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Bringing sufficiency within range: Birss J recasts the Regeneron principles for process claims

Illumina Cambridge Limited v Latvia MGI Tech SIA & Ors[2021] EWHC 57 (Pat)

The case centres on Illumina's contention that MGI's DNA sequencing systems infringe their patents. MGI deny infringement and claim that the patents were invalid.

Birss J's judgment covers a wide range of legal and technical issues. This article will focus on the application of two pivotal Supreme Court cases to the process claims asserted by Illumina.

Regeneron v Kymab – Insufficiency

In the recent Supreme Court decision in Regeneron v Kymab, Lord Briggs set out eight principles to consider when addressing sufficiency arguments where a patent claims a range of products. Commenting on the scope of the authorities drawn on by Lord Briggs,

Birss J said it was clear that the reasoning in Regeneron is not limited to product claims only.

However, he noted that some of the principles set out in Regeneron were tailored to product claims and that "care needs to be when transposing these principles … to different circumstances" and recast several of these principles to better concern process claims, for example replacing "make" with "perform" as used in s72(1)(c) of Patents Act 1977.

The first and underpinning principle of sufficiency, as described by Lord Briggs, is that "the extent of the monopoly conferred by the patent corresponds with the extent of the contribution which it makes to the art". Birss J noted the distinction Lord Briggs made between relevant ranges which need to be enabled across the whole range and ranges based on irrelevant factors where such difficulty does not arise. The enablement must be attainable without "undue burden".

In considering the concept of 'relevant ranges', Birss J referred to the example of a teapot with a novel spout shape, such that it would not drip. Would the incorporation of a new material, not known at the time of the invention infringe the patent claims? Birss J noted that the material from which the spout is made is clearly relevant to its function; however, the material used does not go the "essence" of the invention in this example, that being the shape of the spout. Hence, even though the teapot incorporating the new material would not have been attainable without "undue burden" at the filing date of the patent, the patent claim should not be insufficient as the type of material is not a relevant range.

Summarising matters, Birss J derived seven principles in relation to relevant ranges and enablement which will no doubt be much considered in future.

Actavis v Eli Lilly – Doctrine of Equivalents

The Supreme Court decision in Actavis set the test for equivalence by reformulating the three key questions used to determine whether a product is deemed to infringe a patent claim where it falls outside of the actual language of such claims.

It was common ground in this case that the first two Actavis questions are answered in Illumina's favour. The answer to the third Actavis question, being whether the skilled person would have thought that "strict compliance with the literal meaning of the

relevant claim(s) of the patent was an essential requirement of the invention", was disputed.

MGI's main argument on this point was that the patent strictly requires the presence of a covalent bond in the 'cleavable linker'. Birss J described MGI's arguments on this point as "unconvincing" but ruled in MGI's favour for what he referred to as a simpler reason. In his view the patent specification had "gone out of its way to define [the term 'incorporation'] in a clear and simple way". There was no need for the skilled person to speculate the reason behind that. Based on this definition, the feature was essential. Birss J concluded that "The [MGI] system is in fact an immaterial variant to the invention claimed in claim 1, but the patent is deliberately drafted in such a way as to exclude it."

This approach from Birss J provides a counterbalance to wider interpretations based on the doctrine of equivalents.