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BIOTECH MEDICAL PHARMACEUTICAL

29 April 2022

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Australian Competition & Consumer Commission
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Dear Ms Staltari

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

We write in response to the Generic and Biosimilar Medicines Association's (GBMA) submission dated 8 April, which followed publication of the ACCC's Draft Determination (the Determination) proposing to deny authorisation of Application AA100592 from Juno Pharmaceuticals Pty Ltd & Ors.

We note that of the six submissions made to the ACCC after the Determination was published, the only one that does not support the Determination is the GBMA's.

We disagree with several contentions made in the GBMA submission and draw your attention to the following:

1. While the GBMA represents a number of member companies involved in the business of supplying generic and biosimilar medicines to the Australian market, it does not represent the individual commercial interests of any one company, nor does it concern itself with or have the capacity to provide an independent commercial analysis of an individual company's business. Therefore, it is ill equipped as an organisation to assess the impact on competition in the Australian market of the Agreement and the issues that are the subject of the Application.

2. The GBMA's membership includes Juno Pharmaceuticals, one of the parties to the Application in issue. While we do not suggest that the GBMA's submission has been unduly influenced by Juno Pharmaceuticals, it is fair to question whether the GBMA's support for the Application may be unintentionally biased.

3. The GBMA submission, in the main, consists of a series of motherhood statements lacking in specificity.

4. GBMA's contention that "there would be a potential chilling effect on patent settlements" adversely impacting competition between originators and generic suppliers, if the ACCC were to deny this authorisation is, we believe, fundamentally flawed. Patent settlements benefit the parties involved and deny market entry to other competitors, effectively shutting out competition.

5. We respectfully submit that the GBMA is wrong to contend that "the existing ARTG registrations for lenalidomide as [is] indicative of likely entry by a number of other generic suppliers." While it is necessary for a medicine to be listed on the ARTG before it can be legally supplied in Australia, this requirement should not be interpreted as an intention to market.

6. Our criticism of the GBMA's contention is fortified by legislation that provides, expressly, that it is not an act of patent infringement either, to apply for ARTG listing, to have the TGA accept a medicine for listing on the ARTG, or for a medicine to be listed on the ARTG (see s119A(1)(a) *Patents Act*). Furthermore, in a decision of the Full Federal Court in *Warner-Lambert Company LLC v Apotex Pty Limited* [2017] FCAFC 58 the Court held that even an application for listing a medicine on the PBS, of which ARTG listing is a prerequisite, is not an act of patent infringement. Accordingly, the GBMA's contention has no basis in fact or law.

7. We respectfully disagree with the GBMA's contention that: "There are no features of the agreement that could be expected to result in competitive tension between generic competitors being diminished. To the contrary, it is more likely that the public nature of the Applicants' settlement agreement may bring forward the timing of entry by other generic suppliers." Clearly, the point raised in the submission filed by Pharmacor dated 6 April contradicts the GBMA. Pharmacor explains:

   > "2.7 Under the proposed settlement and licence agreement, Juno will supply its own separate REMS[4] with the result that each prescriber and dispenser of lenalidomide and pomalidomide products in Australia will need to acquire, implement, be trained in, operate and maintain two separate REMS software products - one for Celgene's originator product and one for Juno/Natco's generic product.
   >
   > 2.8 Pharmacor is particularly concerned that once these two separate software products have been implemented, are established and have been in operation, particularly over any significant period of time, to support the risk management steps required by the TGA in the prescribing and dispensing of these products, doctors, hospitals and pharmacists will be particularly reluctant to acquire, establish and operate a third (or any subsequent) REMS for each subsequent generic product as it becomes available."

8. The REMS is arguably a barrier to entry in as much as Pharmacor claims "the additional switching costs, IT interface changes, different user experience, training costs and administrative burden of operating multiple REMS systems for multiple generics are likely to raise significant additional barriers to entry for second and subsequent generic sponsors, over and above the usual factors which give rise to the first generic mover advantage generally."

9. The GBMA's contention that "parties to patent settlements … should be entitled to seek authorisation to mitigate [the risks of patent litigation] where those patent settlements facilitate early entry and as a result generate net public benefits" is, we respectfully submit, a generalisation that wrongly asserts that the mere act of generic entry is sufficient to enhance competition and societal benefit. The statement demonstrates a misunderstanding of the ACCC's role. Moreover, it fails to address the concerns expressed by the Productivity Commission in its IP Arrangements Report, 2016 in which it recommended to the Australian government that 'pay-for-delay' agreements come under the scrutiny of the ACCC (see Recommendation 10.2 at p329). The Productivity Commission explains:

   > "The Commission's preferred option to manage pay-for-delay risks is to improve monitoring and transparency of settlement agreements to detect any pay-for-delay arrangements. Where this indicates further action is warranted, enforcement of existing competition law should be pursued, leaving the courts to determine the legality of any allegedly anticompetitive agreements.

Monitoring would also improve the 'credible threat 'of sanction under the existing regulation, providing a deterrent and potentially reducing the incidence of pay-for-delay agreements." (See p 327)

10. While we agree that the entry of generic and biosimilar medicines has the effect of reducing the price of those medicines consequent to the pricing reforms referred to, whether and to what extent competition in the market for those medicines is enhanced by such an effect depends on several variables. One such variable is the patent landscape. By this we mean the scope of protection afforded by one or more patents that relate to the medicines or medicines in issue.

11. The idea that the scope of protection provided by patents is dependent upon the operation of a single patent, particularly in the pharmaceutical sector is naive, and, in the vast majority cases, simply not true. To the contrary multiple patents and multiple types of patents in operation over periods of time providing enforceable rights, commencing from a minimum of 20 years, may hinder or prevent competition in the market for specific medicines for periods significantly more than 20 years. For example, while the expiration of a compound patent ends the rights of a patentee to restrict others from exploiting the invention protected by the scope of the patent claims, it does not mean that the scope of competition in the relevant market for medicines in which the compound is the active ingredient, is necessarily open to competition. Secondary and tertiary patents relevant to a medicine, particularly to a modified form of the original medicine, pertaining either to a process of manufacture, associated compounds such as enantiomers, dosage, formulation, method of use, method of treatment and so forth, complicate the competitive landscape for such medicines.

12. Patents are, therefore, the most significant and problematic barrier to entry. This is because patent rights are enforceable in law.

13. However, no patent is guaranteed validity (see s.20(1) *Patents Act*). And if a patent is invalidated it is invalid *ab initio* (i.e., from the beginning). Therefore, the successful challenge of a patent renders the rights of the patentee null and void, as if the rights had never existed. The full extent of the retrospectivity of such a result has not, however, been the subject of judicial consideration simply because of the absence of litigation testing the limits of retrospectivity. Accordingly, there is a paucity of law exploring the effect of a finding of invalidity beyond the most immediate, namely, the loss of the patentee's rights going forward.

14. We submit that while a finding of invalidity removes a barrier to entry that benefits the Australian public, the failure to claw back from the patentee the economic benefit derived from its exploitation of the patent rights during the period of time the patent was operational, albeit invalidly, is a most significant detriment to the Australian public and one that is avoided by a pay-for-delay settlement. We postulate that the size of that detriment is quantifiable by reference first, to the improper economic benefit derived by the patentee during the period in which the invalid patent was operational and second, by the improper impact on third parties, such as the Australian government through its funding of the PBS, adversely affected by the invalid patent while in operation.

15. It follows that the successful challenge of patents that hinder or prevent competition for a medicine in the Australian market is not only of paramount importance to the maintenance of a competitive market, but also absolutely dependent upon it. And while the Australian government has since 2012 sought to claw back some of the economic benefit derived by a patent during its exploitation of patent rights subsequently held to be invalid, it is important to understand that the extent of that claw back has been limited to the enforcement of written undertakings given by patentees as a condition of the grant of preliminary injunctions. Moreover, the quantification of that claw back is complex in fact and law, time consuming and expensive, and has been limited to the quantification of the cost to the PBS of the delay of the price reductions applicable to a medicine caused by the preliminary injunction. We

respectfully submit that the Australian government has not yet considered going further and we recommend it should do so in the future.

16. In our opinion, that the Australian government has yet to seek to claw back *all* economic benefits flowing from a finding of invalidity of a patent or patents that hinder or prevent competition in Australia, does not mean that in assessing the impact of the Application on the Australian public the ACCC should ignore the possibility that one day the Australian government may do so (and the value of the benefit if it were to). After all, until 2012 no Australian government had sought to enforce the terms of written undertakings as a condition of the grant of preliminary injunctions, and yet it is now accepted as a factor to be considered by patentees in seeking preliminary injunctions, and by the Courts in deciding whether, or not, to grant them (see *Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591)

17. Accordingly, and in light of the possibility that the Australian government may claw back the entire value of the economic benefit derived from the exploitation by a patentee of a patent that is subsequently held to be invalid, the immediate price reduction that follows on the entry of generic and biosimilar medicines, as the Northern Territory Government's submission explains, is insignificant. Indeed, were the Australian government to undertake such a claw back, as we submit it could and should do, it is likely that the price of the medicines in issue would fall by an even greater amount than 25%.

18. Therefore, the harm that this Application has the potential to unleash on the Australian healthcare system is significant and cannot, with respect, be neutralised by the parties coming to an understanding that facilitates the patentee's avoidance of this possible scenario. In agreeing to bring the patent challenger within the umbrella of protection afforded by the statutory rights pertaining to a patent in return for the patent challenger withdrawing its patent challenge to those rights, the Australian government is being permanently deprived of the total value of such a potential claw back in the event that the relevant patent or patents were to be held invalid. And while there is no certainty that the patents would be held to be invalid, it is the case that no patent is guaranteed validity (see s20(1) *Patents Act*).

We respectfully submit that for the reasons outlined above, the ACCC should not resile from its Draft Determination.

Yours sincerely,

Robyn Ronai, BPharm, Dip Hosp Pharm
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