Testing, Testing, 1, 2, 3 – Illumina v Premaitha

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Few would dispute that the **Actavis v Eli Lilly** decision from the Supreme Court in July 2017 represented – for better or for worse – a major change to the scope of protection of patents in the UK. Four months on, the dust is beginning to settle a little and we now have a handful of judgments from the lower courts evaluating the impact of the **Actavis** decision on areas such as validity.
Handed down by Henry Carr J on 21 November, **Illumina v Premaitha** considered aspects of **Actavis** and much more besides. In fact, the **Illumina** decision is effectively three judgments wrapped into one with just about every aspect of substantive patent law touched on at some point. The judgment is by necessity lengthy. However it is very readable and – to readers of a certain disposition – engrossing – so much so that your author missed his Tube stop when reading it and almost missed his flight as a result. This short article will not attempt to cover all aspects of the decision but will concentrate on the first of the three judgments, all of which related to patents in the field of non-invasive prenatal diagnosis which required sampling of the mother's blood in contrast to the previous methods of sampling cells from the amniotic fluid or placenta (amniocentesis). The technology underlying the patents was recognised to be of major importance and great public benefit.

The patent considered in the first judgment – referred to as "Lo 1" – disclosed that cell-free DNA could be detected in maternal serum in sufficient quantities for it to be used in prenatal testing. The findings in Lo 1 were published to critical acclaim

after the priority date of the patent.

The first issue considered by the Judge in relation to the validity of Lo 1 was obviousness in light of a paper referred to as "Kazakov". Henry Carr J described the legal principles to be applied when assessing inventive step in five short paragraphs, which readers will likely find useful and uncontroversial (these are paragraphs 83(i) to (v)). Two aspects stand out: first the summary of the clarification given recently by the Court of Appeal in ICOS (judgment dated 1 November 2017) that some steps can be characterised as so routine that the skilled person would carry them out regardless of any prospect of success; and secondly the notion that although any cited prior art document should be read properly and in that sense with interest, the skilled person is perfectly entitled to put the prior art to one side as not being a worthwhile starting point for further research. Having considered the evidence, the Judge found that the teaching in Kazakov suggested an implausible theory which was fundamentally flawed. In light of these findings, Lo 1 was perhaps unsurprisingly not held to be obvious over this citation.

The next challenge to the validity of Lo 1 was entitlement to priority/enablement. With respect to enablement, the Judge noted that it is possible to frame a claim in general terms if the teaching of the patent is a principle of general application. The claim would however be insufficient if it was shown that the invention did not work with substantially everything falling within the claims. Some of the Defendants decided to run a squeeze argument in relation to infringement and validity – namely, that if the claims of Lo 1 extended to cover one of the alleged infringing tests referred to as the Polymorphic Assay of Harmony then this approach was not enabled in the priority document and hence Lo 1 would not be entitled to priority and would be invalid. However, the patentee argued that Lo 1 claimed a principle of general application and could extend to improvements enabled by technological developments without becoming susceptible to an insufficiency challenge.

Noting that this was a "key issue which requires a detailed analysis of the legal principles", Henry Carr J considered statements of Lord Hoffmann in **Kirin-Amgen** (2004) and Lord Neuberger in **Actavis** in concluding that: "*fairness to the patentee may require that unforeseeable variants, enabled for the first time by new technology, fall within the scope of protection, although the patentee is unlikely to succeed where the variant was unforeseeable at the priority date. A variant which represents an inventive step may nonetheless infringe… It would not make sense*

if, in those circumstances, the patent was found to be insufficient solely because such an immaterial variant, which it did not enable, fell within the scope of its claims." The Judge seemingly drew comfort in his conclusions from two decisions of the EPO TBA – T292/85 (**Genentech** I) and T636/97 (**Erythropoietin II**). On this basis, this squeeze by the Defendants was unsuccessful and he held the claims to be entitled to priority. However, other challenges to priority and insufficiency did succeed in relation to certain but not all claims of Lo 1.

After a short but interesting passage dismissing an allegation that Lo 1 was a "discovery as such", Henry Carr J considered the issue of scope of protection. Following **Actavis**, the Judge set out a neat summary of the principles to be applied:

i) A problem of infringement is to be determined by addressing two issues through the eyes of the skilled person:

a) Does the product or process in question ("the variant") fall within any of the claims as a matter of normal interpretation, i.e. applying the normal principles of interpretation of documents?; [54] and [58].
b) If not, does the variant vary from the invention in a way or ways which is or are immaterial? That raises a question that normally would have to be answered by reference to the facts and expert evidence; [54].

ii) In deciding whether a variation is immaterial, one should ordinarily ask three questions; [66]:

a) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?
b) If yes, would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
c) If yes, would a reader of the patent have concluded that the patentee nevertheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

One of the points of potential confusion in **Actavis** is the use of the word "normal"

in the first limb of the test, Following Arnold J in **Mylan v Yeda** (judgment dated 26 October 2017), Henry Carr J held that "normal" in this context means purposive interpretation. Ultimately, the Judge concluded that certain claims were infringed by certain of the defendants' products in consideration.

The final point worthy of mention in this short analysis relates to infringement of process claims where part of the process is carried out in the UK and part in another country. Comparing and contrasting the previous decisions of **Menashe v William Hill** [2003] and **RIM v Motorola** [2010], in the third judgment, the Judge held that the crucial question to ask was: where, in substance, was the alleged infringing process taking place? The steps in the alleged infringing process were summarised as follows:

i) receiving a blood sample from a patient in the UK;
ii) carrying out the preparatory steps and the sequencing processes in the UK;
iii) sending the raw data comprising the results of the sequencing reads electronically to Taiwan;
iv) performing the analysis of the data in Taiwan, including the Rx calculation, sex determination and foetal fraction estimation;
v) generating a report in Taiwan;
vi) sending the report back to the UK; and
vii) receiving and unpacking the report in the UK and formatting it for printing, storage and sharing with the patient.

On this basis, the Judge had little hesitation in finding direct infringement that the process of the patent had been used in the UK. Alternative arguments based on, among other things, indirect infringement, were not considered.

It has not been possible in this short summary to do justice to a judgment which is commendable for its clarity and readability. Nevertheless, it is hoped that readers will have picked up some of the many legal issues that were in play and can dig into them in more depth if they are interested.