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Illumina illuminated in the twilight of Birss J's Patents Court career – part I

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On 20 January 2021 Birss J handed down what may be his last first instance decision before he takes his place in the Court of Appeal. If that turns out to the case then *Illumina Cambridge Limited v Latvia MGI Tech SIA and others* is a substantial judgment to mark this departure. In this case Illumina asserted MGI's DNA sequencing systems, which MGI were just introducing to the UK, infringed five of its patents.

The judgment covers numerous technical and legal issues and, as such this summary note will be in two parts. This first part will focus on three particular areas of interest – the identification of the skilled addressee of the patents, insufficiency and infringement – as they apply to three of the patents in issue. The second part of the summary will consider the "collocation" validity challenge made against a fourth patent.

The ABC of DNA Sequencing

Whilst a comprehensive explanation of the scientific background to Illumina's patents is far beyond the scope of this note, a short summary of DNA sequencing may help to provide some context for readers.

DNA sequencing is the technique of "reading" the sequence of molecules that make up a particular DNA strand and thereby identify the genome of the species under investigation. Four bases are identified during the sequencing process (assigned the letters C, G, A or T) and it is the order of these letters which gives the DNA sequence. DNA sequencing was devised in the 1970s and, broadly, two methods were developed. In one method the DNA strands are chemically cut at known places and the separate pieces identified so as to establish the sequence. In another method a template DNA strand is manipulated so as to copy itself into multiple strands that end at a chemically controlled length. The length of the strand depends on a so called chain terminator or blocking molecule and results in strands ending with a particular base (identified with the letter C, G, A or T). These strands can be labelled and analysed to determine the DNA sequence of the template strand. Since this method involves synthesising additional DNA it is an example of "*sequencing by synthesis*".

Three of the patents in suit (the modified nucleotide patents[1]) relate to a method of sequencing or, as described by the judge at paragraph 50: *"Briefly put, the invention(s) claimed in the modified nucleotide patents are concerned with using an azidomethyl group as a reversible chain terminator*

in sequencing by synthesis". The key prior art citation, a pair of papers called "Zavgorodny", also related to azidomethyl blocking molecules but did not concern DNA sequencing. Therefore, in considering how the skilled person would read Zavgorodny a central issue for the judge was to identify the characteristics of the skilled person in the first place.

Identifying the Skilled Person

Almost all issues of patent law revolve around the views of the skilled addressee of the patent(s) in suit. The determination of identity of such a skilled person can often therefore be a crucial issue, not least because it will shape the relevant common general knowledge against which background the patent(s) and the prior art will be assessed. The Defendants contended that the skilled person was "*a team interested in or researching sequencing by synthesis using reversible chain terminators*". Given that the key piece of prior art did not relate to DNA sequencing it is easy to see why the Defendants sought to characterise the skilled person in this way. As the judge put it "*a skilled person who had never heard of the technique of sequencing by synthesis using reversible chain terminators, and who read either Zavgorodny paper in 2002, could not possibly think of the invention because nothing in either paper would prompt someone who had no knowledge of sequencing by synthesis to think of the technique at all*. Illumina contended this characterisation of the skilled person was illegitimate since, at the priority date, there were no teams engaged in such specific research. In view of this dispute, Birss J gave lengthy consideration to the "*correct definition of the person skilled in the art*".

The judge began with a broad definition: *Stated generally the law is clear that patents are directed to those likely to have a real and practical interest in the subject matter of the invention**[2]***. He then noted that this interest includes devising the invention as well as putting it into practice with the consequence that, in some cases, two different skilled persons may be relevant[3]. An important issue, relevant to this case, was not to define the skilled person too narrowly or too broadly[4]. Illumina proposed, based on *Medimmune**[5]***, that "*a sensible test was to require something which could properly be called an established field at the priority date*".

Taking these factors together, Birss J concluded by setting out the following stages[6] to use in identifying the skilled person:

1. *i) To start by asking what problem does the invention aim to solve?*
2. *ii) That leads one in turn to consider what the established field which existed was, in which the problem in fact can be located.*

iii) It is the notional person or team in that established field which is the relevant team making up the person skilled in the art.

Applying these questions to the facts of the case Birss J determined the skilled person to be "a team working on research into sequencing"[7]. Accordingly, this was a more general characterisation than that contended by the Defendants.

Insufficiency: Regenerating Regeneron

Birss J gave extensive consideration to a challenge of insufficiency made by the Defendants in reliance on *Regeneron v Kymab* [2020] UKSC 27. The basis of this challenge was that the patent claims covered "*later developed successful techniques which techniques could not have been arrived at just with the patent (and the common general knowledge) but needed further steps too to*

make them work" or, on the facts of the case, that the patent "*covers methods of sequencing using nucleotides, linkers and labels that would not enable the skilled person to perform a sequencing method across the breadth of the claim without undue burden*"[8].

First the judge noted that, in *Regeneron*, the patent involved a product claim for a mouse that had human gene segments inserted in it (in a range from 1 to 125 segments). In that case the defendant's allegedly infringing mouse had all 125 human gene segments inserted into it but it was found that such a mouse could not be produced with the patent and common general knowledge as it was at the priority date; at that time only a few gene segments could be inserted. It followed that the patent was not enabled across the full range it claimed (i.e. was insufficient). In *Regeneron*, Lord Briggs established a number of principles in this assessment of insufficiency which Birss J sought to adapt for cases involved method claims. In particular, he adapted principle iv) as follows:

1. *iv) The disclosure required of the patentee is such as will, coupled with the common general knowledge existing as at the priority date, be sufficient to enable the skilled person to perform substantially all the types or embodiments [ ] within the scope of the claim. That is what, [ ], enablement means.*

Importantly, as was held in *Regeneron*, it is only relevant ranges of embodiments that need to be enabled. Or, as the judge put it at paragraph 257, "*the fact that one could say that the claim* [in Regeneron] *covered mice with different lengths of tail but the patent had not enabled how to do what it taught with mice with all possible lengths of tail, did not matter because tail length was not a relevant range*". Furthermore, as the Birss J explained at paragraphs 276 to 277, functional language in a claim will inherently cover a variety of things and therefore a range. This will not, however, mean that the patent is insufficient simply because some choices within that range will not enable the invention. Taking the example of a "*new teapot which was inventive and useful because its spout was shaped in a new way so as not to drip*" the judge pointed out that "*The claim might well not say anything about the material from which to make the teapot, because it is irrelevant to the invention*". The skilled person at the priority date could determine "*without an undue burden* [that] *China would work and chocolate would not. However the claim would be infringed later on even if a teapot was made using a new inventive form of Pyrex glass which had not been invented at the teapot patent's priority date*".

In the judge's view, this analogy was apposite to the present case. It did not matter that there were "*methods of sequencing using nucleotides, linkers and labels*" that did not work or that some examples that worked were not known at the priority date, since these variations were not relevant ranges for the purposes of the *Regeneron* insufficiency analysis. What mattered was that skilled person could, without undue burden, identify examples of these *"methods of sequencing using nucleotides, linkers and labels"* that would work as at the priority date. The Defendants' insufficiency challenge therefore failed.

Infringement – applying the Doctrine of Equivalents

At paragraph 304 Birss J noted that "*neither party devoted much effort*" to a point on added matter and, likewise, this note does not consider the point further. Infringement, however, was an issue that requires consideration notwithstanding that the Defendants had admitted infringement in relation to a number of claims[9] since no admissions had been made in relation to Illumina's allegations based on the doctrine of equivalents[10].

Birss J explained that, in this case, only the third question formulated in *Actavis* was relevant. This question asks if the skilled person reading the patent would have concluded that "*strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention*". The question arose in this case since the Defendants contended that one of the chemical tools (a "cleavable linker") used in the patent strictly required a covalent bond, something not present in the Defendants' system. In addressing this point, the judge first found that the patent did not require such a covalent bond at all. This, as he noted at paragraph 322, meant that the question of equivalents did not in fact arise. However, in case he was wrong about this he then addressed the issue "*on the hypothesis that …the term cleavable linker does require a covalent bond*". However, even on this basis he could not see why the skilled person would think that strict compliance was necessary as they would not think it impacted on the invention. Accordingly, infringement was found under the doctrine of equivalents.

Practicalities and qualities of Expert witnesses

Finally, there are several practical points relating to witnesses that are worthy of note. First of all is the judge's criticism of the late arrangements made by the defendants' legal teams in relation to their witnesses providing evidence by video link[11]. It remains to be seen if virtual or "hybrid[12]" trials are here to stay but, in such trials, it is clearly important to make advanced preparations for witness evidence to be given remotely (particularly if witnesses are based abroad). In his summary of the witnesses, Birss J also gave a reminder that the evidence of expert witnesses can be of assistance to the Court regardless of whether the witness had been working on the problem of the patent at the relevant time[13]. What is important, however, is that expert witnesses "*give candid and objective evidence*" and do not argue the case for the party which has called them[14]. The judge also, in addressing a deposition from one of the named inventors on three of the patents in suit, explained why evidence from an inventor is does not assist the Court given that inventors (by their nature) are unlikely to represent the "*skilled person armed only with the common general knowledge*" (paragraph 215). Finally, in a paragraph with the curious heading "*The witnesses not called, and questions not asked*" Birss J noted that both sides contended that the other had access to witnesses (for example the author of prior art) who could have provided relevant evidence but were not called. Instead of drawing any negative inferences from this the judge "*decided to decide this case as best I can based on the evidence that is here, of which there is a lot, rather than speculating about why there is not even more evidence*".

As noted at the start of this summary, the Illumina case could be Birss J's last substantive judgment until his deserved promotion to the Court of Appeal. With Lord Kitchin in the Supreme Court and Arnold and Birss LJJ in the Court of Appeal, the benches of the appellate courts are well stocked with judges who have spent their careers steeped in patent law and other areas of IP. Further, the announcement last week that James Mellor QC will join Meade J in the Patents Court has been universally welcomed by practitioners. We are all living in times of great uncertainty but the strength of the English Patents Court and higher courts is not in doubt.

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[1] Two further patents were considered by the Judge. The 412 patent was found invalid and is not addressed in this note. Following the order in the judgment, the 415 patent is considered after the modified nucleotide patents.

[2] At paragraph 58 Birss J noted that this language is based on paragraph 81 of the judgment of

Henry Carr J in Garmin v Philips [2019] EWHC 107 (Ch)

[3] Following Schlumberger v EMGS [2010] EWCA Civ 819

[4] The oft-quoted example of the "two-hole blue Venezuelan razor blades" designer (Folding Attic Stairs v The Loft Stairs Company Ltd [2009] EWHC 1221 (Pat)) was given as an example of a too narrowly defined skilled person.

[5] Medimmune v Novartis [2012] EWCA Civ 1234

[6] Paragraph 68

[7] Paragraph 96

[8] See paragraphs 247-248

[9] Summarised at paragraph 14 of the judgment

[10] Developed by the Supreme Court in the Supreme Court in Actavis v Eli Lilly [2017] UKSC 48

[11] Paragraph 21

[12] Where the core legal teams are present in Court but witnesses and the rest of the legal teams are dialled in remotely.

[13] At paragraph 24 the judge spoke of "*the frequent fallacy in patent cases that the only experts qualified to comment have to have been working on the very problem the patent sets out to solve at the relevant time*"

[14] See criticism of Prof Winssinger at paragraph 32: "*To reject the entirety of his evidence would be a disproportionate response but I am doubtful I can place much weight on opinions expressed by Prof Winssinger which are not backed up by other evidence such as contemporaneous documents*".

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