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Generics [UK] Ltd (trading as Mylan) v Yeda Research and Development Co. Ltd and Teva Pharmaceutical Industries Ltd [2013] EWCA Civ 925

Brian Cordery (Bristows) · Thursday, September 12th, 2013

Introduction

In my previous [post](#) of 2 August 2013 I made passing reference to the recent decision of the English Court of Appeal in the Copaxone litigation. This case was an appeal of the decision of Arnold J (previously reported [here](#)) where he found Yeda's patent valid and infringed. With permission of the court, Mylan appealed that decision.

Background facts

Yeda is the registered proprietor (and Teva is the exclusive licensee) of EP (UK) 0 762 888 (the "Patent") relating to a synthetic copolymer known as copolymer-1. Teva markets a product containing copolymer-1 under the brand name Copaxone, which is used for the treatment of relapsing-remitting multiple sclerosis (the most common type of MS where symptoms appear and then fade away, either partially or completely). At first instance, Mylan sought revocation of the Patent (based on obviousness over a number of prior publications, obviousness for lack of a technical contribution and insufficiency) and a declaration of non-infringement. As mentioned above, Arnold J refused Mylan both forms of relief.

Mylan's arguments on appeal

Mylan argued as follows:

- (1) Certain claims of the Patent were obvious over a publication referred to as "Johnson 1994";
- (2) The Patent was invalid for obviousness on the basis of a lack of a technical contribution because:
 - a. The specification did not make it plausible that the technical problem which it described was solved by products falling within the claims; or
 - b. Alternatively that problem was not in fact solved by products falling within the claims;
- (3) Mylan's competing product did not infringe the Patent because the copolymer did not conform to the claimed ratio of amino acids on a proper construction of the claims; and
- (4) If the Patent was not construed as Mylan contended then it was invalid for ambiguity-type insufficiency.

The lead Court of Appeal judgment was provided by Floyd LJ (with Kitchin and Moses LJJ in agreement).

Obviousness over Johnson 1994

At first instance, Arnold J had concluded that Mylan's case had been based on hindsight. Floyd LJ considered that the judge had been entitled to reach his opinion based on the evidence before him – there had been no “logical fallacy in the judge's approach” – and accordingly he rejected Mylan's ground of appeal. Floyd LJ's approach is consistent with the usual approach to obviousness that the Court of Appeal will only interfere with the trial judge's findings if an error of principle has been made.

Obviousness on the basis of a lack of a technical contribution

Arnold J had held that where a specification made it plausible that the invention solved the technical problem, it was not open to a party applying for a revocation to rely upon post-dated evidence to cast doubt on this. Floyd LJ found it helpful to review EPO and UK case law in order to understand Arnold J's decision on this matter and in so doing concluded that “*I respectfully disagree with the judge when he concluded that it was not open to Mylan to challenge an effect made plausible by the specification...I cannot see any principled objection to the admission of evidence as to the true nature of the advance made by the invention in connection with an objection of lack of inventive step*”. However, Floyd LJ continued that the mere fact that the primary technical contribution relied upon by the patentee is negated by evidence does not inexorably lead to a conclusion that the patent is obvious – the applicant for revocation would still have to persuade the court that the invention was obvious and do so by reference to what the skilled team would have known and done at the priority date. Floyd LJ held that Arnold J had been entitled to reach a conclusion that a technical contribution was made plausible by the specification and that Mylan had failed to prove that a difference in molecular weight made no difference to the effect of the copolymer-1. Accordingly, this ground of appeal was rejected.

Construction/insufficiency

The question of construction concerned what the skilled person would understand the patentee to mean by “*a molar ratio of approximately 6:2:5:1*”.

Mylan contended at first instance and on appeal that the word “approximately” covered compositions in which the molar fraction of any single amino acid did not differ from those percentages by more than $\pm 10\%$ of their value or if that was not correct, then the Patent failed to provide any criterion by which to determine what was covered by “approximately” and thus was ambiguous.

Yeda's contention was that the word “approximately” reflected that the copolymer-1 is a random copolymer whose composition is not precisely defined. At first instance Arnold J concluded that “approximately” was intended to cater for variations in both amino acid analysis and the copolymer-1 synthesis.

On appeal, Floyd LJ concluded, “*I think that there is very little difficulty over the question of construction. The parties are agreed that the skilled team would understand the patentee to be using the term “approximately 6:2:5:1” to allow for variations in amino acid analysis and variability in copolymer synthesis...It did not matter that the skilled person would not have known from their common general knowledge how to quantify the maximum degree of variability. That was a question of evidence.*”

Regarding insufficiency, Floyd LJ rejected Mylan's contention, holding “*Mylan's difficulties do not arise because the claim is ambiguous, but because they failed to establish that the differences*

between their product and one which has an amino acid molar ration of 6:2:5:1 could not be attributed to errors of amino acid analysis or copolymer synthesis”.

Infringement

At first instance, Arnold J had made a positive finding of non-infringement. Floyd LJ considered that he could not go that far on the evidence before the Court. However he agreed that Mylan had not adduced sufficient evidence to justify a declaration of non-infringement.

Commentary

This Court of Appeal decision is likely to come to be regarded as an important ruling on lack of technical contribution obviousness. Further, it is an interesting case because of the way the Court of Appeal differed in its analysis from that of Arnold J at first instance although ultimately the same substantive conclusion was reached. The decision is also a further demonstration of how well Floyd LJ is settling into his role in the Court of Appeal. English patent practitioners are fortunate to have two former full time judges of the Patents Court (Kitchin LJ and Floyd LJ) in the Court of Appeal as well as Lewison LJ who is no stranger to the field having decided several major patent disputes at first instance before his elevation to the Court of Appeal.

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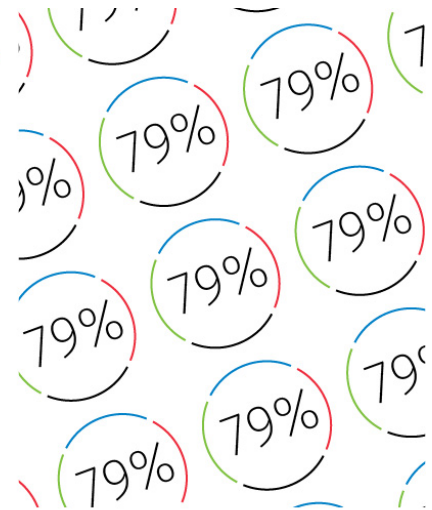
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