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Herceptin Round 2: Hospira enjoys the sweet smell of success once more

Brian Cordery, Steven Willis (Bristows) · Monday, December 1st, 2014

Regular readers of the Kluwer patent blog may recall that in April 2014, the English Patents Court revoked two patents relating to trastuzumab, the active ingredient in Herceptin, which is marketed outside of the US by Roche. One patent was for a dosage regimen and the other related to a composition of trastuzumab containing certain levels of impurities. The SPC for trastuzumab itself subsequently expired in July 2014, but as yet, Hospira has not launched its competing medicine in the UK. As part of its campaign to clear the way for launch, Hospira challenged two further related divisional patents – this time relating to lyophilised formulations of trastuzumab – and in a decision handed down on 21 November 2014, the Court has again found for Hospira.

As the evenings continue to draw in across the northern hemisphere, Birss J's decision may provide thought-provoking fireside reading for patent enthusiasts. Although at a shade under 40 pages, the decision is comparatively short by modern English standards, it is densely packed with issues of law. The judgment covers several areas which are commonly addressed such as common general knowledge and added matter but also considers areas which are not commonly raised such as the interpretation of product-by-process claims and the permissibility of amendments alleged to extend the protection conferred by the patent.

There are at least a dozen points in the judgment which are worthy of comment. However, this short report will briefly consider just three:

(i) Construction

Birss J observed *obiter* that it was not settled as to whether Swiss-type claims should be construed as product or process claims. He did confirm, however, that "treatment" is a functional technical feature of the claim and therefore the claims should be construed not merely as suitable for the specified use, but intended for that use.

On the construction of "product-by-process" claims, Birss J identified the inconsistency in the House of Lords decision in *Kirin Amgen* [2005] that the scope of the claim is apparently different for novelty as opposed infringement/sufficiency, but did not depart from that analysis as it is binding on him under English rules of precedent.

(ii) Obviousness

Birss J accepted as an established principle that information that is not in the cited prior art nor

common general knowledge (CGK) may be taken into account as part of a case on obviousness if it can be shown that the skilled person would acquire that information as a matter of routine when attempting to solve the problem to which the patent is addressed. Furthermore, he held that the law of obviousness cannot be accurately summarised simply by stating the could/would test; the issue is multifactorial and based closely on the particular circumstances. Thus, although it could not be said that the skilled team would arrive at the patented formulation, the Judge held that the fact that the differences between the invention and the prior art were the result of the application of routine screening techniques to excipients which formed part of the CGK by a skilled team with a motivation to solve the technical problem identified by the patent was enough to render the patents obvious.

The multifactorial analysis was neatly encapsulated by Kitchin J in **Generics v Lundbeck** [2007] in the following way: "*The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success*". This passage is almost universally quoted in UK inventive step decisions and seems as a matter of principle to be correct.

It also seems correct that the "could/would" test should not be the be-all and end-all. However, in the authors' view, this should not be taken too far, particularly in the life sciences field, and the comments of Kitchin LJ in the Medimmune [2012] case that: "*there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research*" must be borne in mind.

(iii) Importance of Cross-examination

One of the major issues in the case was the extent to which the idea of using the sugar trehalose as a possible lyoprotectant for proteins was part of the common general knowledge. Hospira contended that it was, Genentech disagreed and naturally each side's expert witness expressed a corresponding position. In his decision, Birss J set out an extract from the cross-examination of Genentech's expert where he was asked to leave toxicology concerns on one side and, on that basis, consider whether he agreed that that if the expert was looking for a non-reducing lyoprotectant at the priority date, the common general knowledge would be that trehalose was just as good as sucrose and potentially better? The expert simply answered "yes" to this leading question asked on an assumption. In placing reliance on this passage, the Judge made it very clear that he was not taking the statement in isolation or acontextually but rather than it reflected "*in summary form the view the professor had been expressing throughout his cross-examination about trehalose*". This serves as a useful example of the English system – the prospect of cross-examination ensures that the parties prepare their evidence in a fair and balanced manner. Further, cross-examination may, and often will, bring out issues that would not have been in play were the case decided on the papers alone. On the other hand, an expert will invariably have ploughed hundreds of hours into the preparation of his or her expert report and, in the intense setting of the trial, often after a long-session of questioning from the advocate for the other side whose job it is to put the case for his client to the expert, it could be unfair to place too much reliance on an answer

to a single question – particularly if the question is complicated or asked on an assumption or both. Thus it must be right that Birss J stepped back to consider the overall position as well as the quotation given in the judgment.

It is not yet known if Genentech will appeal this decision although the earlier decision from April has been appealed and is currently pending.

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This entry was posted on Monday, December 1st, 2014 at 3:24 pm and is filed under Biologics, Inventive step, Second Medical Use, United Kingdom, Validity
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