HIGH COURT OF AUSTRALIA

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Details of Filing

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Important Information

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY **No. S20 of 2026**

BETWEEN:

OTSUKA PHARMACEUTICAL CO., LTD
First Appellant

H. LUNDBECK A/S
Second Appellant

LUNDBECK AUSTRALIA PTY LTD
Third Appellant

OTSUKA AUSTRALIA PHARMACEUTICAL PTY LTD
10 Fourth Appellant

and

SUN PHARMA ANZ PTY LTD
Respondent

AMICUS CURIAE'S OUTLINE OF ORAL SUBMISSIONS

Part I: Certification

1. This submission is in a form suitable for publication on the internet.

Part II: Outline of oral submissions

2. **Purpose of the PTE regime**. The purpose of the PTE regime is to balance a range of competing interests, including the significant public interest in the unrestricted use of a pharmaceutical substance after the expiration of the patent term: *Alphapharm* at [60], [120]. The regime is also intended to provide a level of certainty to third parties as to length of the patentee's monopoly: *Alphapharm* at [120].

3. That balance and certainty is achieved by calculating an extension of term under s 77 of the Act by reference to objective facts and not by reference to subjective choices within the control of a patentee: *Ono* at [137]; *MSD* at [79].

4. **Construing "*pharmaceutical substance*" as a formulation undermines the purpose of the PTE regime**. By construing "*pharmaceutical substance*" as including formulations, the operation of the PTE regime could be dictated by subjective matters within a patentee's control.

5. For example, a patentee could choose to file successive patents for different formulations of the same API, characterising each as a distinct "*pharmaceutical substance*" for the purpose of successive extension of term applications. Further, if a patentee already enjoys protection for the API via an earlier patent, the Appellants' construction would create a structural incentive (contrary to the public interest) for a patentee to defer seeking regulatory approval for later formulations. This is because increased delay between the date of the patent and regulatory approval for that formulation would increase the extension available: *cf* Appellants' Reply (**AR**) [41].

6. By contrast, the construction advanced by Sun Pharma ensures the PTE regime operates by reference to objective facts, being the earliest first regulatory approval date of an API, whatever the formulation and irrespective of whether a patentee chooses to file successive patents for alternative formulations of that same API.

7. **Additional and alternative construction: a formulation is not a pharmaceutical substance *per se*.** Even if a "*pharmaceutical substance*" includes a mixture of an API and excipients (AR [10]), that does not answer the question posed by s 70(2)(a) of the Act, which requires identification of a "*pharmaceutical substance per se*".

8. That composite expression was introduced by the 1998 Amendment Act. The stated intent was to ensure that, "[c]*laims which limit the use of a known substance to a particular environment... are not considered to be claims to pharmaceutical substances per se.*": 1998 REM at [9]. That exclusion was separate to the additional express exclusion of "*method/process claims*": 1998 REM at [10], *cf* AR [53].

9. **The meaning of "*pharmaceutical substance per se*"**. The Respondent contends, and GBMA supports, that the parenthesised words in the definition of "*pharmaceutical substance*" extend only to a mixture or compound of active substances, each of which must meet the requirements of the definition: RS [32]-[34]. But even if the Court considers that the parenthesised words do more than that, it does not follow that those words "*clarify that a substance may be made up of multiple substances*": *cf* AR [12]. There is an intermediate position that the parenthesised words expand the definition of "*pharmaceutical substance*" to include matters (i.e., "*a mixture or compound of substances*", relevantly, an API and excipients) which are not encompassed by "*a substance*", but do not modify the meaning of "*a substance*".

10. On that alternative construction, even if a "*pharmaceutical substance*" includes a mixture of an API and excipients by reason of the parenthesised words, it remains the API alone that is "*a substance...for therapeutic use whose application...involves a chemical interaction, or physico-chemical interaction with human physiological system...*". It is that substance, by or in itself, that constitutes a "*pharmaceutical substance per se*" for s 70(2)(a).

11. This construction is consistent with the observations of this Court in *Alphapharm* at [23] fn 40 that, "... *the extension of term scheme under the Act covers standard patents for pharmaceutical substances per se pursuant to s 70(2)(a), hence patents for ... tablets do not fall within the scheme.*" A tablet, like any formulation, is an API in a particular environment (being the excipients and/or dosage form: FCJ [260]).

12. Whether a formulation is conceptually akin to a "*patent for a pharmaceutical method of delivery*" (*Cipla* at [176], [184]) or a product administered by reference to another product (*Boehringer* at [37]-[42]), it is a mixture of an API and excipients. It is not a "*pharmaceutical substance per se*".

Dated: 16 June 2026

Name: Kate Beattie