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“Independent promises” – Australia’s Full Federal Court provides further guidance on exclusive licences

John Collins, Sumer Dayal (Clayton Utz) · Friday, September 16th, 2016

On 9 September 2016, the Full Federal Court of Australia delivered its judgment in *Actavis Pty Ltd v Orion Corporation* [2016] FCAFC 121 (**Actavis**). The proceedings concerned the infringement/revocation of a patent for Stalevo, Novartis’ 3-in-1 Parkinson’s disease drug.

A related issue was whether Novartis Pharma AG (**Novartis**) was the exclusive licensee of Orion’s 765932 patent and had the right to sue for infringement in these proceedings. The Full Court also considered whether Novartis Australia had standing under an exclusive sub-licence from Novartis.

The Full Court dismissed both the appeal against infringement and the challenge to Novartis’ standing to sue. The challenge to Novartis Australia’s standing was accepted.

Exclusive licences in Australia

Section 120(1) of the Patents Act provides that either the patentee or an exclusive licensee have standing to commence infringement proceedings under the Act.

Previously, the Full Court in *Bristol-Myers Squibb Company v Apotex Pty Ltd* [2015] FCAFC 2 (**BMS**) upheld Justice Yates’ ruling at first instance that the grant of an ‘exclusive licence’ meant an exclusive licence to undertake all of the activities within the meaning of “exploit” as defined in the Patents Act. That is, there could be no reservation of rights on the part of the patentee, or any other person, to undertake any activity falling within the definition of “exploit”. In that case, Otsuka had reserved the right to manufacture the product in Australia. Consequently, BMS was not an “exclusive licensee”.

In the *Actavis* case, the applicants similarly argued that Orion’s agreement to supply finished product, or active pharmaceutical ingredients, to Novartis meant that the arrangement did not constitute an exclusive licence.

However, the Full Court affirmed Justice Rares’ decision at first instance, finding that the agreement between Orion and Novartis was an exclusive licence due to:

- **the terms of the licence** – as held at first instance, clause 1 of the agreement (the grant of an exclusive licence) and clause 2 (Novartis’ agreement to purchase Stalevo products exclusively from Orion, or a party authorised by Orion, as consideration) were “independent promises”. Clause 1 granted the exclusive licence while clause 2 determined how product was to be

supplied;

- **context** – Orion and Novartis had purposefully entered into the licence to cure deficiencies in their previous agreement (identified in *BMS*) and to ensure that Novartis had the status of an exclusive licensee under the Act for infringement proceedings. The Full Court found this to be of “considerable significance”; and
- **no temporal constraints in section 120(1)** – contrary to the applicants’ submission, there was nothing in section 120(1) that required a licence to be of a specific duration, or be a licence that could not be terminated by an agreed event.

It is safe to say that Australian law is now very clear on this issue.

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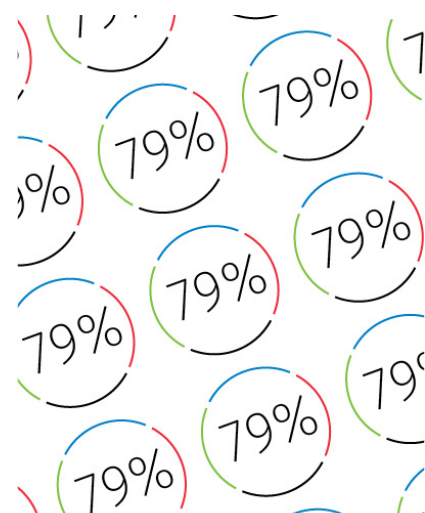
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