AUSTRALIA: WHY YOUR 'EXCLUSIVE' PATENT LICENSE MAY NOT LONGER BE EXCLUSIVE AND WHAT TO DO TO FIX IT

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Life Sciences Alert

By: Simon Casinader

Two recent decisions in Australia have made patent licensees and licensors take another look at their 'exclusive' licences for Australia to determine whether or not they are truly exclusive.

The impact of these decisions is significant, diluting licences which were previously believed to be 'exclusive', to the status of 'non-exclusive', thereby denying licensees the ability to enforce licensed patent(s) in Australia.

Simple amendments to patent licences may redress this impact and savvy patentees/licensees in Australia are amending their agreements accordingly.

EXCLUSIVE/NON-EXCLUSIVE LICENSEE: WHAT'S THE BIG DEAL?

Only an exclusive licensee or the patentee in Australia has the right to enforce a patent in the Courts, seeking remedies for infringement. Whether a licensee is an 'exclusive' or 'non-exclusive' licensee is of great significance – providing or denying a 'seat at the table' in patent enforcement.

Infringement occurs when an unauthorised person exploits the patented invention. The definition of 'exploit' in the *Patents Act* includes (where the invention is a product): make, hire, sell/dispose of, use, import and keep. These are the rights of a patentee under the *Patents Act*, which may be licensed to another person, either exclusively (to the exclusion of the patentee and any other person) or non-exclusively.

Previously, patent licences were considered to be 'exclusive' where the patentee licenses rights to the licensee to do certain acts covering certain parts of the patent to the exclusion of others, (including the patentee). For example, a licence to 'sell, use and keep' would have been considered exclusive, provided the right was granted to the exclusion of all others.

This is no longer the case.

In light of the decision of the Full Court of the Federal Court of Australia in Bristol-Myers Squibb Company v Apotex Pty Ltd [1] (BMS) in early 2015, a licence must provide exclusive rights to exploit (ie make, hire, sell/dispose of, use, import and keep) in order to be truly exclusive.

As a result, many licences intended to be 'exclusive' are now rendered 'non-exclusive', stripping licensees of their ability to enforce the licensed patent(s).

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WHAT OF THE PATENTEE WHO DOES NOT WISH THEIR LICENSEE TO BE ABLE TO MANUFACTURE?

A decision handed down at the end of last year (Orion Corporation v Actavis Pty Ltd (No 3) [2]) (Orion), confirmed that this may be contractually redressed.

In Orion, the patentee granted a licence to exploit the invention (as defined in the Patents Act), but the licence also included a term under which the licensee agreed to purchase product from the patentee's designated supplier.

On the one hand, the licensee had the 'right' to make the product, but on the other hand, they agreed that they would not make it, but would purchase the product from the patentee's supplier.

Justice Rares agreed that the licensee in Orion was an exclusive licensee because it had the 'right' to exploit the invention, irrespective of any agreement regarding product supply.

The decision in the Orion case has been appealed, and the Appeal was heard by the Full Court on 15 and 16 February 2016. Given the importance of this issue, we believe an appeal to the High Court may follow, giving the highest Court in the land the opportunity to weigh in on this important issue. If the matter is appealed to the High Court, we can expect a final decision by mid to late 2017.

WHAT DOES THIS MEAN FOR LICENSEES/LICENSORS IN THE MEANTIME?

In the meantime, patentees and licensees in Australia run the risk of not having their commercial intention worked out in the marketplace, as many 'exclusive' licences will be held to be 'non-exclusive' in light of the BMS decision.

Now is the time to take another look at your 'exclusive' licences and determine whether it might be appropriate to amend those licences to address the BMS decision. In light of Orion, simple amendments can be made to such licences to ensure that commercial intentions regarding exclusivity are appropriately reflected.

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[1] [2015] FCAFC 2

[2] [2015] FCA 1373

KEY CONTACTS



SIMON CASINADER
PARTNER

LONDON
+44.20.7360.8256
SIMON.CASINADER@KLGATES.COM

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