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Our ref: IM-70259

Contact officer: Adrian Hughes / Andy Gallagher Contact phone: 03 9658 6545 / 02 9230 9129

30 August 2019

Dear Interested Party

Re: Request for submissions: iNova's proposed acquisition of Juno PC

The Australian Competition and Consumer Commission (ACCC) is seeking your views on the proposed acquisition of Juno PC Holdings Pty Ltd (Juno PC) by iNova Pharmaceuticals (Australia) Pty Ltd (iNova) (the proposed acquisition).

iNova is a pharmaceutical company which develops, markets and sells a range of prescription and non-prescription pharmacy products, including phentermine based weight loss medication. Juno PC is a special purpose joint venture vehicle seeking to develop, register, manufacture, licence and supply a patent-protected phentermine hydrochloride product in tablet form. Further details regarding the proposed acquisition can be found at **Attachment A.**

The ACCC's investigation is focused on the impact on competition. In particular, we are seeking your views on:

- whether, and to what extent, iNova and Juno PC's products are likely to compete absent the proposed acquisition
- whether a generic phentermine product is likely to commence supply in Australia
- what alternative weight loss solutions compete with phentermine based weight loss medication.

Further issues you may wish to address are set out in **Attachment B**.

This matter is public and you can forward this letter to anybody who may be interested.

The legal test which the ACCC applies in considering the proposed acquisition is in section 50 of the *Competition and Consumer Act 2010*. Section 50 prohibits acquisitions that are likely to have the effect of substantially lessening competition in a market.

Please provide your response by no later than <u>5pm on 13 September</u>. Responses may be emailed to <u>mergers@accc.gov.au</u> with the title: <u>Submission re: iNova / June PC - attention</u>

Adrian Hughes/Andy Gallagher. If you would like to arrange a time to discuss the matter with ACCC officers, or have any questions about this letter, please contact Adrian Hughes on 03 9658 6545 or Andy Gallagher on 02 9230 9129.

Updates regarding the ACCC's investigation will be available on the ACCC's Public Mergers Register at (ACCC mergers register).

Confidentiality of submissions

The ACCC will not publish submissions regarding the proposed acquisition. We will not disclose submissions to third parties (except our advisors/consultants) unless compelled by law (for example, under freedom of information legislation or during court proceedings) or in accordance with s155AAA of the *Competition and Consumer Act 2010*. Where the ACCC is required to disclose confidential information, the ACCC will notify you in advance where possible so that you may have an opportunity to be heard. Therefore, if the information provided to the ACCC is of a confidential nature, please indicate as such. Our *Informal Merger Review Process Guidelines* contain more information on confidentiality.

Yours sincerely

Tom Leuner General Manager

Merger Investigations

Attachment A

iNova

iNova is a pharmaceutical company which develops, markets and sells a range of prescription medicines and non-prescription pharmacy products to over 20 countries across Asia, Australasia, and Africa.

iNova supplies products primarily in the areas of:

- weight management
- pain management
- dermatology
- cardiology
- respiratory health
- allergy.

iNova currently supplies three pharmacotherapy products for weight loss:

- Duromine—a branded, prescription-only, phentermine based medication in the form of a capsule. It works by suppressing hunger and stimulating energy expenditure by directly affecting the area of the brain that controls appetite
- Metermine—a generic version of Duromine, and
- Contrave—a naltrexone hydrochloride and bupropion hydrochloride medication. It works by suppressing appetite and reducing food cravings.

Details of the broader range of products supplied by iNova in Australia can be found at https://www.inovapharma.com.au

Juno PC

Juno PC is a special purpose joint venture vehicle seeking to develop, register, manufacture, licence and supply a patent-protected, branded phentermine hydrochloride product in the form of a tablet. The product is in the development phase, and currently in the process of Therapeutic Goods Administration (**TGA**) review.

Juno PC is partially owned by Juno Pharmaceuticals Pty Ltd (**Juno Pharma**) which specialises in hospital and speciality post-patent pharmaceuticals.

Details of the broader range of products supplied by Juno Pharma in Australia can be found at https://www.junopharm.com.au

The proposed acquisition

iNova is proposing to acquire 100% of the shares in Juno PC.

Competitive overlap

iNova and Juno PC will overlap (once Juno PC's product enters the market) in the supply of prescription weight loss medication, containing phentermine as an active ingredient.

The active ingredient, phentermine, is an amphetamine. Amphetamines indicated for obesity are classified within the EphMRA ATC31 A08A class (anti-obesity preparations, excluding dietetics).

Attachment B

Questions for all market participants

- 1. Please provide a brief description of your business or organisation.
- 2. Please outline the reasons for your interest in the proposed acquisition, including any commercial relationship/s you have with either iNova or Juno PC (or their related companies).
- 3. Identify iNova's closest competitors for weight loss solutions, in particular its Duromine product.
 - Please describe these competitors including whether they supply products with a similar action or effect to iNova, and whether they compete through a particular distribution channel, such as pharmacies or hospitals.
- 4. Please discuss whether, and to what extent, the following types of weight loss products compete with iNova's phentermine based products (Duromine and Metermine):
 - a. class A08A products (including Saxenda, Contrave etc.)
 - class A06A products (diet formulations for treatment of obesity, including Optifast etc.)
 - c. class V06D (other nutrients for weight loss)
 - d. any other products or services you consider relevant, for example bariatric surgery.
- 5. What impact do you think a new phentermine based product from Juno PCwould have on iNova's phentermine based products (if the proposed acquisition does not proceed), including in relation to price?
- 6. In the absence of the proposed acquisition, how could Juno PC bring its product to market? For example, could Juno PC partner with any other market participant to market and distribute its product?
- 7. Are patients likely to switch to or from alternative products and/or services in response to a change in the price of phentermine based weight loss medication? In your answer, please consider the costs involved in patients switching and any history of such switching.
- 8. Please discuss the likelihood of new entry into the supply of A08A class pharmaceuticals.

In your response please have regard to:

- a. costs and time required to develop and supply a new product
- b. scale required to be competitive
- c. importance of brand and customer relationships
- d. intellectual property and licensing
- e. regulatory approvals
- f. exclusivity arrangements

- g. any differences between branded and generic entry
- h. any examples of recent or failed entry, and
- whether the proposed acquisition would impact the likelihood of new entry.

Questions for customers (pharmacies and wholesalers)

- Please describe your organisation's supply of prescription, over the counter (OTC) or off-the-shelf weight loss products. Outline the specific types of products you supply, how you source these, how they are utilised by customers, and volumes/value of your supply.
- 10. Please identify and describe other suppliers of prescription and OTC weight loss products or off-the-shelf weight loss products, including the extent to which they compete with iNova. Relevant factors may include product ranges, scale, brand recognition, product quality or service standards. Please provide specific examples where possible.
- 11. Please address the extent to which there are pharmacy chains with the ability to bypass supply from the combined iNova/Juno PC, by compounding phentermine products, establishing direct importation arrangements, or sponsoring new entry.

Questions for doctors or medical bodies

- 12. In relation to iNova's weight loss products (Duromine, Metermine and Contrave), please comment on your ability to replace them with different products or services, having regard to each product or service's:
 - a) clinical use and treatment profile
 - b) mode of administration and design
 - c) active ingredient, and
 - d) side effect profile.
- 13. If the price of phentermine-based medication were to change, how would this affect your recommendations to patients?

Would you recommend alternative pharmacotherapy medication or other treatment options to your patients if the price were to rise? Conversely, would you recommend phentermine based medication over other treatment options if the price were to lower?

Questions for competitors

- 14. Please describe the products or services your business supplies with the therapeutic effect or purpose of weight loss.
- 15. Who do you consider to be your closest competitors in the supply of weight loss products or services? Please have regard to pricing, non-price incentives, range, types and sizes of customers, tendering activity, distribution capacity, brands, service and quality.

Other information or competition issues

16. Please provide any additional information or comments, or identify other competition issues, that you consider relevant to the ACCC's consideration of the proposed acquisition under section 50 of the Act.