions on the Australian public or the Australian Treasury when examining a pharmaceutical-patent application. As a result of which the fact that the only indications ever approved by the TGA and, therefore, the only medicines containing lenalidomide that are capable of being listed on the PBS, are medicines used in the treatment of multiple myeloma, myelodysplastic syndrome and mantel cell lymphoma, is not something that IP Australia considered in making its decision to grant Celgene a series of evergreening patents. Therefore, IP Australia, in complete ignorance of this fact, extended the original patent monopoly over a medicine well beyond the legislatively imposed maximum of 25 years.[2] Thus Celgene will control the market access of these kinds of medicines in the treatment of multiple myeloma, myelodysplastic syndrome and mantel cell lymphoma and will continue to have an absolute control over these medicines until August 2027.

Accordingly, it is irrelevant in practical terms that the compound patent expires in a few weeks. Celgene will, with one exception that will be discussed later in this submission, continue to be able to exercise absolute control of its further extended patent monopoly over <u>all and any</u> medicines

[2] The normal maximum period is 20 years, but as lenalidomide was a new pharmaceutical substance, the patent was eligible for a patent term extension, the maximum for which is 25 years.

containing lenalidomide beyond a period of 25 years due to the operation of the 'evergreening' patents. Apart from the patent monopoly extension itself being a substantial, significant and real detriment to the Australian public and the Australian Treasury, the Proposed Conduct will not only sustain it, but will facilitate the establishment of a duopoly through which Celgene will continue to maintain its grip on the supply of medicines containing lenalidomide in Australia.

Relevantly, under the Proposed Conduct the current challenge to the validity of each of these patents by Juno and Natco, in suspension pending the outcome of this Application, will be discontinued. In our opinion, a substantial, significant and real detriment to the public of the Proposed Conduct is the ceasing of the patent litigation between Celgene and Juno/Natco. This will deny the public the benefit that flows on the removal of invalid patents from the Australian Register of Patents. And this benefit is not speculative. The Commonwealth is adversely affected when an invalid patent has the effect of maintaining a patent monopoly over a medicine that is listed on the PBS in the F1 PBS formulary when, but for the invalid patent, the medicine would be in the F2 PBS formulary.

The legitimacy of the Commonwealth's standing to bring proceedings to recoup the overpayment by the PBS in such circumstances been established in the Commonwealth's litigation[3] against Wyeth (venlafaxine), Sanofi (clopidogrel) and others. And although the Commonwealth was unsuccessful at first instance against Sanofi,[4] it has appealed that decision to the Full Federal Court, which has reserved its decision. Furthermore, although in each of the cases mentioned the Commonwealth pursued claims for compensation on the basis of written undertakings given to the Federal Court by the respective patentees, with it being a third party adversely affected by the grant of such preliminary injunctions, the Commonwealth's claims to compensation consequent to the invalidity of a patent are not, in our opinion, confined to those precise circumstances.

Therefore, the discontinuance of the legal proceedings by Juno and Natco represents a very substantial, significant and real detriment to the Australian public and the Australian Treasury for the following reasons.

The first is that an invalid patent, after it is declared so, is invalid *ab initio*. This means that whatever patent monopoly rights were enjoyed by the patentee while the patent was in operation are absolutely and forever revoked ***as if they never existed in the first place***. This is significant because any commercial agreement conditional upon the validity of a patent which is the subject of that agreement, such as a patent licence granted by the patentee to a third party, is automatically terminated.

The second is that thereafter anyone can do whatever they like with the product covered by the scope of monopoly of the invalid patent. In other words, competition is freely exercisable and this means that others can supply the market with the product covered by the scope of the patent monopoly and this in turn means mean that the price of that product will fall. Furthermore, it is possible that the quality of the same product will rise. Ultimately, free competition is a substantial, significant and real benefit to the Australian public and the Australian Treasury that will be denied to them if the present legal proceedings by Juno and Natco are discontinued.

The third is that if the evergreening patents, either all or individually, are held to be invalid by the Federal Court, the Commonwealth can bring a claim against Celgene to compensate it. And although there is no guarantee that Juno and Natco will prevail in the proceedings, the fact that

---

[3] *Commonwealth of Australia v Sanofi* [2015] FCAFC 172.

[4] *Commonwealth of Australia v Sanofi (No 5)* [2020] FCA 543. It is relevant to note that the Commonwealth failed in its claim because Justice Nicholas held at para 351 "In the result, I am not persuaded that Apotex Australia would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 even if the interlocutory injunction had not been granted. It follows that the Commonwealth's claim for compensation must be dismissed."

they have commenced the proceedings means that they have been advised by lawyers and patent attorneys suitably qualified to give such advice that they have a claim that is not hopeless. In the final analysis, should one or more of these evergreening patents be held to be invalid, it is foreseeable, and Celgene have gone to some length to explain the rationale behind such a claim in its submission, the Commonwealth will seek to recover from Celgene an amount equivalent to the 25% price reduction to the PBS that would have occurred, but could not occur due to the impact of the evergreening patents.

What this third contingency, which is neither fanciful, unreasonable or unforeseeable (given the proceedings the Commonwealth has already brought against Wyeth (venlafaxine) and Sanofi (clopidogrel)),[5] means is that the benefit the Proposed Conduct is claimed to provide in the form of a 25% price reduction to the Commonwealth, is so illusory as to not constitute any benefit at all. What the Proposed Conduct does is substitute one trigger of a 25% price reduction for another. That is, the listing of Juno's second brand of medicine containing lenalidomide on the PBS (authorised by Celgene) on the one hand, against, either a listing of such a medicine on the PBS by another generic medicines company (prior to undertaking an 'at risk' launch) or a successful claim for compensation by the Commonwealth through which the 25% price reduction is recouped from Celgene (if one or more of the evergreening patents are invalidated), on the other. In the final analysis it is a zero-sum game for the Commonwealth. Ergo, there is no benefit to the Australian public or the Australian Treasury.

And while the Proposed Conduct provides more certainty than does a challenge to the validity of the evergreening patents and, further, reduces the commensurate legal costs expenditure for all Parties to the Agreement, and, additionally, for the Commonwealth (to be incurred in bringing a claim against Celgene if and when the evergreening patents are invalidated), the Proposed Conduct is disadvantaged in so far as it undermines the commercial case for other generic medicines companies that would, but for the Proposed Conduct, attempt to enter the market for medicines containing lenalidomide. Apart from facing the prospect of a patent infringement suit if other generic medicines companies sought to enter the market with their own generic medicine containing lenalidomide, Juno would have a first mover advantage enabling it to secure a significant share of the market for such generic medicines sufficient to snuff out any realistic prospect of generic competition. It is, therefore, unlikely that any other generic medicines company would seek PBS listing until all of the evergreening patents have expired in August 2027.

Most importantly, without generic competition, it is more likely than not that the price of medicines containing lenalidomide will remain higher than they would otherwise be. This means that another substantial, significant and real detriment of the Proposed Conduct to the Australian public and to the Australian Treasury is the establishment of a defacto duopoly[6] between Celgene and Juno in the Australian market resulting in the Commonwealth being denied the full benefits of the price reductions for such medicines (applicable to medicines in the F2 PBS formulary) until August 2027. Indeed, we go so far as to contend that this is precisely what provides the commercial justification and motivation for the Proposed Conduct; namely, the establishment of a defacto duopoly from which the fruits (being the higher-than-normal price of medicines containing lenalidomide) are shared between Celgene/Juno/Natco and coming, specifically, at the expense of the Commonwealth.

The fourth is that upon the invalidity of a pharmaceutical patent the Commonwealth has the option to seek to recoup from those that have benefited from the invalid patent any overpayment it has made to them through the PBS from 2009. Although Celgene submits that this possibility is

[5] That the Commonwealth failed at first instance in its claim for compensation against Sanofi is irrelevant. The decision is on appeal and the appeal decision has been reserved.

[6] Meaning, not in law but in practice.

unprecedented and seeks to play it down by contending that it is speculative and therefore does not rise to the requisite level in the context of an assessment by the ACCC of the Proposed Conduct, we strongly disagree with this contention.

The fact that the Commonwealth has never sought to do so, does not mean that it cannot, nor should not, do so in the future. It is worth reminding Celgene and others that it was only prior to 2011 that the Commonwealth had never sought to claim compensation from the patentee of a pharmaceutical-related patent declared to be invalid.

Celgene, from its submission, is clearly aware of the rationale for such a claim, so there is no reason for us to labour the point in our submission. Clearly, today it is universally accepted that the Commonwealth is entitled to claim compensation for the overpayment it makes to the patentee under the PBS in the eventuality that a pharmaceutical-related patent is held invalid. That this acceptance is based upon the terms of a written undertaking as to damages does not mean, however, that there is no prospect whatsoever of the Commonwealth seeking to extend the operation of the principles applicable in those circumstances, to enable it to claw back the totality of any overpayment it has made under the PBS, either to the patentee, or to any other party that has also benefited from such overpayment, including Juno (in the event that the Proposed Conduct is authorised) given that (a) a patent that is held invalid is invalid *ab initio* and (b) there is no, and, contrary to Celgene's contention, cannot be, any presumption or guarantee of validity (s.20(1) *Patents Act, 1990*).

Indeed, there is recent legal authority, albeit from the Israeli Supreme Court, which supports our contention that the Commonwealth may be able to bring such a claim based on the application of equitable principles. Prof Hacohen, an Assistant Professor of Law, Tel Aviv University, in his paper entitled: "*Autumn is coming: A novel liability theory that may kill pharmaceutical evergreening*"[7] explains as follows:

> "Attempts by brand-name manufacturers to leverage patent rights to artificially extend legal protection for drugs—is among the most pressing and unresolved public policy challenges of our time. On July 14, 2021, in Sanofi et al. vs. Unipharm Ltd., the Israeli Supreme Court adopted a novel and internationally unprecedented legal policy to combat the evergreening pandemic. By using its equitable powers, the Israeli court empowered a generic manufacturer, Unipharm, to claim on behalf of the public interest the wrongly obtained monopoly profits that a brand-name manufacturer, Sanofi, obtained by improperly leveraging its improvement patent to impair generic market entry. This article introduces and critically evaluates the provocative Israeli decision. It explains that the logic of the new remedial mechanism that the Israeli court adopted—while sensible from a domestic perspective—is also more powerful and more convincing when adjusted and applied to US health policy. Finally, this article provides such an adjustment. Generalizing from the Sanofi case, the article structures a desirable and feasible policy mechanism to combat the evergreening pandemic. Many of the suggested policy prescriptions are equitable in nature and can be adopted by the Federal Courts without the need for legislative reform. If adopted, the suggested remedial solutions would contribute greatly to aligning pharmaceutical innovation incentives with the welfare of drug-seeking patients."

While a decision of the Israeli Supreme Court is not binding on an Australian court, it does, however, show that the Commonwealth may have the capacity to prosecute such a claim and that it should not be ruled out of contention. Therefore, Celgene's opinion that our contention is merely speculative and has no merit in law, should be treated with extreme caution by the ACCC. We are

[7] Soon to be published in Cordozo Arts & Entertainment Law Journal (2022) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3940350

strongly of the opinion that if and when the Commonwealth brings such a claim that it will prevail in the Australian courts.

Apart from the detriment that the discontinuance of the current challenge to Celgene's evergreening patents will have on both the Australian public and the Australian Treasury consequent on the approval by the ACCC of the Proposed Conduct, if the Proposed Conduct fails to pass the ACCC's scrutiny we contend there are benefits that will flow through to the Australian public and the Australian Treasury. These are as follows.

First, going back to the exception we referred to earlier in our submission, we believe that if the Proposed Conduct is refused authorisation by the ACCC, it is more likely than not that Juno and Natco will continue to prosecute their challenge to the Celgene evergreening patents. The benefits which follow from a successful challenge to either one or more of these patents has been discussed above. But, even if Juno and Natco were to discontinue the legal proceedings, we believe it is more likely than not that one or more of the other generic medicines companies that already have registered their respective medicines on the ARTG will seek PBS listing.

And it is at this point that the falsity of the claim, made by Celgene/Juno/Natco, of the benefits the Proposed Conduct brings to the Australian public, is exposed.

It is a matter of public record that the TGA has included on the ARTG medicines containing lenalidomide that are not Celgene's. It is noteworthy that an application for ARTG registration is not an act of patent infringement (s.119A Patents Act, 1990). Indeed, apart from Juno, there are five other generic medicines companies that have already secured ARTG registrations. This is consistent with longstanding Australian Government policy designed to encourage generic medicines companies to 'springboard' cheaper generic medicines at the expiry of 'valid' patent protection. And consistent with this policy is their ability to also apply for the listing of their respective medicines on the PBS without such an application being treated as an act of patent infringement (*Warner-Lambert Company LLC v Apotex Pty Limited* [2017] FCAFC 58).[8]

Relevantly, the trigger for the transfer of a medicine from the F1 PBS formulary to the F2 PBS formulary, thereby causing a legislatively-imposed price reduction of 25% to the PBS listed price, is the listing of a second brand of a medicine in the F1 PBS formulary (*Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591 at para 171 sub para 41 and at para 174). We are fortified in our opinion by Justice Rofe who held on the facts of that case:

> "***The listing*** of the Pharmacor products as the first generic DMF to be listed ***on the PBS <u>will cause</u>*** Tecfidera to automatically ***move from Formulary F1 to F2*** and to be subject to a mandatory 25% reduction to the AEMP." (Emphasis added)

Accordingly, it is the listing of a second brand of a medicine containing lenalidomide on the PBS by any one of six generic medicines companies that already have ARTG registration for a medicine containing lenalidomide that will trigger a 25% price reduction. Indeed, the trigger event may, in the end, have nothing whatsoever to do with the Proposed Conduct if the ACCC were to refuse authorisation.

Second, after a PBS listing has been obtained by a generic medicines company, it is possible that it may be the subject of patent infringement litigation coinciding with when it seeks to launch its medicine containing lenalidomide for use in one of the TGA approved indications on the market, but whether Celgene would be successful in preventing the launch of such a medicine will depend on whether (a) it applies for a preliminary injunction enjoining the product launch and (b) it is

[8] We note that Celgene is unable to provide any authority in support its contention at para 4.67, p 14 of its submission. We contend that s.119A means precisely what it says especially in view of the Explanatory Memorandum reference to 'spring-boarding'. This point is expressly dealt with in footnote 9, *supra*.

successful in its application for a preliminary injunction. While it is true that the Proposed Conduct will avoid the above scenario, it is not to be assumed that a patent owner will succeed as the Federal Court decision in *Biogen International GmbH v Pharmacor Pty Ltd* demonstrates. In that case Pharmacor was able to resist Biogen's application and a preliminary injunction was refused.

Third, contrary to Celgene's contention, no patent is guaranteed validity. The claim that Celgene make in its submission that a granted patent has the benefit of a presumption of validity, is inconsistent with s.20(1) *Patents Act, 1990*, which provides as follows:

> "***Nothing done under this Act … guarantees*** the granting of a patent, or ***that a patent is valid***, in Australia or anywhere else." (Emphasis added)

The passages from Federal Court decisions that Celgene refers to in its submission at paras 4.17-8 in support of its contention are neither binding on any Australian court, nor are they the law. This is because they are *obiter dicta*. And in any event, the words in s.20(1) *Patents Act,1990,* are unambiguous. Therefore, in the absence of the Proposed Conduct it is more likely than not that the validity of Celgene's evergreening patents will be challenged, if not by Juno and Natco, then by another generic medicines company. Such action is consistent with the longstanding policy of successive Australian Governments that generic medicine companies should be able to 'springboard' the launch of their medicines after the expiry of a valid patent, the emphasis being on the word 'valid'.

Fourth, the 'spring-boarding' policy ultimately ensures the long-term viability of the PBS, and this is in the best interests of the Australian public and the Australian Treasury. The final decision of the Howard government in 1997 to incorporate spring-boarding as a feature of the patent term extension for pharmaceuticals, as the previous Hawke government had done, recognised the inherent threat that its absence posed to the local generic pharmaceuticals industry. The Minister acknowledged the risk of losing a viable, local generic pharmaceuticals industry:

> A patents regime which lacks the flexibility to allow spring-boarding would also put at risk generic development and manufacturing in Australia. This is because of the significant advantage which derives from being first in the market with a generic product. A lack of spring-boarding provisions in Australia will encourage generic drug importers to undertake development work offshore, in countries like the United States, which allows spring-boarding throughout the patent term, or in countries with weak patent protection and access the Australian market immediately the patent expires.[9] (Emphasis added)

Spring-boarding has been designed to provide a check against the potential imbalance created within the pharmaceutical industry in Australia by patent term extensions. The Minister explained its supposed benefits:

> Allowing spring-boarding ... would place Australian companies on a more equal footing with their international competitors. It would do so without reducing the period during which the originator company retains an exclusive right to sell its product on the Australian market. [It] also reduces the risk of pushing development work on generic drugs offshore, either to the United States where spring-boarding is allowed, or to countries providing weak patent protection. It also gives the industry more flexibility in preparing to access the Australian market. As such, [it] would be of particular benefit to Australia's fledgling pharmaceutical active ingredient manufacturers as well as to Australian producers of 'innovative' generic drugs.[10]

---

[9] Intellectual Property Laws Amendment Bill, 1997 Explanatory Memorandum, 7.

[10] *Ibid.*

The Minister also acknowledged the potential downside:

> At risk is a generic drug sector currently worth approximately $600 million per annum to Australia, plus spillovers into employment and collaborative development work.[11]

What the Proposed Conduct does is provide Juno and Natco with a disincentive to challenge Celgene's evergreening patents because under the Agreement the present patent litigation will be discontinued. This result is inconsistent with the 'spring-boarding' policy which is designed to encourage all generic medicines companies to challenge pharmaceutical patents of dubious validity in return for the reward of "being first in the market with a generic product." Consequently, adherence to the 'spring-boarding' policy requires the ACCC to refuse authorisation of the Proposed Conduct because to do otherwise is to undermine the effectiveness and purpose of this long-standing policy which is designed to protect and promote a viable generic medicines industry.

Viewed in its totality, specifically in the context of the Pharmaceutical Regulatory and Patent System, the Proposed Conduct constitutes a substantial, significant and real detriment to the Australian public and to the Australian Treasury, the consequence of which is to provide an incentive to generic medicines companies to enter into similar arrangements with pharmaceutical patent owners, thereby encouraging the evergreening of pharmaceutical patents, enabling the effective and absolute control over life-saving medicines to continue well beyond the statutory maximum period of patent protection of 20 years. Furthermore, it provides a disincentive to challenge pharmaceutical patents of dubious validity. This is a result that threatens the very sustainability of the PBS; one of the most relevant and important government-funded schemes providing a most valuable benefit by ensuring timely access for Australians to quality, safe, efficacious and affordable medicines at a cost the PBS and taxpayers can afford.

All the Proposed Conduct with Celgene/Juno/Natco does is remove the threat of patent litigation that would otherwise apply to Juno and Natco. That is not "a benefit to the public" under s.90(7) of the *Competition and Consumer Act, 2010*. And, therefore, it follows that the ACCC was correct to refuse authorisation in its Draft Determination. We have urged, and will continue to urge, the ACCC not to resile from its preliminary position in the Final Determination.

We respectfully submit that for the reasons outlined above, the ACCC should refuse authorisation of the Proposed Conduct.

Yours sincerely,

Robyn Ronai, BPharm, Dip Hosp Pharm
Principal
T:
E:

Luigi Palombi, LLB, BEc, PhD
Principal
T:
E:

[11] *Ibid.*