SLAUGHTER AND MAY/

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PATENT RIGHTS TRUMP TORTIOUS ONES IN PHARMACEUTICAL CASE

One of the unique features of registered intellectual property (IP) rights is that once granted, they are never completely immune from challenge. Indeed, an almost automatic response to the threat of enforcement action by an IP rights holder is to attack the validity of the underlying registered IP right. But what happens if an IP right is later found to be invalid? Can tort law help those who are adversely affected by previous enforcement actions in the meantime?

The Supreme Court has recently had to consider these issues in relation to a pharmaceutical patent, a generic medicine and the UK National Health Service (NHS): *Secretary of State for Health v Servier Laboratories Ltd* [2021] UKSC 24. Once a patent has expired or been declared invalid, then others are free to use the invention that is the subject of the patent. This is particularly relevant with pharmaceutical patents, where generic manufacturers seek to create the equivalent medicine at a lower cost. Not surprisingly, the NHS likes generic medicines as they are cheaper for the UK taxpayer.

Servier and its EP for perindopril

In 2001, Servier filed for a European Patent for the heart medication known as 'perindopril'. The European Patent Office (EPO) granted the patent in 2004. The granted patent was challenged during the opposition period, but in 2006, the EPO upheld its validity. Servier then used the patent against generic manufacturers to prevent them from selling the equivalent medicine more cheaply to the NHS - Servier obtained an injunction against Apotex and settled with many other generic manufacturers including Teva, Krka and Lupin (and it is worth noting that the latter "pay-for-delay" settlement type agreements have been subject to scrutiny by competition regulators).

In 2007, the patent was challenged again in the UK Courts: both the High Court (in 2007) and the Court of Appeal (in 2008) found that the patent was invalid due to lack of novelty or, alternatively, was obvious with respect to another existing patent. In 2009, the EPO followed suit and revoked Servier's patent. With the patent knocked out in the UK and centrally at the EPO, the UK and European markets were open to a generic equivalent of perindopril.

In 2011, the Secretary of State for Health ("SOSH") brought a claim against Servier alleging that Servier, in enforcing its patent rights, had deceived the EPO and the UK courts as Servier knew of (or was recklessly indifferent to) the patent's lack of novelty and/or obviousness. As generic manufacturers were prevented from entering into the market at an earlier stage, Servier could charge higher prices to the NHS. SOSH claimed that this amounted to the tort of causing loss by unlawful means, and claimed damages and interest in the region of £200m.

As stated by Lord Hoffmann in the leading case of *OBG Ltd v Allan* [2007] UKHL 21, loss by unlawful means "consists of acts intended to cause loss to the claimant by interfering with the freedom of a third party in a way which is unlawful as against that third party and which is intended to cause loss to the claimant" and does not include acts that "may be unlawful against a third party but which do not affect his freedom to deal with the claimant."

So did Servier commit the unlawful means tort? The High Court, the Court of Appeal and now the Supreme Court have said no. This was on the basis that the EPO and/or the UK Courts did not have any dealings with SOSH.

What did the Supreme Court decide?

There were two issues before the Supreme Court:

(1) *whether it was a necessary element of the unlawful means tort that the unlawful means should have affected the third party's freedom to deal with the claimant (known as the "dealing requirement" in the OBG decision)*

Yes. First, the rationale for the unlawful means tort is to preserve a person's liberty to deal with others. Second, it is also clear from the *OBG* judgment that the dealing requirement is an essential element of the tort and is consistent with the authorities in which liability for the unlawful means tort was established (which all involved dealings). In particular the Court was concerned to keep the tort within "reasonable bounds" and the dealing requirement ensures that there is a sufficient nexus between the parties. Looking at other Commonwealth jurisdictions, Australia (*Hardie Finance Corpn Pty Ltd v Ahern (No 3)* [2010] WASC 403), Canada (*A I Enterprises Ltd v Bram Enterprises Ltd* (2014) SCC 12), New Zealand (*Intellihub Ltd v Genesis Energy Ltd* [2020] NZHC 807) and Singapore (*Wolero Pte Ltd v Lim* [2017] SGHC 89), have also interpreted the *OBG* decision as imposing a dealing requirement.

(2) *if yes, whether the dealing requirement should be departed from*

SOSH contended that the dealing requirement is undesirable because it narrowly restricts the interest protected by the tort to the claimant's economic interest in the third party's freedom to deal or trade with the claimant. SOSH also claimed this requirement is unnecessary because the other elements of the tort are adequate to explain the existing authorities and to keep the tort within reasonable bounds. SOSH then invited the Court to "refashion" the tort.

The Supreme Court refused to depart from the test for loss by unlawful means as set out in the *OBG* judgment.

First, SOSH did not provide any real life examples of the dealing requirement causing difficulties, creating uncertainty or impeding the development of the law. In particular, SOSH failed to show that any lies were being told by Servier about SOSH or its property or anyone they dealt with. The alleged lie is about Servier's own purported invention and SOSH failed to address the risk of creating indeterminate liability if it is extended to claimants, such as public authorities, who have no dealings with the third party.

Second, the Supreme Court did not accept any of the three attempts by SOSH to 'refashion' the tort. In general, this was because the SOSH tried to leave out fundamental requirements of the *OBG* test (i.e. the dealing requirement). SOSH also suggested partially adopting an alternative test of loss by unlawful means as proposed by Lord Sales and Professor Davies in their 2018 Law Quarterly Review article (which the Court ultimately rejected as it did not include the dealing requirement and partial adoption would make the test incoherent and unsustainable).

What does this mean for parties affected by the enforcement of IP rights later found to be invalid?

The Supreme Court's confirmation of the dealing requirement emphasised the importance of having a control mechanism on the unlawful means tort, especially as it permits recovery for pure economic loss and by persons other than the immediate victim of the wrongful act. The dealing requirement minimises the danger of there being indeterminate liability to a wide range of claimants. Indeed as the High Court noted, to allow SOSH to succeed in their claim would have meant that health authorities, all potential generic competitors who suffered loss through their inability to supply the generic version due to the patent, and private medical expenses insurers who paid higher prices for reimbursement could all potentially have a claim. And not only could these claimants be in the UK but also in Europe.

Removing the dealing requirement could also have stifled future R&D - if companies could be faced with wide-ranging liability implications in circumstances where their patent be found to be invalid, they might think twice about obtaining and defending their patents.

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