Kluwer Patent Blog

Actavis and Equivalents – One Year On

Brian Cordery (Bristows) · Thursday, July 12th, 2018

On 12 July 2017, the UK Supreme Court handed down a ruling which caused a shockwave to resound across the UK patent community. For more than a decade, when addressing the issue of the construction and infringement of a patent, every practitioner would have focussed on the question prescribed by Lord Hoffmann in **Kirin Amgen**: "what would the skilled person have understood the patentee to have used the language of the claim to mean?". They would also have said that there is no doctrine of equivalents in the UK. In **Actavis**, we were told that this approach was wrong in principle and that instead the issue of infringement should be addressed first by considering the "normal interpretation" of a claim and secondly whether a variant differed only in immaterial ways. In addressing the second issue, the Supreme Court instructed us to use three questions which were by and large based on the old **Improver** questions dating from 1989 but with the second question being slightly adjusted. For ease of reference, the **Actavis** questions are reproduced at the end of this commentary.*

Time is a great healer, so the saying goes. But one year on, has the UK patent community adjusted to the new rules and have we concluded that the Supreme Court was, on reflection, right to reset the rules as it did?

The second half of 2017 and the first half of 2018 did not provide the Patents Judges in the High Court or the Court of Appeal with a real opportunity to reflect on **Actavis**. There have been half a dozen rulings which touch on the issues and one or two helpful summaries of the new approach. However there has not been a case where an allegedly infringing product or process was clearly outside the claims as a matter of "normal interpretation" (which appears according to subsequent rulings to mean "purposive construction") but was an immaterial variant. Even if such a case were to come along, the rules of precedent which apply to English jurisprudence do not permit for more than a little tinkering at the edges of the *ratio* of a ruling from the UK's highest Court.

In autumn 2017, a seminar took place at University College London at which the decision was evaluated. The panel included two of the Supreme Court Judges who had decided **Actavis** – Lord Neuberger and Lord Sumption as well as leading patents judges from Germany, the Netherlands and the US and attracted an audience of over 600 people. It seemed that just about every patent specialist in London was present with one notable exception. At the end of the evening, a show of hands indicated that the profession was split on whether **Actavis** had adopted the right approach or not.

The notable absentee from the UCL event was Lord Hoffmann himself, due to a pre-existing

personal commitment. However, at subsequent public events, Lord Hoffmann has been quite clear that he himself is not in any doubt about the correctness of **Actavis**. He believes it to have been wrongly decided and that he would have followed the approach taken by the Court of Appeal.

So which is the better approach – the approach taken by Lord Neuberger and Lord Sumption in **Actavis** or that taken by Lord Hoffmann in **Kirin Amgen**? Having listened to seminars given by several judges and other experienced figures in the field post-**Actavis**, this author considers that there are pros and cons in both positions. Like many others, he had perhaps come to apply the **Kirin Amgen** principles somewhat literally whereas Lord Hoffmann had probably intended for more flexibility. The key to unlocking the true meaning of **Kirin Amgen** is context – Lord Hoffmann was telling us that the skilled person needed to view the claims with the context of the specification and the common general knowledge in mind. This can be illustrated by an example given by Lord Hoffmann himself after the **Kirin Amgen** decision: imagine a person approaches a gate to a field and on the gate is a sign saying "FOUR WHEELS NOT PERMITTED". What can pass into the field: A bicycle? A car? A baby stroller with four wheels? A tank with tracks but no wheels? Clearly the context is likely to permit the bike and the stroller but not the car and the tank even though the strict language of the sign would permit the tank but not the stroller. Turning to **Actavis**, the second of the modified **Improver** questions does not sit well with the author. Why should the skilled person be taken to know that the variant achieves substantially the same result as the invention? Doesn't this mean that the answer to this question will always be yes? The author has wondered from time to time if this adjustment was made so that the Supreme Court could find infringement in light of the findings from the trial judge, particularly the finding that the skilled person would not know that potassium salt behaved in the same way as the sodium salt without testing it (assuming, of course, that it could be made).

What should the correct approach be? Those practitioners who have studied the development of the law of patent construction in the UK, or who have been in the field for a long time, will recall that pre-**Improver** (decided in 1989), in **Catnic** (decided in 1982), and in several House of Lords cases pre-**Catnic**, the Courts decided that the first question should be to identify what the patentee had described as the essential features of the invention. In relation to those features, variation would not be permitted. However in relation to non-essential features, variation was permitted provided the variant did not have a material effect on the way the invention worked and that this was obvious to the skilled person. The author considers that this approach – essentially putting the third **Improver/Actavis** question first, might be easier to apply and lead to fairer results.

A further important issue which remains to be considered is the extent to which the **Actavis** decision impacts on validity. Validity was not in issue in **Actavis** and so the topic was not addressed. Arguably, the ideal case to consider equivalents would have involved both issues. Since **Actavis**, no judge has formally ruled on the point though informal observations from first instance suggest that there is no clear consensus at this time on the extent to which **Actavis** impacts on validity.

At the time of writing, a further decision from the Supreme Court on several fundamental issues of patent law is imminently expected. The **Warner-Lambert v Actavis** case concerning the drug pregabalin was heard by the Supreme Court in mid-February 2018 and considered, among other things, plausibility, infringement of second medical use patents and abuse of process. Decisions from the Supreme Court from hearings in January and early February 2018 have been handed down which causes practitioners to sense that the pregablin ruling could be handed down this side of the summer vacation. There are a number of rumours circulating in the patent community that

the Supreme Court is once again going to re-set the law in at least one of the areas it was asked to consider. Looking forward, the Supreme Court has also accepted an appeal in the tadalafil case concerning dosage regimen patents and the law on inventive step.

Despite all of the above, in what was clearly a most welcome development for all IP professionals, on 27 June 2018 it was announced that Lord Justice Kitchin will be promoted to the Supreme Court this October. Whilst the newly promoted Lord Kitchin will not be able to form part of the panel hearing the tadalafil case, it is inevitable that he will play a major role in patent and other IP cases in the Supreme Court going forward. Having already established himself as a Judge of exceptional talent in the lower courts, there is every reason to think that Lord Kitchin's influence in the highest court will be extremely beneficial to the entire IP community.

*The **Actavis** questions:

i) 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, ie the inventive concept revealed by the patent?

ii) 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?

iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

This entry was posted on Thursday, July 12th, 2018 at 3:19 pm and is filed under literally fulfil all features of the claim. The purpose of the doctrine is to prevent an infringer from stealing the benefit of an invention by changing minor or insubstantial details while retaining the same functionality. Internationally, the criteria for determining equivalents vary. For example, German courts apply a three-step test known as Schneidmesser's questions. In the UK, the equivalence doctrine was most recently discussed in Eli Lilly v Actavis UK in July 2017. In the US, the function-way-result test is used.">Equivalents, Extent of Protection, Infringement, Litigation, Pharma, Pharmaceutical patent, Scope of protection, United Kingdom
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