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The Future of UK PIs – Cyanamid, Skat and injunction creep

Claire Phipps-Jones (Bristows) · Tuesday, July 2nd, 2024

The recent rivaroxaban PI cases may have caused you to ask yourself whether the American Cynamid principles for determining whether or not to grant preliminary injunctive relief in the UK are dead or at least dying. In this article we consider the facts of the rivaroxaban PI applications and aim to tease out some principles of general applicability.

Firstly, it is worth remembering that the American Cynamid principles from the House of Lords decision in 1975 provides for a staged, gated approach for PI relief, which focuses more on economic factors and the balance of justice than the merits of the case. It's also worth noting that the rivaroxaban case is somewhat unusual. Multiple generic companies sought to invalidate a dosage regime patent in order to "clear the way" for launch on 1 April 2024 when SPC protection based on a compound patent for rivaroxaban expired. While the trial on the merits of the validity of the dosage regimen patent had been heard by that date, the trial having taken place in February 2024, the a first instance decision had not yet been handed down, which ultimately precipitated 3 consecutive preliminary injunction applications brought by the patentee, Bayer.

The first application was for an injunction pending an order made following the first instance decision. At the hearing of the first PI application, HHJ Hacon gave an indication that the judgment on the merits of the validity of the dosage regimen patent would be handed down 9-10 days after the PI hearing. Despite Bayer's suggestion that the relevant period when considering whether to grant an injunction should be deemed to be much longer (i.e. the period to judgment on appeal, in light of Bayer's intention to appeal any negative decision), Judge Hacon considered that the application notice itself concerned only an injunction for a period of 9-10 days. Acknowledging the apparent importance of the American Cyanamid principles, he also gave permission for Teva to rely on economic expert evidence to support its case on the quantifiability of each party's loss.

Noting the "*short and crucial point*" that the injunction period was limited to 9-10 days, Judge Hacon found that no great deal of irreparable harm would occur to either party in that period and that Bayer's loss would be "*fairly easy to calculate*". However, despite this seemingly positive finding for the generics on the American Cyanamid principles, which suggested that the balance of justice lay in refusing the PI since damages would be an adequate remedy for the patentee, he granted the injunction as a result of the Court of Appeal's[1] emphasis on the "*importance of maintaining the status quo*", which he considered to be all the more important given the short duration. Interestingly, at the same hearing, Judge Hacon gave permission for Bayer to respond to Teva's economic expert evidence and rely on that response in any injunction request that followed the hand down of the first instance decision.

The first instance decision was then handed down invalidating the patent, permission to appeal was refused and immediately following that, the second injunction application made by Bayer was heard. This time, it was an application for an injunction pending determination of the application to the Court of Appeal for permission to appeal and, if granted, pending determination of the appeal. That request altered during the hearing to be either an injunction pending determination for permission to appeal or for a limited period of 14-21 days (requiring the Court of Appeal to extend the period as it saw fit assuming that there was no decision on permission during in that time). Despite having previously granted Bayer permission to adduce evidence on the American Cyanamid principles, Judge Hacon was solely concerned with the principles arising in the affectionately nicknamed "Skat" case *(*Skatteforvaltningen (the Danish Customs and Tax Administration) v Solo Capital Partners LLP *[2021] EWHC 1683 (Com) 7216)* noting that the *"American Cyanamid principles must cede to the overriding requirement that the Court of Appeal should be put in the best position to do justice between the parties when a decision on permission to appeal is made"*. And so a further injunction was granted[2] for a period of approximately 16 days, along with a requirement that Bayer seek expedition of their application to the Court of Appeal. Interestingly, the scope of the injunction at this stage was limited to sale or supply (being the acts that would actually cause harm to the patentee), rather than other 'infringing' acts e.g. offer.

Roll on Bayer's next injunction request, this time to the Court of Appeal, for an injunction pending determination of the application to the Court of Appeal for permission and, if granted, pending determination of the appeal. Permission to appeal was granted and the case was expedited, with the court requesting that the hearing be listed some 17 days later. In granting a further injunction to cover that short intervening period, Arnold LJ considered that the *"balance of the risk of injustice favours the continuation of the injunction, in particular because doing so will preserve the status quo, for the relatively short period until the appeal can be heard and determined on an expedited basis."*. For completeness, the Court of Appeal upheld the decision to revoke Bayer's dosage regime patent at the end of the hearing which took place 17 days later.

The upshot of this case is that if the period for which a preliminary injunction requested is short, absent some significant event in the intervening period, it seems likely that maintaining the status quo will play a substantial role in judicial thinking. It also demonstrates the Court of Appeal's ability to move swiftly and decisively in circumstances where the commercial situation requires it, both in terms of its decision on PI relief and also on the merits.

One wonders whether this line of PI decisions, which ultimately maintained an injunction on an invalid patent for over an month with an estimated value of tens of millions of pounds to Bayer, bolsters the pro-patentee approach developed in Novartis v Hospira in 2013. In the Novartis case, the Court of Appeal decided to award a PI to Novartis pending an appeal notwithstanding a finding of invalidity by the first instance judge following the trial. The Novartis case was viewed by some as something of a one-off, where the patent had been held invalid because of a lack of entitlement to priority coupled with a disclosure in the priority year which clearly disclosed the invention in the patent; absent the priority ruling, the patent was considered inventive at first instance By contrast, the rivaroxaban case led to a finding of obviousness, which is an issue on which the trial judge is unlikely to be overturned absent a manifest error in approach. One sensible school of thought is that the safest option now is to clear the way sooner, with a view to obtaining a Court of Appeal decision prior to launch. That does rather require some crystal ball gazing: when will the first instance trial be listed? (within a year as proposed by the guidelines, or longer which seems to accord with realistic listing windows); when will the decision be handed down? (sometime

between 1 month and a year post hearing); when will the court accede to the requests of a party to obtain a decision by a given date? (as proposed by Judge Hacon, but equally with acknowledgement that *"it may or may not be possible for a preferred deadline for the handing down of a judgment to be met"*); will the patentee appeal? will they be willing to offer the cross-undertaking required in order to obtain a preliminary injunction and, if so, will and by how much will the Court of Appeal expedite? On the commercial side any challenger will want to be as certain as they can be that they will be ready to launch at the time that the relevant IP is held to be invalid, including but not limited to having a valid UK marketing authorisation. If there is one thing worse than not being able to launch a product having spent considerable sums on legal fees invalidating any IP potentially standing in the way, it is to do those things and watch your competitors launch whilst you are not yet ready do so.

Perhaps more interesting to the broader PI landscape is the court's willingness to allow economic evidence of the *American Cyanamid* principles (and how relevant such evidence will be to the ultimate decision). Should this now be the standard expectation for preliminary injunction requests? In cases where the injunctive relief is requested for a longer period, will we see a shift towards judges critically evaluating the quantifiability of each party's losses, not only in tender markets (as has recently been successfully argued), but also in the primary care markets, as was the case here?

One rather expects that there will be more argument on the scope and duration of the injunctive relief sought. Perhaps patentees will consider applying incrementally for short injunctions to align with Skat, an approach which has some tension with arguments on the American Cyanamid principles where unquantifiability of damages is likely to be easier to support over a prolonged period. One might also expect argument on the harm of each infringing act, with patentees in future cases resisting any narrowing of the scope to supply/sale given any likely chilling effect on sales in the short term.

While this line of cases does not yet mark the end of the American Cyanamid era, it seems that the PI landscape in the UK is in a period of flux, with exciting times, and argument, ahead.

Bristows represented Teva in the rivaroxaban case and Novartis in the Novartis v Hospira case mentioned in the text.

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[1] Particular reliance was placed on Neurim v Generics (UK) *[2002] EWCA Civ 370.*

[2] *[2024] EWCA Civ 852*

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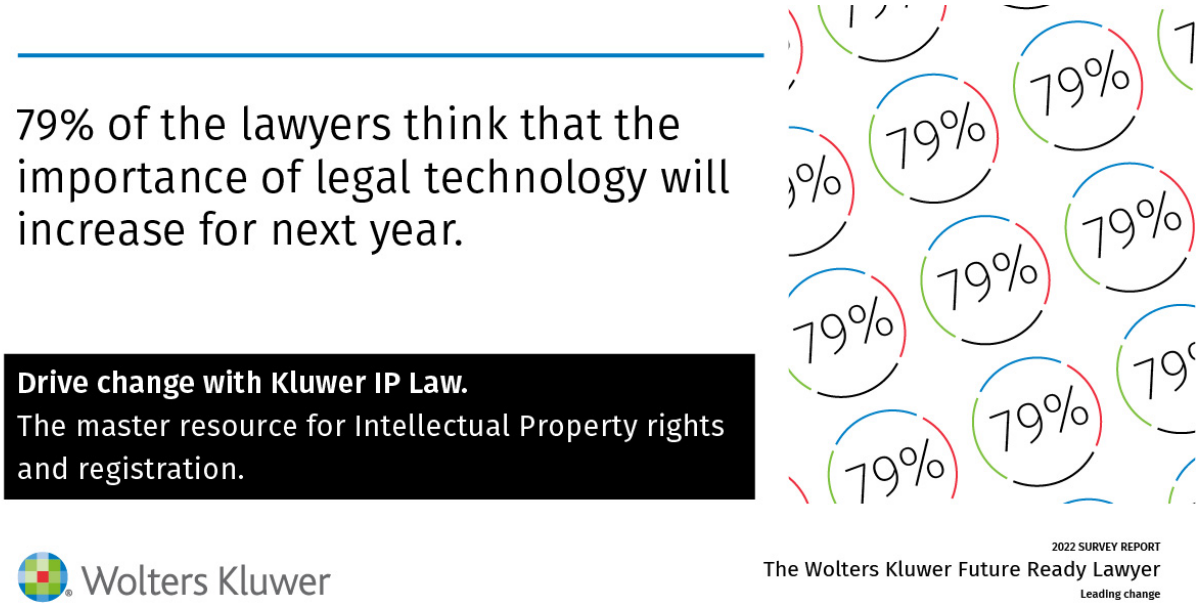

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