Australian Patent Term Extensions - Pharmaceutical Substance Combinations

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Two recent cases before the Australian Patent Office highlight what can be a problem area when seeking to extend patent term under the Australian Patents Act 1990.

The issue in these cases was whether the products as disclosed and claimed in the patents in question were "pharmaceutical substances" within the meaning of the Australian Patents Act 1990. In particular, the issue was whether those products as claimed were "substances (including a mixture or compound of substances)" for therapeutic use as provided in the definition given in Schedule 1. In both cases, the substances claimed were combinations of a substance having a therapeutic effect together with other components.

Section 70 of the Act provides that the patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements

set out in subsections (2), (3) and (4) are satisfied. Relevantly here, section 70(2)(a) provides that:

"one or more pharmaceutical substances per se must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification"

“Pharmaceutical substance” is defined in Schedule 1 of the Act to mean:

"a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:
(a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or
(b) action on an infectious agent, or on a toxin or other poison, in a human body; but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing"

The meaning of the words "pharmaceutical substance per se" in s 70(2)(a) was interpreted by the Full Federal Court in *Boehringer Ingelheim International GmbH v Commissioner of Patents* [2001] FCA 647, as limiting applications for extension of patent term to patents disclosing and claiming a pharmaceutical substance "by or in itself, intrinsically, essentially" or "taken alone; essentially; without reference to anything else". Thus the words "per se" had a clear limiting effect. In *Pharmacia Italia SpA v Mayne Pharma Pty Ltd* [2006] FCA 305, the Federal Court considered the question of substances comprising a number of components. The Court found that it was not necessary that all chemical entities within that combination be therapeutically active. It is the substance as a whole that must meet the requirements for therapeutic action or interaction within the

definition of a pharmaceutical substance.

A "pharmaceutical substance per se" can include a claim to a compound in combination with other elements if, as a whole, it can still be considered a “pharmaceutical substance”. However, a claim to a substance which combines a compound with a separate physical device, layer or structure may not be considered to be a “pharmaceutical substance”. Therefore, how the invention is disclosed and claimed in the patent in question can be critical in whether or not an extension of patent term can be obtained.

In the first case, *N. V. Organon* [2009] APO 8 (28 May 2009), the patentee applied for an extension of term of its Australian patent No. 726934 based on the inclusion of NUVARING® on the Australian Register of Therapeutic Goods. If allowed, the patent term would be extended from 8 April 2018 until 27 June 2021.

NUVARING® is a vaginal drug delivery system for the steroids etonogestrel and ethinyloestradiol. A key aspect of the invention was that the steroidal mixture in the delivery system was contained in a thermoplastic polymer core over which was laid a permeable thermoplastic skin.

Claim 1 of AU726934 read:

"A drug delivery system comprising at least one compartment which comprises a thermoplastic polymer core and a thermoplastic polymer skin covering the core, said core comprising a mixture of a steroidal progestogenic compound and a steroidal estrogenic compound in a ratio by weight that allows a direct release from the said polymer of both the said progestogenic compound and the said

estrogenic compound in physiologically required amounts, said progestogenic compound being initially dissolved in the said polymer core material in a relatively low degree of supersaturation, said estrogenic compound being dissolved in the said polymer core material in a concentration lower than that of the said progestogenic compound, and said thermoplastic skin being permeable for the said progestogenic and estrogenic compounds"

The Deputy Commissioner of Patents held that:

(1) as the steroidal components are mixed with and necessarily diffuse through the thermoplastic materials in the core and skin regions; and
(2) as the product as a whole exhibits a level of integration or interaction between the component parts that was considered more characteristic of a pharmaceutical substance in itself rather than a substance combined with another element or thing;
(3) the combination met the requirements of a "pharmaceutical substance per se".

Consequently the application to extend the term of AU726934 was allowed.

In the second case, *LTS Lohmann Therapie-Systeme AG and Schwarz Pharma Limited* [2009] APO 16 (21 August 2009), the patentee applied for an extension of term of Australian patent No. 746856 based on the inclusion of NEUPRO® on the Australian Register of Therapeutic Goods. If allowed, the patent term would be extended from 18 March 2019 until 22 November 2022.

NEUPRO® is a transdermal therapeutic system (transdermal patch) for the known active ingredient (rotigotine). It includes an acrylate or silicone based non-aqueous polymer adhesive compound into which rotigotine free base is able to be dissolved to enable transdermal application. Transdermal administration of rotigotine via a patch is known, but the key to the invention lies in the matrix

formulation which allows the transdermal administration of the active, free base form of rotigotine.

Claim 1 of AU746856 read:

"A pharmaceutical compound for the treatment of disease adapted to be transdermally administered to a patient in need of said treatment comprising:
an effective amount of a free base (-)-5,6,7,8,tetrahydro-6-[propyl[2-(2-thienyl)-ethyl]amino]-1-naphthol and an acrylate or silicone based non-aqueous polymer adhesive compound, wherein the solubility of the (-)-5,6,7,8,tetrahydro-6-[propyl[2-(2-thienyl)-ethyl]amino]-1-naphthol base is greater than or equal to 5% (per weight); and
a backing layer, which is inert to the (-)-5,6,7,8,tetrahydro-6-[propyl[2-(2-thienyl)-ethyl]amino]-1-naphthol base and the adhesive compound, having a protective layer, which is to be removed prior to administration of the pharmaceutical compound to the patient"

The Deputy Commissioner of Patents found that the pharmaceutical compound as claimed comprised three components - a polymer matrix containing rotigotine, an inert backing layer and a protective layer. As the protective layer needed to be removed before use, the Deputy Commissioner of Patents held that this protective layer constituted a separate integer, and consequently the claimed pharmaceutical compound, as a whole, was not a "pharmaceutical substance".

The application to extend the term of AU746856 was therefore not allowed.

The two cases highlight that when the invention is a combination of a substance having a therapeutic effect together with other components, the combination as a whole can still be considered a “pharmaceutical substance per se”. The drafting of the patent specification and claims in such cases is critical if there is an

intention to apply for patent term extension and should not require the presence of an integer that is not integral with the requirements for therapeutic action of the pharmaceutical substance.