

Actavis v Lilly – A Year After the Revolution

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Katharine Stephens sets the decision in *Actavis* in context and discusses its effect on subsequent cases.¹

Key Message

On 12 July 2017, Lord Neuberger, President of the Supreme Court, dropped something of a bombshell on the patent profession in the UK in the case of *Actavis v Lilly*.² He informed us that by following the 2004 decision of the House of Lords in *Kirin-Amgen v Hoechst Marion Roussel*,³ we had been using the wrong approach when considering the issue of infringement.

In *Kirin-Amgen*, there was only one compulsory question: what would a person skilled in the art have understood the patentee to have used the language of the claim to mean? Lord Neuberger, giving judgment for the court, stated that this conflated the issues of interpretation and scope of protection. The correct approach should, instead, be determined in two stages. The first stage required asking whether the variant infringes as a matter of normal interpretation and the second stage gives effect to the doctrine of equivalents.

Why is Actavis Important?

Deciding the scope of protection of a patent is the key aspect of any patent action. The scope of the monopoly granted by the patent legislates what the patentee can stop others from doing. It therefore determines when potential infringers need to take a licence in order to avoid an infringement action.

The decision in *Actavis* opens the door to the doctrine of equivalents and, in any one case, may broaden the scope of protection afforded by a patent. This is of enormous importance, as it could mean that where a third party thought they had freedom to act before, they no longer do.

It will also affect the way in which patent actions are fought and the squeezes that can be applied. *Actavis* does away with the old certainty of that which infringes if done after grant, anticipates if performed before the priority date. Furthermore, a variant which represents an inventive step may nonetheless infringe.

The Starting Point

The standard that applies to patent infringement in all EPC member states is that set out in Article 69 of the European Patent Convention (“EPC”) and the Protocol on its interpretation. However, unsurprisingly given the difficulty in interpreting the text of the Protocol, each national court uses its own guidelines. This has led in

the past to courts in different European countries coming to different decisions; famously in the decision in *Improver v Remington*, where, in the UK, the defendant’s hair remover (or epilator) was held not to infringe the EP (UK) 0,101,656.⁴ In contrast, in Germany, Italy and the Netherlands, the patent was found to be infringed.

Under Article 69, the scope or extent of protection is determined by the claims which are to be interpreted using the description and the drawings. Article 69 is given effect in UK law with the Protocol applying to UK law as it does for the purpose of Article 69.⁵

The Protocol represents a compromise between two extremes. Article 1 states that it is wrong to interpret the scope of protection using a strict, literal meaning of the words used in the claim where the description and drawings are only employed for the purpose of resolving an ambiguity found in the claims. In contrast, it is also wrong to interpret the scope of protection using the claims only as a guideline for what the patentee contemplated. It then states:

“On the contrary, [Article 69] is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.”

As was noted in *Kirin-Amgen*, this is not a compromise between different approaches to interpreting the scope of protection, but a compromise in the exercise of fairness to both the patentee and third parties.

The Protocol was revised by EPC 2000 and a new Article 2 introduced into the Protocol. It is entitled “Equivalents” and states that, when determining the extent of protection, “due account shall be taken of any element which is equivalent to an element specified in the claims”. *Kirin-Amgen* was decided on the law as it stood before EPC 2000, but Lord Hoffmann suggested that it would not change his analysis. Indeed, the introduction of Article 2 to the Protocol does not seem to have featured in the decision in *Actavis*.

The Old Test for Infringement

In *Kirin-Amgen*, Lord Hoffmann stated that the principle of purposive construction as explained by Lord Diplock in *Catnic*⁶ was precisely in accordance with and gave effect to the Protocol, despite this being a case decided under the purely domestic legislation contained in the Patents Act 1949. It is intended to give the patentee the full extent, but not more, of the monopoly which a person skilled in the art, reading the claims in context, would think he was intending to claim.

Lord Hoffmann also noted that Article 69, in stating unequivocally that the extent of protection shall be “determined” by the “terms of the claims”, firmly shut the door on any doctrine which extended protection *outside the claims* (emphasis added).

Despite this, under *Kirin-Amgen*, equivalents are not excluded entirely from consideration, since Article 2 to the Protocol does not prevent them from being an important part of the background of facts known to the skilled man when considering what the claims mean. It is therefore legitimate to use them as a guide to construction.

Later, Jacob LJ explained in *Virgin Atlantic Airways v Premium Aircraft Interiors*⁷ that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement could fall within the meaning of the claimed element, not because there was a doctrine of equivalents under UK law, but because that was the fair way to read the claim in context.

Further guidance for applying purposive construction to equivalents can be found in the three *Improver* questions, later called the Protocol questions.⁸ The questions are useful as they have a predictive value, but even before *Kirin-Amgen*, there had been a perception that they were unsuited to their task in some cases, particularly those relating to pharmaceutical and biotechnological inventions. Since *Kirin-Amgen* (a biotechnology case), Lord Hoffmann's comment that the Protocol questions are only guidelines has been used as an excuse not to use them at all. But that may have changed with *Actavis*.

Did the Test Need to Change?

The purposive construction approach to deciding infringement has a simplicity and elegance. It provides clarity for potential infringers and, as noted by Lord Hoffmann in *Kirin-Amgen*, is therefore less expensive for litigants than the American doctrine of equivalents. It can therefore be argued that no change is needed.

However, the key limitation is that it does not protect against a variant which lies beyond the language of the claim. As such, it could be viewed as providing certainty for third parties at the expense of providing a fair protection to patentees.

Certainly, this was the view of Hugh Laddie. In his article "Kirin Amgen – the end of equivalents in England?"⁹, which was referred to by Lord Neuberger in *Actavis*, he referred to *Catnic* as the penultimate step on the road to the adoption of a narrow, unforgiving approach to the determination of the scope of protection with *Kirin-Amgen* being that ultimate step. Whilst *Catnic* and *Improver* suggested that a small number of cases might still exist in which the scope of protection would be expanded by applying principles of equivalents and pith and marrow, *Kirin-Amgen* went a long way to undermine such vestigial flexibility by asserting the primacy of the claims.

Furthermore, Lord Hoffmann's statement that purposive construction was not unfair to the patentee because, if it were otherwise, the patent would be unreasonably exposed to claims of invalidity on grounds of anticipation or insufficiency was described by Hugh Laddie as an attempt to make the blow more palatable. He likened Lord Hoffmann to a physician administering a noxious medicine to a patient, telling the patentee that the narrow approach is for his own good.

Not for the first time, Lord Neuberger expressed his opinion in *Actavis* that there were two issues, not one, when considering infringement. He had previously made the same statement when he heard the *Kirin-Amgen* case at first instance. *Actavis* was his opportunity to impose this view on future cases. He held that the approach in *Kirin-Amgen* conflated the issues of interpretation and scope of protection. This was wrong in principle and risked leading to error.

He used the facts in *Improver* as an example. Lord Neuberger commented that he could not see how principles of interpretation could possibly lead to the conclusion that the slotted rubber rod used

by Remington was within the expression "helical metal spring" used in the claim, even when construing those words in the context of the specification. Thus, treating the scope of protection as a question of interpretation on facts such as those in *Improver* could, on that point alone, be thought to put an end to the patentee's infringement arguments. There would, therefore, seem to have been little purpose in going through the three questions in that case.

What is the New Actavis Test?

Lord Neuberger stated that the problem of infringement was best approached by addressing the following two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, i.e. the person skilled in the relevant art:

- (1) does the variant infringe any of the claims as a matter of normal interpretation; and, if not
- (2) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

As Lord Neuberger stated, this second question squarely raises the principle of equivalents and involves not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent, if any, to which the scope of protection afforded by the claim should extend beyond that meaning.

What is "Normal Interpretation"?

Lord Neuberger stated that a patent should be interpreted according to normal principles of interpreting documents; that is, the court should follow the principles affirmed by the Supreme Court in the contract case of *Wood v Capita*.¹⁰ Lord Hoffmann in *Kirin-Amgen* had also referred to the principles by which contracts should be interpreted and cited *Investors Compensation Scheme v West Bromwich Building Society*¹¹ in which he had given the leading speech.

The principles Lord Hoffmann set out in *Investors Compensation Scheme* underlined the importance of context; what is important is what a document conveys to the reasonable person given the relevant background. The decisions that followed first approved this line, but then appeared to sound the retreat, laying more emphasis on the primacy of language. In *Wood v Capita*, whilst not admitting that there was any conflict in previous decisions, the Supreme Court confirmed that the task in contract interpretation is to ascertain the objective meaning of the language, not as a literalist exercise, but considering the wider context. In that specific case, the court held that the contractual context was significant.

The reason for belabouring the point is this, does the reference to the normal principles of interpreting documents in the first stage in *Actavis* mean that there is a move towards literalism and away from contextualism or, as patent lawyers would call it, purposive construction?

Lord Neuberger also refers in the reformulated *Improver* questions (see the section immediately below) to the first stage of his test for infringement as being the "literal meaning" of the relevant claims. Is he therefore intending to set up a test where the first step is a strict literal test which is then supplemented by a doctrine of equivalents? If so, this is contradicted by his preamble to the first stage where he refers to the skilled person, his reference to *Wood v Capita* and what he said about *Catnic*. In relation to *Catnic*, he noted that "normal principles of interpretation could, I think, accommodate the notion that 'vertically' extended to an item which is not at precisely 90 degrees to another item".

At the very least, Lord Neuberger appears to intend that a contextual construction is given to claims, although he appears deliberately to eschew the use of the word “purposive”, using “normal” instead. In this, it is suggested, he is trying to underline the break with *Kirin-Amgen* for the very reasons he gave in his judgment.

What is an Infringing Variant?

In deciding what makes a variant immaterial, Lord Neuberger thought the *Improver* questions helpful, not least because similar tests have been adopted in other EPC jurisdictions, but that they required some exegesis and reformulation.

He considered question (1), which asks whether the variant has a material effect on the way in which the invention works was generally satisfactory, but that the court needed to be reminded to focus on the inventive concept in the patent. The question was therefore reformulated as follows:

“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?”

In doing so, the old *Improver* question has been twisted around so that now, if the answer to the first question is “no” then there would be no infringement. If the answer is “yes” then the variant may infringe and the questioning has to continue.

Question (2), in particular, needed reformulating as it imposed too high a burden on the patentee to ask whether it would have been obvious to the skilled reader that the variant would have no material effect on the way in which the invention works, given that he was not told whether the variant worked or not. Therefore, it was better expressed as:

“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?”

If the answer to this question was “no”, there would be no infringement, but if “yes” then the third question would need to be asked.

This reformulated second question marks a considerable change. Lord Neuberger considered it to be not only a fairer balance between patentee and third parties than the original, but also consistent with the approach of the German, Italian and Dutch courts. The same question, including the assumption (i.e. that the variant works) would also apply in all cases, even those cases where the variant was unforeseeable at the priority date, although in this instance the skilled person was less likely to answer the question with a “yes”.

Question (3) is a question of construction and, as originally formulated, asks whether the skilled reader would have understood from the language of the claim that the patentee was intending strict compliance with the primary meaning as being an essential element of the invention. As with question (1), Lord Neuberger thought this question an acceptable test, but four points had to be borne in mind when applying it:

- (1) although “the language of the claim” is important, it does not exclude the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have;
- (2) the fact that the language of the claim does not on any sensible reading cover the variant is certainly not enough to justify holding that the patentee does not satisfy the third question;
- (3) it is appropriate to ask whether the component at issue is an “essential” part of the invention; and

- (4) when one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is necessary to imbue the notional addressee with rather more information than he might have had at the priority date.

He then changed the wording of question (3) very slightly to the following:

“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?”

If question (3) is answered “no”, then there is infringement.

Applying the New Test to the Facts in Actavis

Since so much has been written about this case, only the briefest of descriptions is given here. Pemetrexed is a chemical which has been known for some time to have therapeutic effects on cancerous tumours; however, it can have seriously damaging, even fatal, side effects which could largely be avoided if administered with vitamin B12. Claim 1 of the patent in suit was in the Swiss form claiming the use of pemetrexed disodium in a medicament to be administered with vitamin B12. Actavis proposed, in place of pemetrexed disodium, the use of pemetrexed diacid, pemetrexed ditromethamine or pemetrexed dipotassium.

Lord Neuberger started his infringement analysis by pointing out that, obviously, none of the Actavis products infringed on the basis of normal interpretation. However, each was considered an immaterial and infringing variant. In relation to the recast *Improver* questions, Lord Neuberger found as follows: in relation to (1) each of the Actavis products achieved substantially the same result in substantially the same way as pemetrexed disodium; in relation to (2), the notional addressee would have appreciated at the priority date that each of the products worked in precisely the same way as pemetrexed disodium when included in a medicament with vitamin B12; in relation to (3), the Court of Appeal had placed too much emphasis on the words of the claim, demonstrating the risk of treating the issue as being one of normal interpretation. The fact that the specification taught that there were other anti-folate drugs having a similar effect to pemetrexed disodium coupled with the fact that it was known that cations other than sodium could be successfully used with anti-folates meant that it was very unlikely that the notional addressee would have concluded that the patentee could have intended to exclude any pemetrexed salts other than pemetrexed disodium from the scope of protection.

Reference to the Prosecution History

Actavis contended that the court should have recourse to the prosecution history of the patent when considering whether a variant infringes. If the court did so, Actavis further contended that the prosecution history would make it clear that the claims should be interpreted as being limited to pemetrexed disodium. They won the first but not the second point.

Lord Neuberger stated that the courts should adopt a sceptical, but not absolutist, attitude to a suggestion that the prosecution history should be referred to. Although not completely ruling out other circumstances, he considered that reference to the file would only be appropriate where:

- (1) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point; or

- (2) it would be contrary to the public interest for the contents of the file to be ignored, such as where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.

What Has Happened Since *Actavis*: What is “Normal Interpretation”?

The first issue that the courts have been grappling with is what Lord Neuberger meant when asking, as a first stage, whether the variant infringes any of the claims as a matter of normal interpretation. Does it require a literal interpretation (as suggested by the reformulated *Improver* questions) or is it the same as purposive construction?

To date, the Court of Appeal has unanimously accepted purposive construction of claims. There has been no debate recorded in the courts’ judgments, in part, because in none of the cases was it necessary to consider infringement by equivalence. Thus, in *Actavis v ICOS*,¹² Kitchen LJ giving the lead judgment stated that “the claims are to be read not literally but purposively”. This was important because, read literally, the words “up to a maximum total dose of 5mg per day” were not a limitation on the relevant claim but when the claim was read in the context of the specification they were.

In *Regeneron Pharmaceuticals v Kymab*,¹³ the Court of Appeal stated that it was unnecessary to consider equivalents under *Actavis* because as a matter of normal interpretation the Court found that the defendant’s transgenic mice infringed the patent in suit. In *Saab Seaeye v Atlas Elektronik*,¹⁴ there was no dispute about applying purposive construction and, most recently, in a case relating to numerical limits,¹⁵ the Court of Appeal did not mention *Actavis* at all. This was disappointing, as numerical limits present an interesting case for the assessment of “normal interpretation”. What could be easier to interpret literally but a number? Instead, the court referred to earlier case law which dealt specifically with numerical ranges.

It has therefore been left to the Patents Court to discuss the issue. In *Generics v Yeda*,¹⁶ in the first decision to be handed down after *Actavis*, Arnold J was emphatically of the opinion that the law remained that a patent claim should be given a purposive and not a literal construction. He also pointed out that patents and commercial contracts differed in two key ways. A patent is unlike a contract, firstly because it is a unilateral statement made to a class of persons represented by the person skilled in the art and describes, and secondly because it claims an invention for the purposes of establishing a legal monopoly with regard to that invention. A claim therefore could not be rationally interpreted without taking this into account and he did not read Lord Neuberger as meaning anything different. After all, Lord Neuberger stated that both stages of the infringement enquiry should be considered through the eyes of a notional addressee and that the exercise involved interpreting the words of the claim in context (see the section above entitled “What is the New *Actavis* Test?”). That context had to include the very purpose for which the patent existed; namely to describe and claim an invention.

Arnold J’s decision on this point has been followed by the judges of the Patents Court who have had the opportunity to express themselves.¹⁷ As Carr J put it in *Illumina v Premaitha*,¹⁸ “normal interpretation means purposive interpretation”.

In *Fisher & Paykel v ResMed*,¹⁹ Meade QC commented that, as matters stood, he should follow Arnold J’s approach. He also noted that “it may be preferable to refer to ‘claim scope’ rather than to ‘claim construction’, to indicate that (at least for the purposes of deciding whether a claim extends to equivalents in relation to infringement) it is no longer permissible to use the one-stage purposive construction familiar from *Kirin-Amgen*”.

The only note of caution has been sounded by Birss J in *Liqwd v L’Oreal*.²⁰ Although he agreed with Arnold J, Carr J and Meade QC, he nevertheless pointed out that he could see scope for debate about whether every nuance of the *Kirin-Amgen* approach to purposive construction would produce the same result at the normal interpretation stage of *Actavis* because of the fact that, in *Kirin-Amgen*, account was taken of equivalents in the process of determining the purposive construction of the claim. In this, it is suggested, he is correct.

How Has the Doctrine of Equivalents Been Applied in Infringement Cases?

In two judgments to date, consideration has been given to whether there is infringement under the doctrine of equivalents. Both were judgments of Carr J and in both his decisions on equivalence were purely *obiter*. In *Illumina v Premaitha*, there were a number of patents and infringing products all relating to non-invasive prenatal diagnosis, i.e. genetic testing on a foetus that required only sampling the mother’s blood or other non-invasively collected material. The Lo 1 patent concerned a method of detecting the presence of a paternally inherited nucleic acid sequence of foetal origin, which was not possessed by the pregnant female, in a maternal serum or plasma sample.

The issue of infringement in relation to one of the defendant’s tests, the IONA test, turned upon the proper construction of “detecting” and “detection” of a nucleic acid sequence that was paternally inherited and not possessed by the pregnant female. The IONA test identified whether the level of sequences from the X chromosome was high or low. If low, it was because of the presence of the Y chromosome occupying the space in the foetal genome which would otherwise be occupied by a second X chromosome. By identifying a low number of X chromosome fragments, the IONA test therefore indirectly detected the presence of the Y chromosome in the maternal sample and thus enabled a confident prediction that the foetus must be male. Carr J accepted that although the indirect detection method did not provide the same degree of certainty as direct detection, the difference was not significant.

Carr J concluded that, according to its normal interpretation, both direct and indirect detection were within the scope of claim 1. Such a construction was commensurate with the technical contribution of the patent. The IONA test therefore infringed claim 1.

As a consequence, it was unnecessary for him to determine infringement by equivalents but nevertheless he went on briefly to consider the issue. His starting point was that he would not have found infringement on a normal interpretation because Lo 1 was limited to direct detection. On that basis, he would not have been satisfied that the variant of indirect detection achieved substantially the same result in substantially the same way as the invention, nor that this would have been obvious to the person skilled in the art at the priority date. Therefore, if there had been no infringement under the first stage of the *Actavis* test, there would not have been infringement under the doctrine of equivalents.

In the second judgment in which he considered the issue of infringement by equivalence, *L’Oreal v RN Ventures*, Carr J again held that there was infringement on a normal interpretation but, if he was wrong, the variant would not infringe under the doctrine of equivalents. This case related to electronic facial skin care devices for the deep cleansing of pores. The devices work by manipulating the skin using contact elements moving relative to one another. One of these relative movements was called the “shear mode”. The defendant submitted that the shear mode was outside the claim based on an interpretation of the wording of claim 1 which Carr J did not

accept. The specification made clear that this was the patentee's preferred mode and it should not be excluded from claim 1 on a purposive construction. As a consequence, RN Venture's product infringed. However, if this was wrong, and the shear mode did not fall within the scope of claim 1, it would not be an infringing variant. Although it would produce substantially the same result in the same way, because the shear variant was discussed at great length in the specification, the skilled addressee would have assumed that the patentee had intended to exclude it. Therefore, the variant would not be an equivalent in the light of the third "Actavis question".

Has the Prosecution History Been Used to Aid Interpretation?

The prosecution history has not been used in any cases since *Actavis* to aid interpretation, although it was pleaded in both the cases heard by Carr J referred to in the above section.

In *Illumina v Premaitha*, the defendants ran what Carr J referred to as an initially powerful argument. It was based on a statement made by the patentee's representative in the oral hearing during the opposition and the subsequent amendment to narrow the claim to prevent it being insufficient. The defendants claimed in the High Court action that the infringement argument advanced by the patentee was the very type of detection that was found by the EPO to be insufficient and which the claim was limited to exclude. Therefore, it would be wrong, and contrary to the public interest, to find that such a process infringed. Despite its initial attractions, Carr J noted that "as is often the case with arguments based on prosecution history, greater knowledge of the contents of the file suggested otherwise". As a consequence, he did not accept the argument.

In *L'Oréal v RN Ventures*, Carr J held that the prosecution history was inadmissible and, in any event, was of no assistance. Neither of the circumstances contemplated by Lord Neuberger in *Actavis* applied. He warned that reference to the prosecution history was "the exception, and not the rule" and that "parties should think carefully in future before incurring the additional costs in arguing about the prosecution history".

Is There Anticipation by Equivalence?

There is (or at least was before *Actavis*) a general principle under patent law that if an act would amount to an infringement after a patent has been granted, the same act done before granting the patent would amount to an anticipation and so invalidate the claim. This squeeze between infringement and anticipation is the basis of the "Gillette" defence, so called after *Gillette Safety Razor v Anglo-American Trading*.²¹ But whether used formally as a defence or not, an infringement/validity squeeze is often used in patent cases where the patentee is seeking to construe the claims too widely to catch the infringement, the argument being that such a construction is also wide enough to cover the prior art. The squeeze works because, as Kitchin LJ put it in *Smith & Nephew v Convatec*,²² "the scope of any ... claim must be exactly the same whether one is considering infringement or validity".

Since *Actavis*, this old certainty has fallen away. It can be seen from the discussion above that whilst the normal interpretation given to the claim will be the same for both infringement and validity, the scope of protection afforded by the doctrine of equivalents means that the claim no longer sets absolute boundaries for what is protected. Thus, there is a mismatch between the scope of protection and the scope as interpreted "normally" for the purposes of anticipation; a very considerable advantage to the patentee.

In *Generics v Yeda* Arnold J stated, *obiter*, that a claim cannot be anticipated by equivalence for the following reasons: firstly, he dismissed the arguments based on *Synthon v SKB*²³ (where the House of Lords held that whether something is novelty-destroying depends on whether the information it discloses falls within the claims, i.e. whether, if performed, it would infringe the patent) because at that time it was not possible to infringe by virtue of a doctrine of equivalents. Secondly, the jurisprudence of the Boards of Appeal of the EPO establishes that a claim is not deprived of novelty by an obvious equivalent of a feature in a prior publication.²⁴ His third point was that the decision in *Actavis* was based on Article 2 of the Protocol which is concerned with the extent of protection conferred by a European patent, i.e. with infringement and not with validity.

In this case, Arnold J held that a certain piece of prior art did not deprive claim 1 of novelty on a normal interpretation as it taught a different dosage regime; the prior art described administration of the drug every other day, whereas the patent prescribed administration of the drug three days in every seven with at least one day between each injection. Despite this, Arnold J concluded that, if it was legally possible for a claim to be deprived of novelty by virtue of the doctrine of equivalents, then claim 1 lacked novelty over the same piece of prior art. This was because the skilled person would think that missing one dose every fortnight was unlikely to have a detrimental impact on the efficacy of the treatment. Therefore, on the balance of probabilities (there was no clinical trial data in evidence) the answers to the reformulated *Improver* questions (1) and (2) were both "yes". Finally, the answer to question (3) was "no" because there was nothing in the specification to suggest to the skilled reader that strict compliance with the literal meaning was required.

Meade QC in *Fisher & Paykel v ResMed* found that one piece of prior art did not anticipate on a truly literal approach, but that there would have been anticipation by equivalence in the event that the jumping-off point for the *Actavis* questions was the truly literal meaning and if the law permitted it. The argument related to the interpretation of the word "protrusion". The prior art did not anticipate on a truly literal meaning as it did not have the necessary protrusions. Nevertheless, it anticipated on a proper purposive interpretation as the surfaces of the cylindrical collar acted as protrusions and achieved the same result.

Birss J observed in *Liqwd v L'Oreal* that he could "see room for arguing that for validity purposes some account ought to be taken of the wider scope". But he did not offer any further thoughts.

Obviousness and Insufficiency

In *Illumina v Premaitha*, Carr J was presented with an infringement/insufficiency squeeze. As mentioned above, he found the claims of the Lo 1 patent included a method of indirect detection. The defendant submitted that, as that was the case, then the patent was insufficient because it did not enable such a method.

Lord Neuberger did not address this issue. However, he stated, "if the variation represents an inventive step, while it may render it less likely that the patentee will succeed on the second reformulated question, I find it hard to see why that alone should prevent the resultant variant from infringing the original invention". This arose in the discussion of the reformulated second *Improver* question where he also reviewed the jurisprudence from other EPC member states and noted the German courts, at least sometimes, appeared to require the variation not to be inventive. Although unnecessary to decide, he did not consider this an appropriate requirement.

Given the above, Carr J noted that it would not make sense if the patent was found to be insufficient solely because an inventive

variant, which it did not enable, fell within the scope of its claims. His conclusion was supported by the case law of the Boards of Appeal in the EPO²⁵ from which it follows that if future inventive improvements fall within the claim because they adopt a principle of general application, the patent is not necessarily invalid for insufficiency.

Carr J accepted that the Lo 1 patent did not disclose a method of indirect detection, which was unsurprising as such a method could not have been made to work at the priority date. Despite this, however, he held that the patent was sufficient and infringed by the indirect detection method.

Points on Evidence

There have been a couple of interesting points on evidence following *Actavis*.

The first is to note that *Actavis* has, if anything, increased the potential role that expert evidence may play in the question of scope of protection.²⁶

The second is to note that it may increase the information and disclosure that the parties have to give to each other. In *Pacific Biosciences v Oxford Nanopore Technologies*,²⁷ Norris J acceded to an application for further information of the claimant's case on infringement by equivalence. If the claimant's case was that the defendant's sequencing adapters achieved the same result as the connecting nucleic acid referred to in claim 1 and in substantially the same way, it was permissible to ask the claimant to identify what was said to be the result, what was alleged to be the way in which its connecting nucleic acid achieved that result and what was alleged to be the way in which it was said that the defendant's sequencing adapter achieved that result. He also permitted a request asking the claimant to identify what part of the teaching in the patent was to be relied upon as demonstrating the purpose of the invention, i.e. its inventive core.

Conclusion

Having dropped his bombshell, Lord Neuberger has now retired. In the autumn, Kitchin LJ will be elevated to the Supreme Court. Whether he will have the opportunity whilst in the Supreme Court to consider the issues in *Actavis* and particularly the issue of anticipation by equivalence is uncertain.

Therefore, as matters stand at present, *Actavis* appears to have given real life to Prof. Mario Franzosi's Angora cat: "When validity is challenged, the patentee says his patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze."²⁸

Endnotes

1. This article is up to date as of 20 July 2018.
2. [2017] UKSC 48.
3. [2004] UKHL 46.
4. [1990] FSR 181.
5. Ss.125(1) and (3) and 130(7) Patents Act 1977.
6. [1982] RPC 183.
7. [2009] EWCA Civ 1062 at para 5.
8. *Wheatley v Drillsafe* [2000] EWCA Civ 209.
9. [2009] 40 IIC 3.
10. [2017] UKSC 24.
11. [1997] UKHL 28.
12. [2017] EWCA Civ 1671.
13. [2018] EWCA Civ 671.
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Katharine Stephens is co-head of the London Intellectual Property Group, and has been a partner at Bird & Bird since 1999. She specialises in patent, trade mark and design litigation, often coordinating and running actions in more than one jurisdiction.

With a Master's degree in Mechanical Engineering from Bristol University, Katharine has a particular interest in the electronic, computer technology and engineering sectors. Many of the patent actions which she has been involved in over the years concern standard essential patents and patent pools, and she is therefore experienced in dealing with the patent and competition law issues raised in such cases.

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Katharine has been recognised as one of the 'Top 250 Women in IP' by Managing IP for the second year running and is highly ranked across all areas of IP in the major legal guides.

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