No stay as Alzheimer antibody patent proceeds to trial

Kluwer Patent Blog
March 18, 2016

Brian Cordery (Bristows)

Please refer to this post as: Brian Cordery, 'No stay as Alzheimer antibody patent proceeds to trial', Kluwer Patent Blog, March 18 2016, http://patentblog.kluweriplaw.com/2016/03/18/no-stay-as-alzheimer-antibody-patent-proceeds-to-trial/

Case reported and summarised by Gregory Bacon, Bristows LLP
The UK does not operate a system of automatically staying proceedings which concern validity of a European patent where there are ongoing opposition proceedings at the EPO. Nevertheless, the Court retains discretion to stay such proceedings, and a recent judgment of Mrs Justice Rose on 18 February 2016 illustrates the principles applied.

In *Eli Lilly v Janssen*, Eli Lilly brought an action to revoke specified claims of a divisional patent in Janssen's name and for a declaration of non-infringement in relation to its solanezumab product. Solanezumab is an antibody proposed to be used in the treatment of Alzheimer's disease. The timing of the parent and divisional patents is important to the application and is therefore set out here.

The UK designation of the parent to the patent in suit had already been revoked by the English Patents Court for insufficiency (the patentee's appeal to the Court of Appeal was withdrawn before it could be heard) in June 2013. Also in June 2013, the EPO Opposition Division had held the parent to be invalid for insufficiency although that decision is subject to an appeal to the Technical Board of Appeal with the hearing scheduled for May 2016. The divisional patent in suit was granted shortly after the UK judgment at first instance, and oppositions to its grant have been filed. The oral hearing before the Opposition Division is scheduled to take place in June 2016, with both the parent and divisional patents expiring in November 2018.

The patentee Janssen applied for an order that the proceedings brought by Eli Lilly be stayed pending the decision of the EPO in the opposition proceedings against the divisional patent. In deciding the application, Mrs Justice Rose considered the factors set out by Lord Justice Floyd in *IPCom v HTC* [2013] EWCA Civ 1496, the leading case on whether to stay English patent proceedings pending EPO oppositions. In that case, the Court of Appeal stated that if there are no other factors, a stay of the national proceedings is the default option as there is no purpose in pursuing two sets of proceedings simply because the EPC allows it.

In an attempt to limit to the prejudice to Eli Lilly, and following the approach of the patentee in the *Actavis v Pharmacia* case [2014] EWHC 2265 (Pat), Janssen offered the following undertakings: (i) to support the expedition of the EPO proceedings; (ii) not to seek any injunction for the duration of the patent and any SPC that may be granted; and (iii) if validity is upheld, not to seek damages other than on a reasonable royalty basis. These mirrored the undertakings that had persuaded Mr Justice Arnold to grant the stay sought by the patentee in the *Actavis v Pharmacia* case, albeit that Janssen did not put a figure in this case on the royalty that it would seek if the patent was held to be valid and infringed.

In the Judge's view, the advanced stage of the EPO proceedings and the likelihood that any appeal from the decision of the Opposition Division on the divisional patent will be accelerated (the appeal in respect of the parent patent was accelerated on request) were factors in favour of a stay given the English proceedings are at an early stage (the claim was issued on 2 December 2015 and the Defence filed on 13 January 2016). The Judge also noted that Eli Lilly could have started the revocation action earlier than it did.

Against that, Eli Lilly relied on three factors to support its argument that there was still a sufficient degree of commercial uncertainty if the stay was granted, even with the undertakings offered, to override the default position of granting a stay:

1. The existence of the claim for a declaration of non-infringement, as if there is a finding of non-infringement that would be the end of the matter regardless of the result at the EPO. It was not suggested by Janssen that the issues regarding infringement would be insubstantial if the case went ahead. Although this was an important factor in favour of refusing a stay the Judge said it was not determinative.

2. The importance to Eli Lilly of knowing where they stood in relation to any future application by Janssen for a supplementary protection certificate (SPC). It was unlikely that Janssen will receive a marketing authorisation for a product exploiting the patent before patent expiry on which to base an application for an SPC. However, case law supported (although the Judge noted that the point was not beyond doubt) that a patentee could apply for an SPC on the basis of a third party marketing authorisation. It might therefore be in Eli Lilly's advantage not to obtain a marketing authorisation prior to patent expiry if it wished to launch post expiry otherwise they could trigger an SPC which would result in an additional five years of royalties if the patents are held to be valid and infringed. Eli Lilly therefore wanted to know whether to submit the application for approval with the EMA in the first quarter of 2017 or whether they should delay, as once the application is submitted it was argued that it would be very difficult to apply the brakes to the EMA process and delay grant of the authorisation until after patent expiry.

3. Janssen could not say what the reasonable royalty rate would be. That also compounded the uncertainty created by the second factor relating to a potential SPC based on Eli Lilly's own marketing authorisation application.

Taken together, these factors favoured a refusal to grant the stay sought, which is what the Judge ordered.

Eli Lilly had also sought to rely on two additional factors. The first was the value of an exportable judgment. In *TNS Group Holdings v Nielsen Media Research*, it was held that it is legitimate for a claimant to seek to obtain a judgment on the validity of a European patent in the UK in the hope that it would lead to settlement throughout Europe and that it is also legitimate to seek to rely on that judgment in other European courts or at the EPO. The Judge only considered this to be a neutral point given that, if the EPO revoked both patents, those rulings would resolve all such disputes. Eli Lilly also pointed to the public interest in dispelling uncertainty because of the very great benefit their product might bring to patients. Again, the Judge did not consider this to be a weighty factor given that Janssen had offered undertakings which would ensure that Eli Lilly's product would come to market (if approved).