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Should High stay, for EPO? Actavis and Pharmacia clash in the High Court

Mr Justice Arnold in the Patents Court of the High Court of England and Wales (the 'Patents Court') initially refused a request by the patentee, Pharmacia, for a stay of UK revocation proceedings brought by Actavis, pending the outcome of opposition proceedings at the EPO based on three undertakings. When Pharmacia then offered additional undertakings, which "substantially eliminate the commercial uncertainty to which Actavis will be exposed in the UK as a result of a stay", the stay was then granted in a second decision.

These two decisions apply the guidance recently provided by the Court of Appeal of England and Wales in *IPCom v HTC*, as to when UK proceedings should be stayed pending the outcome of opposition proceedings at the European Patent Office (EPO). Although *IPCom v HTC* introduced the notion that the default position should be to grant a stay of the UK proceedings, this is another case where the initial request for a stay was refused when all factors were considered.

Staying UK proceedings

Once granted, the validity of a European patent may be challenged centrally at the EPO (in the nine months after grant), and also in each country in which the patent has been validated (at any time). In some countries, such as Germany, national revocation proceedings are stayed automatically while an EPO opposition is pending. However, in the English courts this is determined on a case-by-case basis taking into account all relevant circumstances. Initially in the current case, when all relevant factors were taken into account, the result was finely balanced but the stay was refused.

The relatively low cost of EPO proceedings compared to national proceedings is highlighted in the present case (with estimates of around £1million to £1.8million for each side's costs for first instance proceedings in the English Patents Court, compared with EPO oppositions costing "a fraction of these amounts"), but the potential for such "wasted costs" was outweighed by the longer time that it takes to obtain a final decision at the EPO, and the commercial uncertainty that would be prolonged by a stay.

Background

Pharmacia's patent, EP1536792, relates to sustained release dosage forms of pramipexole suitable for once daily administration for the treatment of Parkinson's disease and restless leg syndrome (patent protection for pramipexole itself having expired). The patent is exclusively licensed to Boehringer Ingelheim GmbH, and will not expire until 2023.

With the intention of launching a generic sustained release form of pramipexole, Actavis commenced revocation proceedings (against the UK patent) in the High Court on 3rd April 2014, having already filed an opposition to the patent at the EPO on 14th October 2013 (which was well before the opposition deadline). Actavis had also applied for a marketing authorisation for a generic sustained release form of pramipexole, which it expects to be granted before June 2015. Despite this clear threat to infringe the patent, Pharmacia had not yet counterclaimed for threatened infringement.

Pharmacia requested a stay of the UK revocation proceedings pending the outcome of the EPO opposition and in doing so offered three undertakings: (a) to seek expedition of the EPO proceedings, (b) not to seek an injunction against Actavis or its customers until the determination of the EPO proceedings, and (c) only to seek damages of 1% of Actavis' net sales during the period from launch until the determination of the EPO proceedings if the patent is held valid both by the EPO and by the English courts. Actavis opposed the stay.

The first decision

The relative timing of the national and EPO proceedings was an important factor in the present decision. Actavis commenced its UK revocation action relatively soon after its opposition was filed at the EPO, and well before the end of the opposition period. The judge, Mr Justice Arnold, estimated that the UK proceedings would take around two years to be resolved (including an appeal), but that even expedited proceedings at the EPO would take at least three years to resolve, and potentially longer.

A delay of at least three years to the UK proceedings would therefore be caused by a stay, if the EPO were to reject the opposition. Of course if the EPO revoked the patent then the UK patent would cease to exist and there would be no resumption of national proceedings.

Pharmacia's view was that the delay in commercial certainty that would be caused by staying the UK action was eliminated by the undertakings not to seek an injunction until the determination of the EPO proceedings and only to seek limited damages during the EPO proceedings (which were estimated at around £189,000 based on selling at 90% of Pharmacia's average price and a market share of 50%). Actavis argued that the undertakings did not mitigate the risk that it would start to market its product and subsequently be restrained from doing so, resulting in damage to its commercial position.

Actavis also noted the difficulty of predicting the market five years ahead of time and that there may be an effect from further generic competitors.

Arnold J found the considerations to be finely balanced, but determined that the delay that would be caused by a stay would result in unacceptable commercial uncertainty for Actavis. Arnold J considered that Pharmacia's undertakings did not go quite far enough to eliminate commercial uncertainty for Actavis in the UK if the national proceedings were stayed, even though they allow Actavis the benefit of ensuring that it can get onto the market; the undertakings did not address the uncertainty caused by the prospect that Actavis may be removed from the market by an injunction at a later date, at which point the limited damages referred to in Pharmacia's undertakings would not apply. This, he said, would "have a chilling effect" on Actavis' investment decisions.

So, despite some factors in this case favouring a stay, including the risk of potentially wasted costs arising from the UK proceedings (estimated to total in excess of £2.5million), the stay was refused to reduce commercial uncertainty. Arnold J also notes that refusal of a stay is supported by the possibility that an English decision may promote a settlement and by the public interest in determining the validity of the patent.

The second decision

This was not the end of the story, as a postscript to the first judgment notes that after receiving the judgment in draft, Pharmacia offered two additional undertakings in return for a stay of the UK proceedings. Pharmacia offered (i) not to seek an injunction in the UK against Actavis or its customers in relation to Actavis' sustained release pramipexole product during the life of the patent and (ii) only to seek damages of 1% of Actavis' net sales in the UK during the life of the patent if the patent is ultimately held valid by the EPO and valid and infringed by the English courts. These additional undertakings were enough to tip the balance in favour of a stay, on the basis that the commercial uncertainty to which Actavis will be exposed in the UK as a result of a stay was substantially eliminated.

Practical implications

It is clear from this case that claimants seeking to revoke a UK patent when an EPO opposition is pending, and avoid a stay of the national proceedings, should not delay in starting the national proceedings. Even an estimate of only three years for the conclusion of the proceedings at the EPO was considered to cause unacceptable commercial uncertainty for Actavis. However, if the claimant had delayed its UK action by, say, a year then the timings of the EPO and UK proceedings would start to align and a stay would seem to be more likely.

For patentees wishing to obtain a stay of UK revocation proceedings in favour of the vastly lower cost of opposition proceedings at the EPO, careful consideration must be given to the undertakings that they are prepared to offer, to eliminate the commercial uncertainty that a stay would cause.

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Need advice?

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This briefing note was first published in the IAM IP Newsletter.

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