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AIPPI Milano – UPC mock trial

Dominic Adair (Bristows) · Wednesday, September 21st, 2016

The final morning of the AIPPI Milano Congress contained a blockbuster, 4-hour, 3-part session on Brexit and the UPC: “Panel Session IX: Patent – The UPC – Brexit or business as usual?” The structure and panellists for the session were as follows:

Part 1 – Brexit implications for the UPC Moderator: Thierry Calame, Lenz & Staehelin (CH) Speakers: Daniel Alexander QC, 8 New Square, Intellectual Property (UK) Margot Fröhlinger, Principal Director of patent law and multilateral affairs, European Patent Office Clemens Heusch, Nokia Solutions & Networks GmbH & Co KG (DE) Thierry Sueur, Vice-President, Intellectual Property and Vice-President, European & International Affairs, Air Liquide / Chair, Patents Working Group, Business Europe (FR)

Part 2 – UPC Mock trial Moderator: Thierry Calame, Lenz & Staehelin (CH) Judges: Mr Justice Carr, High Court (UK) Judge Rian Kalden, Court of Appeal, The Hague (NL) Chief Judge Marina Tavassi, IP Division, Court of Milan (IT) Dr. Matthias Zigann, Presiding Judge, Munich Regional Court (DE) Counsel: Christof Augenstein, Kather Augenstein (DE) Peter-Ulrik Plesner, Plesner – Copenhagen (DK) Mark Van Gardingen, Brinkhof, Amsterdam (NL) Annsley Merelle Ward, Bristows (UK)

Part 3 – Q&A Moderator: Alan Johnson, Bristows (UK)

In brief, the Brexit debate covered the thorny question of whether, and if so when, the UK will ratify the UPC Agreement, and, if not, what will become of the UPC project. Unsurprisingly, there were strong views expressed that the UK should not only ratify, but do so quickly. Margot Fröhlinger took the view that if the UK does not do so quickly, the rest of Europe would not wait and that the UPC could come into effect without the UK by amending the UPC Agreement with “a couple of small technical changes”. It seemed to be common ground among the panellists that all wanted the UPC system to succeed and that industry wished the UK to be part of the system. The worst of all worlds would be an in-and-then-out scenario in which the UK allowed the ship to set sail but then got thrown overboard. There were pleas to take a logical, not emotional approach (Daniel Alexander QC) and to approach the issue rationally, avoiding a “project” mentality. In direct contradiction, others said clearly that Brexit should not be allowed to derail what was very much a European project (Thierry Sueur).

The debate having set the scene, the meat of the session came with the UPC mock trial. The aforementioned judges and counsel had been provided with a factual scenario beforehand, available via the AIPPI website (http://aippi.org/panel-session-ix-background-documents/). This

was a preliminary injunction application before the local Italian division of the UPC in the context of a biosimilar product making preparations to launch in the face of two patents, a dosage regimen patent and a formulation patent relating to a fictional fusion protein called rantracept. The defendant/respondent (biosimilar) had started a national revocation action against both patents in Italy, in order to torpedo the jurisdiction of the UPC, and the claimant/applicant (patentee) had already lost its dosage regimen patent in France but succeeded in maintaining the patent at the EPO Opposition Division and in Germany and the UK.

The first instance proceedings dealt with several issues: jurisdiction, validity and infringement, the test for a preliminary injunction and whether a cross-undertaking in damages should be awarded. On the jurisdiction issue, the claimant asserted that the local Italian revocation action did not torpedo the jurisdiction of the UPC because lis pendens only applies to cases on the merits – here, a preliminary measure such as a PI is permitted by Article 35 of the recast Brussels Regulation. The UPC Local Division is counted as the court of a contracting member state. Furthermore there is no risk of conflicting decisions because PI applications and revocation actions do not share the same subject matter. The defendant countered that the UPC local division cannot be carved out of the wider UPC jurisdiction – a court for all countries – and that lis pendens is very much a block on the PI action proceeding in the UPC. Both sides acknowledged that a reference was required to the CJEU on the issue; the defendant maintained that the UPC should not grant the PI in the meantime, the claimant asked the court to grant the PI and then stay the case, pending resolution of the reference.

On the validity and infringement issues, the claimant took the position that the patents should be presumed valid for the purpose of the PI application, pending adjudication by the Italian national court. It said that the formulation patent required the product in liquid form; the defendant's dry powder product would infringe this when reconstituted as a solution. The claimant also argued that the dosage regimen patent should be interpreted purposively such that the function of the molecule as an anti-TNF inhibitor is taken into account (although not so far as to say that any molecule that worked would be infringing). Furthermore, biologic products are never identical, even within batches of innovator product, so a certain amount of variability would be understood by the skilled addressee. The defendant countered that rantracept means rantracept and biosimilars were not within the scope of the claim.

On the question of whether or not the preliminary injunction should be granted, the claimant argued that the initial merits test should ask whether the patent is more likely than not to be infringed. It also argued that it would suffer irreparable harm owing to price competition with the defendant upon launch. The claimant was willing to provide a cross-undertaking provided it was limited to the defendant and did not include any loss sustained by third parties. The defendant argued against a threshold test on the merits of the infringement issue, noting that Art 9(3) of the Enforcement Directive required "a sufficient degree of certainty", a burden that lies on the claimant. On the irreparable harm point, the defendant pointed out that the market dynamics for biosimilars are very different to small molecules such that aggressive competition on price is not expected.

Giving judgment extempore for the court, Mr Justice Carr decided that an Italian national revocation action could not torpedo the jurisdiction of the UPC to grant PIs (a decision he admitted was driven by policy). Article 35 of the recast Brussels regulation makes it clear that the UPC can grant PIs because the UPC is treated as a member state. Any doubt on this issue is resolved by the CJEU decision in Solvay v Honeywell which provides a clear analogy. There is no identity

between the causes of action so no risk of irreconcilable judgments. No stay need be granted under Article 29 of the recast Brussels Regulation for this reason. Accordingly, the court could deal with the PI application.

On the merits question within the test for granting a PI, Carr J was not persuaded that there was a sufficient degree of certainty that the patent was invalid, despite the revocation decision in France (the defendant was criticised for not producing for the benefit of the court a written copy of the French decision). Carr J acknowledged that the infringement question was the most difficult. When considering what evidence a "sufficient degree of certainty" requires, context is key. A PI application should not require very much. Although the defendant was right to rely on Art 54 UPCA as shifting the burden of proof for infringement onto the claimant, the burden could shift back again. Here, crucially, the defendant had failed to provide any evidence on the ways in which its biosimilar product was different to the originator product. It was common general knowledge that biologic products carry with them a certain amount of variability and hence the claims would be interpreted accordingly. Were it to be any different, patents such as the dosage regimen patent in suit would not be infringed by biosimilars and would therefore be toothless. On the formulation patent, the reconstitution of the defendants dry powder into a solution also was likely to constitute infringement (direct, or more likely indirect infringement).

On the balancing of the parties' interests, the court found that a price spiral could still take place and cause irreparable harm, even with a duopoly in the marketplace. The claimant had delayed in seeking relief for 2 months but this was not a problem given that one of the months was August when Continental Europe tends to shut down.

As to the cross-undertaking, Carr J noted that the court would not have granted the PI had the undertaking not been offered. Particularly because the lack of evidence on product differences for the purpose of the infringement assessment meant that there was a reasonable chance that the defendant might prevail at trial. The quantum of the cross-undertaking was set as the value of the dispute. The rules of procedure did not permit the cross-undertaking to be ordered for the benefit of third parties.

Hence, the court granted the preliminary injunction sought. It's scope was set to encompass any acts of manufacture in any member state in which the patent had effect.

During the course of the coffee break that followed, the defendant lodged an appeal with the UPC Court of Appeal, staffed by Chief Judge Marina Tavassi of Milan (who has recently been appointed to the Italian Court of Appeal in real life).

The key point on appeal was whether new evidence could be admitted, and, in particular, evidence to show that the claimant's expert witness had been untruthful in providing his evidence by omitting mention of an inventive step-destroying disclosure at a conference before the priority date. Judge Tavassi refused to admit the evidence for a number of reasons, including the basis that it would not be determinative of the dispute because it concerned only one of the two patents in suit.

The session concluded with a question and answer session moderated by Alan Johnson of Bristows, the Brexit panellists and the judges returning to the stage. Interestingly, Carr J noted that he would have probably come to the same decision in the UK court as he did in the UPC. Judge Zigann from Munich noted that he would not have granted the PI if sitting in his home court

because the Munich court has a upper threshold of one month for delay in bringing a PI application. Judge Kalden found it difficult to say if her decision would have been the same if sitting in the Netherlands as the case was somewhat artificial. Nevertheless, at least on the appeal question, she noted that the evidence could have been heard because in the Netherlands an appeal hearing deals with the case de novo.

The final questions of the morning returned to the issue of Brexit and the UPC and, in particular, how much time the UK is likely to need before reaching a decision on ratification. It was agreed that UK ratification in the short term was not a realistic prospect. Daniel Alexander QC suggested that to do the necessary due diligence around the issue may only take a few extra months – and hence a UK ratification in late summer next year might be possible. However, Margot Fröhlinger disagreed that any further research on the issue was required. She cautioned that if the UK drags its feet for too long, the issue will become wrapped up with the wider Brexit negotiations and hence the momentum will be lost. Dr Fröhlinger asserted once again that time is of the essence and that if the UK does not board the ship, it will be left at the dockside.

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This entry was posted on Wednesday, September 21st, 2016 at 10:23 am and is filed under Brexit, UPC
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