



BUSINESS GUIDE SERIES:

CASE NOTE: ACTAVIS PTY LTD V ORION CORPORATION [2016] FCAFC 121

EXCLUSIVE LICENCES IN AUSTRALIA REVISITED - A TIMELY REMINDER TO PATENTEES AND LICENSEES TO REVIEW THEIR LICENSING ARRANGEMENTS IN AUSTRALIA

On 9 September 2016, the Full Federal Court of Australia handed down its judgment in *Actavis Pty Ltd v Orion Corporation* [2016] FCAFC 121. The decision provides further practical guidance on the requirements for drafting an effective exclusive license of a patent so as to ensure that it constitutes an effective “exclusive” license agreement. It serves as a timely reminder to patentees and licensees that they should review the terms of their licensing arrangements so as to ensure that they meet the relevant requirements under Australian law.

Background facts - Licensing Arrangements

The proceedings relate to infringement/revocation of a patent for a 3-in-1 Parkinson’s disease drug known as Stalevo. Orion Corporation (**Orion**), the first respondent on the appeal, was the patentee. Orion and Novartis Pharma AG (**Novartis**), the second respondent on the appeal, had formal commercial arrangements in place since 2000.

The agreement was a licence, supply and distribution agreement for the product which contained the three active pharmaceutical ingredients, in all territories excluding the USA and Europe (Rest of World “**ROW**” Agreement). The ROW Agreement effectively granted Novartis a number of exclusive rights, but that expressly reserved manufacturing rights for Orion. The ROW Agreement provided Orion with a right to terminate the ROW Agreement in the event that Novartis decided to manufacture or distribute a product that would compete with the product.

In light of the landmark decision *Bristol-Myers Squibb Company v Apotex Pty Ltd* (2015) 228 FCR 1 (**BMS v Apotex**), on 7 March 2014 Orion granted a new licence of the patent to Novartis. The new licence agreement described the rights granted to Novartis as:

an exclusive licence under the Patent from the date of the grant thereof to exploit (as that term is defined in Schedule 1 to the Patent Act 1990)... to the exclusion of all other persons (Clause 1)

Clause 2 of the 2014 agreement provided that, in consideration of the rights granted under Clause 1, Novartis “*undertakes to purchase the Products and the active ingredients that are contained in the products, exclusively from Orion or a party authorised by Orion*”.

Crucially, the licence agreement did not reserve any of the patent rights for Orion (i.e. the right to manufacture). The same commercial effect was achieved by Novartis promising to purchase the products the subject of the patent from Orion as consideration for the licence. On 11 March 2014, Novartis granted a sub-licence to the third respondent, Novartis Pharmaceuticals (Australia) Pty Limited (**Novartis Australia**).

Proceedings in the Court below – is there an exclusive license and what is the standing of the Novartis parties to sue?

In the Court below, Orion, Novartis and Novartis Australia (**Novartis parties**) alleged that Actavis Pty Ltd (Actavis) had threatened to infringe various claims of the patent by seeking to market in Australia, certain pharmaceutical products, referred to collectively as the Actavis products. Actavis, and its related company Media Pharma Pty Ltd (the **Actavis parties**) argued that the new licence arrangement was not sufficient to give the Novartis parties standing to sue.

It argued that there was no exclusive licence on the basis that the 2014 licence agreement simply confirmed Novartis' existing distributorship rights, which excluded the right to manufacture. The Actavis parties submitted that Orion had, by virtue of the wording contained in Clause 2, reserved itself the exclusive right to manufacture the three active pharmaceutical ingredients, because Orion was entitled to terminate the ROW Agreement if Novartis manufactured the product which, in turn, would result in the termination of the 2014 licence agreement. This was an agreed fact between the parties.

It was common ground between the parties that the Novartis parties did not have standing under the previous agreement. Actavis denied infringement and cross-claimed for revocation of various claims of the patent.

On 21 August 2015, the primary judge (Rares J) published reasons for judgment in which he found that all the challenged claims were valid and that Actavis had threatened to infringe some of the claims of the patent: see *Orion Corporation v Actavis Pty Ltd* [2015] FCA 909.

On 16 September 2015, the primary judge published reasons for judgment which contained a Confidential Exhibit, in which his Honour provided more detailed reasons for the finding that Actavis had threatened to infringe a particular claim (Claim 17) of the patent: *Orion Corporation v Actavis Pty Ltd* (No.2) [2015] FCA 1026.

On 4 December 2015, the primary judge published reasons for judgment in which he made certain findings about the legal effect of both the recent licence agreement and sub-licence agreement under the Patents Act 1900 (Cth) (the Act) and the standing of each of Novartis and Novartis Australia to sue for infringement: *Orion Corporation v Actavis Pty Ltd* (No. 3) [2015] FCA 1373. Relevantly, his Honour said that the parties had chosen terminology in accordance with the Patents Act 1990 (Cth) in which to express the nature and extent of the exclusive licence. The commercial result that the parties desired was to create an exclusive licence arrangement, including granting Novartis the right to sue under s.120(1) of the Act.

In consideration of Clause 2, his Honour rejected the argument of Actavis that Clause 2 had the effect of altering the grant of the exclusive licence, pursuant to Clause 1. His Honour held that each clause was an independent promise. In respect of Actavis' argument that by virtue of Novartis entering third party agreement, it had breached the agreement, his Honour rejected this, being firmly of the view that an exclusive licensee may need to contract with third parties for the supply of goods or services that the exclusive licensee wishes to use in order to exploit the exclusive licence, and that any such third party is irrelevant.

In respect of Novartis Australia's position, Rares J held that by virtue of the 2014 sub-licence, Novartis Australia had the exclusive right to exploit the patent in Australia. He deemed that agreement to have the effect of being an assignment of rights to Novartis Australia by the exclusive licensee in accordance with the provisions of the Act. It followed, his Honour held, that "as the legal assignee of the statutory right, Novartis Australia, together with the assignor (Novartis) and the patentee, had title to sue Actavis, and that Novartis Australia was a proper and necessary party to the claim and the cross-claim": at [62]. The effect of the finding would be that s.120(1) does not preclude persons other than the patentee or exclusive licensee from bringing infringement proceedings.

The Actavis parties appealed the decision.

The Appeal

On appeal, the Full Court (Allsop CJ, Nicholas and Yates JJ) **unanimously** upheld the primary judge's finding that the licence granted to Novartis was an exclusive licence. Accordingly, Novartis had standing to sue the Actavis parties for patent infringement. However, on the issue of whether Novartis Australia had standing to sue, the Full Court overturned the primary judge's decision.

The Full Court held that the primary judge erred in finding that s.120(1) was merely indicative of who may sue for infringement, instead finding that that provision was specific as to who may sue – the patentee or an exclusive licensee. Further, the Full Court accepted that neither the 2014 licence or the sub-licence involved an assignment of rights that effectively passed from Orion to Novartis Australia. Accordingly, as Novartis Australia was not an exclusive licensee (because it did not hold a licence from the patentee), it had no standing to sue for infringement. However, because Novartis Australia did have certain rights to exploit the patented invention within Australia, the Full Court found that this was a sufficient enough interest to engage s.139(1) of the Act. Thus, Novartis Australia was a proper party on the cross-claim: *Actavis Pty Ltd v Orion Corporation* [2016] FCAFC 121 at [249]-[252].

Lessons

The decision of the Full Court provided some helpful guidance to patentees and licensees as to what will constitute an exclusive patent licence under Australian law as follows:

- A licensee must be granted all the rights to “exploit” the patent to the exclusion of all others, including the patentee itself, in order to be an “exclusive licence”.
- An exclusive licensee who has been granted all of the rights to “exploit” a patent in Australia may agree with another party (including the patentee) as to how those rights are to be exercised.
- Any promises by the licensee relating to the exercise of the rights granted to it under the licence agreement (for example, an agreement to purchase) should be drafted as a stand-alone “promise” and not as a condition of the exclusive licensee’s right to exploit the patented invention.
- Sub-licensees will not be exclusive licensees for the purpose of s.120(1) of the Act, if there is no assignment of rights from the patentee and will not have standing to sue in those circumstances.
- Licensees and patentees should review their licence agreements to ensure that they do, in fact, meet the necessary requirements under Australian law.

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