It is now two years since the UK Supreme Court's judgment in Actavis v Eli Lilly [2017] UKSC 48 (12 July 2017) re-steered in a markedly different direction the law of patent infringement in the UK, stating that there is a doctrine of equivalents. How has English patent law developed its doctrine of equivalents since then, and how has the Supreme Court's judgment impacted other aspects of patent law? We thought this was a good moment to reflect on the activity in the courts since the ground-breaking judgment of 2017.

Background: what the UK Supreme Court said in Actavis v Eli Lilly and the questions arising

In Actavis v Eli Lilly, Lord Neuberger said ([54]):

"...a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, ie the person skilled in the relevant art. Those issues are: (i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not, (ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial? If the answer to either issue is "yes", there is an infringement; otherwise, there is not."

This gave rise to a two-limbed approach to the assessment of infringement in the UK, a departure from decades of practice under the "purposive approach", as explained in our 2017 article "UK Supreme Court introduces doctrine of equivalents in patent law in Actavis v Lilly".
The Supreme Court's judgment in Actavis v Eli Lilly, however, gave rise to a number of questions; both on the detail of the new approach to infringement and the implications of the ruling for other aspects of patent law. In the course of the last two years, the English courts have been grappling with these questions, as a result of which patent law in the UK has become better developed and settled.

Patent infringement under the "normal interpretation" (limb (i))

Immediately following the Supreme Court's judgment in Actavis v Lilly, questions arose as to what, exactly, was meant by infringement "as a matter of normal interpretation". How much of the former purposive approach remained intact?

Under the purposive approach (as laid down in Catnic [1982] RPC 183, Improver [1990] FSR 181 and Kirin-Amgen [2005] RPC 9), the reach of a patent claim for the purposes of assessing infringement was defined by giving effect to "what the skilled person in the art would have understood the patentee to be claiming". This was an objective interpretation of the language of the claim, through the eyes of the skilled addressee (who brought with them their common general knowledge) in light of the description and drawings of the patent. The purposive approach was a contextual interpretation, intended to be contrasted with "old English literalism" which had characterised the approach to the interpretation of commercial documents under English law until the 1970s. Such old English literalism did not permit consideration of the contextual background to the making of a commercial document when considering its objective interpretation, and so in that sense could be described as acontextual. The purposive approach was also to be contrasted with assigning meaning to claim language according only to the conventional rules for the use of language, such as one finds in a dictionary or the rules of grammar. In the interpretation of patent claims under the purposive approach, the employment of the person skilled in the art, imbued with their common general knowledge, imported contextuality, along with the necessary consideration of the description and drawings of the patent specification. Claim language could not be ignored if it did not appear to make any difference to the inventive concept.

Further, under the purposive approach, it was permissible, when construing the claim language, to have regard to the alleged infringing product or process. The court could consider a series of questions (the Improver or "Protocol" questions) to assist in deciding whether the alleged infringing product or process fell within or outside the claim, albeit that the House of Lords had discouraged their use in Kirin-Amgen and they had seen less
employment in patent judgments in the years preceding Actavis v Eli Lilly. Lord Neuberger said that this aspect of the purposive approach conflated the issues, was wrong in principle and therefore could lead to error. But Lord Neuberger did not expressly state how much of the purposive approach he intended to undo. In particular, did the principles described in the previous paragraph remain intact?

Two years on, the following can be said:

- The former Improver/Protocol questions form no part of the assessment of the normal interpretation of the claim (Icescape v Ice-World [2018] EWCA Civ 2219 (Kitchin and Floyd LLJ), Regen v Estar [2019] EWHC 63 (HHJ Hacon); notable earlier commentary in Liqwd v L’Oréal [2018] EWHC 1394 (Birss J)).
- The "normal interpretation" is a purposive interpretation because it is the ascertaining of the objective meaning of the words of the claim in their context to the skilled addressee (Icescape v Ice-World [2018] EWCA Civ 2219 (Kitchin & Floyd LLJ), Regen v Estar [2019] EWHC 63 (HHJ Hacon); notable earlier commentary in Generics v Yeda [2017] EWHC 2629, Actavis v ICOS [2017] EWCA Civ 1671 (Kitchin LJ), Illumina v Premaitha [2017] EWHC 2930 and Liqwd v L’Oréal [2018] EWHC 1394).

In other words, "normal interpretation" is the pre-Actavis v Eli Lilly purposive approach but without the Improver/Protocol questions. Accordingly, the principles of construction originally set out in Kirin-Amgen, then elaborated on by the Court of Appeal in Virgin v Premium [2009] EWCA Civ 1062 at [5] remain good law in respect of normal interpretation (Saab v Seaeye [2017] EWCA Civ 2175 at [19]). This now represents the minimum protection afforded by the patent (Icescape v Ice-World [2018] EWCA Civ 2219).

**Patent infringement under the doctrine of equivalents (limb (ii))**

The resolution of a question of infringement under the normal interpretation (Lord Neuberger’s limb (i)) will only conclude the issue of infringement between the parties if a finding of infringement is reached under that limb (or if the patentee does not assert the doctrine of equivalents). If infringement is not established according to the normal interpretation, then following Actavis v Eli Lilly, the court will consider whether there is nevertheless infringement under the doctrine of equivalents (Lord Neuberger’s limb (ii)).

In Actavis v Eli Lilly, Lord Neuberger described limb (ii) as addressing the following issue:
"does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?"

In this context Lord Neuberger considered that the Improver/Protocol questions provided helpful assistance but needed some reformulation. He proceeded to undertake the reformulation, emphasising that the 'reformulated questions' remained only guidelines, not strict rules, and that they might sometimes have to be adapted to apply more aptly to the specific facts of a particular case. In Icescape v Ice-World, the Court of Appeal (Kitchin LJ) subtly re-stated the limb (ii) approach.

First, without acknowledging Lord Neuberger's comments about the reformulated questions being guidelines, not strict rules, and sometimes needing adaption, Kitchin LJ said that the limb (ii) question "is to be determined by asking these three questions".

By making this statement, Lord Kitchin indicated that the reformulated questions should be considered the mandatory approach to the assessment of limb (ii), moving the emphasis away from Lord Neuberger's phrasing "does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial". While this is unlikely to make a difference in most cases, in the occasional case it will be worth remembering that there is a conceptual difference and Lord Neuberger's approach potentially permits more flexibility in the assessment of limb (ii). Lord Neuberger's judgment remains the authority on the point. Nevertheless Lord Kitchin is now the intellectual property specialist in the Supreme Court, so he may embody his elaboration at some future date.

Turning to the reformulated questions, Kitchin LJ's modification (shown in bold text below) of Lord Neuberger's language results in the following:

1. Notwithstanding that it is not within the literal (that is to say, I interpolate, normal) 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?
2. 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?
3. 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?

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes"
and that the answer to the third question was "no".

Kitchin LJ's interpolation of "normal" for "literal" in the first of the reformulated questions would introduce a change if Lord Neuberger had meant an acontextual (i.e. the dictionary meaning) literal construction of the wording in the claims. If this was the correct interpretation of Lord Neuberger's judgment, then the analysis of limb (ii) would involve first stepping back from the normal interpretation of the claim language to a stricter, less contextual one (if different), before then considering the issue of equivalents. However, adopting Kitchin LJ's approach, no stepping back is needed and in the overwhelming majority of cases, Icescape v Ice-World can be expected to provide welcome clarity on the legal test.

Lord Neuberger's additional guidance, in paragraphs [59]-[65] of his judgment in the context of the reformulated questions, should also be noted.

Turning to the application of the doctrine of equivalents in practice, since the Supreme Court's judgment in Actavis v Eli Lilly there have (at the time of writing) been 42 substantive judgments in which issues of infringement and/or validity have been considered. The court has considered a question of infringement under the doctrine of equivalents in nine of those cases. Only in one of those cases (Marflow v Cassellie [2019] EWHC 410 (Pat)) may the court's reasoning in respect of the doctrine of equivalents presently be considered ratio.

The trial of the first of these cases, Illumina v Premaitha [2017] EWHC 2930 (Pat), took place from 4-27 July 2017, during which time the Supreme Court's judgment in Actavis v Eli Lilly was handed down (on 12 July 2017). In his judgment in Illumina, Henry Carr J made a number of findings of infringement on the basis of the normal interpretation, but in case he was wrong on those conclusions, followed up with some observations that he would have concluded, if necessary, that infringement under the doctrine of equivalents had not been established. The judgment flags a need for parties to address, by way of evidence, whether the alleged infringing product or process amounts to an immaterial variant. For example: (going to the first reformulated question) does the variant achieve substantially the same result in substantially the same way as the inventive concept revealed by the patent? - if not, then this goes against infringement; (going to the second reformulated question) does the variant represent an inventive step over the patent? - if so, then this a factor against infringement and (going to the third reformulated question) is the component or claim feature at issue (i.e. which is not present in the variant) an essential part of the inventive concept - if so, then its omission is a factor against infringement.
In L'Oréal v RN Ventures [2018] EWHC 173 (Pat), Henry Carr J concluded that the patent was infringed upon the normal interpretation of claim 1. Nevertheless he considered and dismissed two strands of argument made on the basis of the doctrine of equivalents: one fell at the first reformulated question, in light of the evidence; the other fell at the third question, because the patentee having discussed the relevant feature at great length in the specification but excluded it from the claims, the judge considered that the skilled addressee would have concluded that this was intended, possibly in light of prior art cited during the course of prosecution. The trial of the L'Oréal case had been heard in December 2017, several months after the Supreme Court's judgment in Actavis v Eli Lilly was handed down.

The next judgment to consider a question of infringement under the doctrine of equivalents was the Court of Appeal's judgment in Icescape v Ice-World (October 2018). The Court of Appeal confirmed the first instance finding that the patent in issue was not entitled to its claimed priority and so was invalid but proceeded nevertheless to consider the question of infringement. Essentially, after concluding that a parallel connection of elements did not infringe a claim to a series connection upon the normal interpretation (which was in keeping with the Patents Court's conclusion on the old purposive approach) the Court of Appeal considered and found infringement under the doctrine of equivalents. Kitchin LJ reasoned that a parallel connection was an alternative way of implementing multiple elements, the difference from the claimed means had nothing whatever to do with the core inventive contribution of the patent, which was the provision of a joint member forming a connection between the rigid pipe sections which was fluid tight and flexible and allowed the connected pipe sections to fold relative to one another for the purposes of transportation. There was nothing to suggest that the patentee regarded series connection as essential in any relevant sense, given that the language of the claim alone was not to be taken to be sufficient to give rise to this inference. Accordingly, if the patent had been valid, infringement would have been established.

Since Icescape v Ice-World, infringement has been found under the doctrine of equivalents in six first instance judgments. Three of those judgments are of HHJ Hacon in the Intellectual Property Enterprise Court, the others are of Nugee J and Arnold J in the Patents Court.

In Regen v Estar, HHJ Hacon said that if there are multiple differences between the claim and the variant, the differences should be considered together. On the other hand, in Emson v Hozelock [2019] EWHC 991 (Pat), Nugee J took the opposite approach.

In Regan v Estar, Judge Hacon also said that in the application of the doctrine of
equivalents, numerical claims should be treated no differently to any other claim. In that case, the patented method for obtaining platelet-rich plasma involved taking blood from a patient, transferring it to a tube containing a thixotropic gel and an anticoagulant and centrifuging it at a slow rate. The variant alleged to infringe employed a gel that was not polyester-based and a buffered sodium citrate solution at 0.136M, not 0.1M as required by the claim language. Applying the normal interpretation (drawing on Smith & Nephew v Convatec [2015] EWCA Civ 607, which drew upon Virgin v Premium for the principles on claim interpretation) the claim did not stretch to cover the variant. However, the judge concluded that neither of the differences mattered much; it was the density of the gel that mattered. Accordingly the variant was caught by the doctrine of equivalents.

This is a very strange turn of events. It would seem that, on considering the third amended question in the test for assessment of equivalence under limb (ii), the existence of clearly delineated numerical limits would have been a very clear signpost of the patentee intending strict compliance.

Judge Hacon noted too that Lord Neuberger’s reformulation of the Improver questions, in particular the first and third questions, had made significant changes. The focus had been shifted from the invention as claimed to the "core of the inventive concept or core of the invention", this being "the new technical insight conveyed by the invention - the clever bit - as would be perceived by the skilled person", assessed by reference to the specification and the evidence.

This last point seems to have underpinned the court's findings of infringement by equivalents in Regen v Estar and the next three cases to consider the doctrine - Technetix v Teleste [2019] EWHC 928 (Pat), Marflow v Cassellie [2019] EWHC 410 (IPEC) and Emson v Hozelock [2019] EWHC 991 (IPEC). In each, the variant was considered not to be essential to the inventive concept of the patent.

Marflow’s patent concerned a mounting plate for pipes for use with a fluid-using appliance. The claim language required a 'locking member' in or on the body of the mounting member. The variant employed a screw thread on the mounting member and a nut, which did not infringe on the normal interpretation because the nut was not in or on the body of the mounting member. Turning to the doctrine of equivalents, HHJ Hacon considered the inventive concept of the patent to be the idea of using a plate (mounting member) to install a fluid-using appliance by securing a plate to the wall receiving the fluid pipes extending out of the wall through apertures in the plate and using a locking means to lock the pipes to the plate. The inventive concept did not include a specific locking means. The variant screw and nut arrangement achieved the results achieved by the inventive concept and the
judge concluded that the first reformulated question was answered 'yes'. Since the defendant did not separately contest the second and third reformulated questions, a finding of infringement on the doctrine of equivalents was reached. Nevertheless, the judge noted that there remains a question of whether an advantage consequent upon the use of an inventive concept is invariably a "result" achieved by the inventive concept as contemplated by Lord Neuberger in the first and second reformulated questions.

In Eli Lilly v Genentech [2019] EWHC 387 (Pat), understanding of the technical field had advanced considerably between the priority date of the patent (2003) and the date of the trial (2019). The first reformulated question was assessed on current evidence, the judge concluding that the variant antibody did achieve substantially the same result in substantially the same way. This seems in keeping with the first reformulated question being posed in the present - 'does the variant achieve substantially the same result…' - (i.e. at the date of the infringement). It seems also in keeping with Lord Neuberger's guidance, in the context of the third reformulated question, that 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. In respect of the second reformulated question (in which the notional addressee is taken to know that the variant works to the extent that it actually does work), Arnold J noted that there are likely to be few cases in which the question will be answered in the negative.

Finally, in Conversant v Huawei [2019] EWHC 1687 (Pat), the claim language was to a method for autonomous enhanced uplink transmission (i.e. for use in telecommunications). As a matter of construction, this involved checking whether the medium access control was transmitting at the end of the current transmission time interval (TTI). The patentee, Conversant, accepted that there was no infringement on the normal interpretation. The variant carried out the check with respect to the previous TTI rather than the current TTI, which Arnold J concluded infringed on the doctrine of equivalents.

In the Icescape, Regen, Technetix, Emson, Eli Lilly v Genentech and Conversant cases, the patents in issue were found invalid. In the Illumina, L’Oréal and Eli Lilly v Genentech cases, the relevant claims were held infringed on the normal interpretation before the doctrine of equivalents was considered nevertheless. The court's reasoning in respect of the doctrine of equivalents in each of those cases was therefore obiter, but the judgments undoubtedly provide useful guidance on the doctrine of equivalents in the UK.

From the case law discussed above it may be concluded that, contrary to the position under the purposive approach, when assessing the reach of the patent's monopoly on the
The doctrine of equivalents, claim language which does not appear to make a difference to the inventive concept may in some cases be treated, essentially, as struck out (subject of course to this being prevented by the application of the third reformulated question).

In all cases, the correct identification of the inventive concept - the 'clever bit' - is now key to assessing a question of infringement on the doctrine of equivalents.

From a patentee's perspective, the simpler the inventive concept, the more likely it is that the concept has been exploited in substantially the same way to achieve substantially the same result; but the more likely also that a Formstein defence could apply (on which please see below). From an alleged infringer's point of view, the more detailed the inventive concept, the less likely it is that the concept has been so exploited.

It is not entirely clear, though, exactly what is meant by the term 'inventive concept'. In the context of an assessment of obviousness on the Windsurfing/Pozzoli approach, the skilled person is called upon to identify the inventive concept of a claim before any comparison with the prior art - self-evidently this may be broader than the 'clever bit' in view of the prior art (therefore covering material that could engage Gillette/Formstein), yet it is also constrained by the claim language (apparently in conflict with the purpose of the doctrine of equivalents explained by Lord Neuberger). In the context of an entitlement dispute, it may be possible for the inventive concept to be gleaned from the specification, outside the language of any pending claims - but a question of infringement may only be determined once claims have been finalised and the patent granted, so query whether this is the correct approach either.

In Marflow v Cassellie, for example, the inventive concept was identified by the court as a development over the prior art discussed in Marflow’s patent specification, not by reference to the prior art relied upon by Cassellie in its challenge to the validity of the patent. Similarly, in Technetix v Teleste, the inventive concept was defined without reference to the disclosures of the invalidating prior art. This seems likely to be an area of the law that will be tested in the coming years, quite likely in conjunction with any emerging Formstein defence.

So, to summarise, two years on from Actavis v Eli Lilly, we can now say:

- The doctrine of equivalents (re-)introduced by the Supreme Court in Actavis v Eli Lilly along with guideline 'reformulated questions', and re-stated by the Court of Appeal in Icescape v Ice-World, is now an established part of patent law in the UK.
- Whether the use of the 'reformulated questions' in the application of the doctrine is mandatory remains to be settled; in practice they can be expected to form the usual
approach to the court’s determination of a question of infringement if a finding of infringement is not reached on the normal interpretation.

- The doctrine of equivalents, in the guise of the reformulated questions, is directed to immaterial variants to the inventive concept i.e. the 'clever bit' of the patent; compared with the purposive approach, this shifts the focus of the enquiry away from the language of the claim and requires the court to consider whether the relevant integer missing from the variant would have been regarded by the skilled person as an essential part of the inventive concept; the correct identification of the inventive concept is likely to be tested in the jurisprudence in the coming years.
- In litigation concerning a question of infringement, evidence is needed directed to the application of the doctrine of equivalents.
- The jurisprudence indicates that since the Court of Appeal’s judgment in Icescape v Ice-World (October 2018), infringement by equivalence has been found in every case in which such arguments have been made at trial.

Prosecution history estoppel / file wrapper estoppel - how is this working in the UK?

In Actavis v Eli Lilly, Lord Neuberger concluded that it was appropriate for the UK courts to adopt a "sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file should be referred to when considering a question of interpretation or infringement" i.e. to any arguments of file wrapper estoppel. He said there would be occasions when justice may fairly require this. However, Lord Neuberger's view was that such circumstances should be limited, that reference to the file would only be appropriate where:

i. 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
ii. it would be contrary to the public interest for the contents of the file to be ignored.

In the Actavis v Eli Lilly case, after provisionally concluding that the Actavis products infringed Lilly's patent under limb (ii), Lord Neuberger considered and rejected Actavis' prosecution history estoppel arguments. He said that the whole point of the doctrine of equivalents was that it entitled the patentee to contend that the scope of protection afforded by the patent extended beyond the ambit of the claims "as construed according to normal principles of interpretation". He also expressed the view that the examiner had been wrong. For more on the Supreme Court's approach to the prosecution history in
Actavis v Eli Lilly, please see our article "UK Supreme Court introduces doctrine of equivalents in patent law in Actavis v Lilly".

In the cases since Actavis v Eli Lilly, arguments in reliance on the prosecution history made by the party alleged to infringe have been considered in four cases and rejected in each (Illumina, L’Oréal, Icescape, Regen). Lord Neuberger’s sceptical approach is reflected in the reasoning of each judgment and his circumstances referred to and discounted on the facts. As noted in our article What does Actavis v Eli Lilly mean for European patent litigation strategy?, the scepticism of the UK approach may be contrasted with that taken in some other European jurisdictions.

For example, in L’Oréal v RN Ventures [2018] EWHC 173 (Pat), Henry Carr J said that he did not consider that L’Oréal had been under a duty to correct any misunderstanding about the scope of the claims on the part of the examiner. Emphasising that reference to the prosecution should be the exception, not the rule, he warned parties to think carefully before incurring additional costs in arguing about the prosecution history. In Icescape v Ice-World [2018] EWCA Civ 2219, Kitchin LJ observed that the case was an example of why it is "generally so unprofitable to explore the prosecution history".

That said, it is easy to see how it will always be tempting to look to the prosecution history for support if seeking to answer the third reformulated question under limb (ii). If ever the patentee is going to offer a sign as to its intention that strict compliance is necessary, it may be in office actions at a patent office. This should not be ruled out. One day it will be relevant.

To summarise, the courts in the UK take a sceptical approach to arguments that the contents of the prosecution file should limit the scope of the monopoly conferred by the patent. Judges in the UK are less deferential to the views of European Patent Office examiners than appears to be the case in some other European jurisdictions.

Claim construction for the purpose of assessing validity: is there a validity gap?

Some of the most interesting questions arising from the Supreme Court’s judgment in Actavis v Eli Lilly concern the law regarding validity.

Under the purposive approach (as laid down in Catnic, Improver and Kirin-Amgen), the claims of the patent as construed defined both the reach of the monopoly for the purpose of infringement and the target for any validity challenge. This meant that in order to
anticipate a patent, matter relied upon as novelty-destroying prior art had to disclose subject matter which, if performed, would necessarily result in an infringement of the patent; consequently whenever the prior disclosure was capable of being performed and was such that, if performed, it must result in the patent being infringed, the disclosure condition (of anticipation) was satisfied.\[6\]

Following Actavis v Eli Lilly, commentators questioned how patent claims should be interpreted or "construed" for the purpose of assessing validity. In particular, did the purposive approach (permitting consideration of equivalents) continue to apply in this context or was normal interpretation now the correct course?

Twice since Actavis v Eli Lilly, the UK Supreme Court has had an opportunity to provide guidance on this question, and twice it has not done so.\[7\]

In the meantime, the jurisprudence that has emerged from the lower courts indicates the following:

- However, the Improver/Protocol questions, which could be drawn upon in the construction of a patent claim on the purposive approach, may not now be drawn upon in the context of construction (Icescape v Ice-World [2018] EWCA Civ 229, Regen v Estar [2019] EWHC 63, Eli Lilly v Genentech [2019] EWHC 387 - although this is not settled as observed in Icescape and Liqwd v L'Oréal [2018] EWHC 1394)
- The process of construing a patent for the purpose of assessing its validity is the same as the 'normal interpretation' stage of the assessment of infringement (Icescape v Ice-World [2018] EWCA Civ 229, Eli Lilly v Genentech [2019] EWHC 387 (Pat))
- Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean - this is not "the meaning of the words the author used", but rather what the notional addressee would have understood the author to mean by using those words - it depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience (Network Homes v Maurice Harlow [2018] EWHC 3120 (Ch), drawing upon Language and Lawyers [2018] LQR 553 (Lord Hoffmann); see also Generics v Yeda [2017] EWHC 708 (Pat))
Further, when assessing the validity of a patent in view of earlier published information, it remains the case that the court must identify what was made available to the public by the publication, and then consider whether this anticipates or renders obvious the claimed invention. No doctrine of equivalents is drawn upon in the interpretation of the prior art or the assessment of novelty or inventive step and it is the patent claim, construed as explained in the bulleted paragraphs immediately above, for which the validity assessment is made. Examples of this approach being taken may be found in Generics v Yeda [2017] EWHC 708 (Pat), Actavis v ICOS [2017] EWCA Civ 1671, Fisher & Paykel v ResMed [2017] EWHC 2748 (Pat), Illumina v Premaitha [2017] EWHC 2930 (Pat), Saab v Atlas [2017] EWCA Civ 2175, L’Oréal v RN Ventures [2018] EWHC 173 (Pat), Cantel v Arc [2018] EWHC 345 (Pat), Regeneron v Kymab [2018] EWCA Civ 671, Bose v Freebit [2018] EWHC 889 (Pat), Liqwd v L’Oréal [2018] EWHC 1394 (Pat), Technetix v Teleste [2019] EWHC 126 (IPEC), Marflow v Cassellie [2019] EWHC 410 (IPEC), Eli Lilly v Genentech [2019] EWHC 387 (Pat), TQ Delta v ZyXEL [2019] EWHC 562 (Pat), Emson v Hozelock [2019] EWHC 991 (Pat), and Illumina v TDL [2019] EWHC 1497 (Pat).

Accordingly, as indicated by Arnold J in Generics v Yeda [2017] EWHC 708 (Pat), it appears no longer to be the law that a patent claim lacks novelty if the prior publication disclosed subject-matter which, if performed, would infringe the claim. In order to anticipate, such infringement must be on the normal interpretation (rather than the doctrine of equivalents). For the discussion of the legal principles, see also Fisher & Paykel v ResMed [2017] EWHC 2748 (Pat).

Consistently with this, in Conversant v Huawei [2019] EWHC 1687 (Pat), Arnold J stated that infringement by equivalence cannot give rise to an added matter challenge.

To summarise, on the basis of the jurisprudence to date, it appears that where infringement is established on the basis of limb (ii) (the doctrine of equivalents), and therefore, by definition not under limb (i) (the normal interpretation of a claim), there will be a difference between the reach of the claim for the purposes of infringement and the scope of the claim for the purposes of validity. We will call this the "validity gap".

**Why does it matter if there is a validity gap?**

A consequence of the purposive approach to the construction of patent claims, which was the law before the Supreme Court's judgment in Actavis v Eli Lilly, was that the determination of an issue of claim interpretation could also be determinative of issues of both infringement and validity. This meant that in practice, parties alleged to infringe a patent often ran "squeeze" arguments between infringement and validity such that if the
claim was broad enough to cover the product or process complained of, then it must be invalid.

For example, there could be a squeeze between infringement and sufficiency: a party alleged to infringe could argue that if the claims were to be interpreted broadly enough that the alleged infringing product or process fell within their scope (and so infringed) then they would be insufficient because the patent did not enable a claim of such scope i.e. the claim was of excessive breadth. Arguments of this nature succeeded, for example, in the House of Lords in Kirin-Amgen and the Court of Appeal in AHP v Novartis [2000] EWCA Civ 231.

However, if there is now a validity gap, such that a patent need only be sufficient to the extent that its claims are construed according to the normal interpretation, then if a variant is found to infringe on the doctrine of equivalents the patentee could side-step an insufficiency squeeze by merely establishing the sufficiency of the claim as normally interpreted.

Interestingly, in each of the Kirin-Amgen and AHP cases, the judge at first instance had, somewhat rebelliously at the time, extended the scope of the claimed protection, in light to the inventive concept or "contribution" of the patent, to find infringement, while also finding the patent sufficient. In the Kirin-Amgen case[8], Neuberger J (as he then was) assessed the sufficiency of the claimed invention before applying the Improver questions and concluding that there was infringement too. In the AHP case[9] Laddie J considered the gap between the claimed "rapamycin" and the infringing class as he had determined it - derivatives of rapamycin that worked in the same way - not to represent an undue burden. In AHP the Court of Appeal overturned Laddie J's conclusion on sufficiency on the basis of the factual findings; in Kirin-Amgen both the appellate courts considered that Neuberger J had erred in his identification of the level of generality at which the skilled person would understand the invention to be operating. Nevertheless, in each case, the party alleged to infringe succeeded as a consequence of its infringement/sufficiency squeeze arguments employed in the context of the purposive approach applied by the appellate courts. So these cases represent interesting studies on the consequence of adopting the alternative approaches to claim construction and infringement as represented by Catnic / Improver / Kirin-Amgen on the one hand and Actavis v Eli Lilly on the other.

On the purposive approach, another squeeze argument that could be made was between obviousness and infringement i.e. that if the claim language was interpreted broadly enough that the alleged infringing product or process fell within the scope of the claim, then it would encompass material that was obvious in the light of the prior art and the
claim would therefore be invalid. For example, such an approach was successful for the party alleged to infringe in Chiron v Evans [1997] EWHC 359 (Pat) and SKB v Apotex [2004] EWCA Civ 1568.

Similarly, a squeeze between infringement and anticipation could be employed, invoking the principle illustrated by the House of Lords' judgment in Synthon v SKB [2006] RPC 10. For example, such an approach was successful in Apimed v Brightwake [2012] EWCA Civ 5.

The so-called 'Gillette defence' to infringement is a type of squeeze between infringement and validity (anticipation or obviousness). First recognised in the judgment of Lord Moulton in Gillette v Anglo-American (1913) 30 RPC 465, it stems from the principle that, it being impossible for an ordinary member of the public to keep watch on all patents, "he is entitled to feel secure if he knows that that which he is doing differs from that which has been done of old only in non-patentable variations, such as the substitution of mechanical equivalents or changes of material shape or size". In Merrell Dow v Norton [1996] RPC 76, Lord Hoffmann put it this way:

"Ever since the power of the Crown to grant monopolies was curbed by parliament and the courts at the beginning of the seventeenth century, it has been a fundamental principle of United Kingdom patent law that the Crown could not grant a patent which would enable the patentee to stop another trader from doing what had been done before."

A Gillette defence concerns the obviousness or lack of novelty in the defendant's own product or process as at the priority date of the patent alleged to be infringed (i.e. the date at which the novelty or inventive step of the patent is to be assessed). This is subtly different to a more general infringement/anticipation or infringement/obviousness squeeze, which concerns the validity of the patent directly. The Gillette defence is therefore a type of short-cut, but while its conceptual importance has continued to be recognised, the courts have been slow to rely upon it, since it is seen to be in the interests of the parties and the public that issues of infringement and validity be severally adjudicated on.

Nevertheless, recent English case law has developed the use of the Gillette defence into a type of shield from future patents, in the form of Arrow declaratory relief. Arrow relief is a declaration that the applicant party's own product or process, or aspects of it, were known or obvious at a relevant date - this being the priority date of a relevant patent or application. Arrow relief was awarded in FKB v AbbVie [2017] EWHC 395 (Pat) and GSK v Vectura [2018] EWHC 3414 (Pat).
If there is now a validity gap, such that a patent need only not be obvious to the extent that its claims are construed according to the normal interpretation, then if a variant is found to infringe on the doctrine of equivalents the patentee could side-step an obviousness or anticipation squeeze by merely establishing the inventiveness or novelty of the claim as normally interpreted.

However, a validity gap would seem not to offer a side-step around a Gillette defence, due to the focus of the defence upon the alleged infringing product or process and the employment of the principles explained in Gillette and Merrell Dow. Consistently with this, in Technetix v Teleste [2019] EWHC 126 (IPEC) at [90], HHJ Hacon said that it would be "surprising" if the Supreme Court in Actavis had intended to abandon the Merrell Dow principle without expressly saying so. Also notable are some interesting parallels between the Gillette defence and defences to infringement by equivalents available in other jurisdictions in respect of known or obvious subject matter.

To summarise, the apparent presence of a validity gap, in cases where infringement is established not on the normal interpretation but on the doctrine of equivalents, may enable patentees to side-step 'squeeze' arguments between infringement and validity. However, to date, no case has reached judgment in the UK in which the patentee appears to have benefited from such a validity gap. It would seem possible for a party alleged to infringe a patent to avoid or close a validity gap by relying upon a Gillette defence or, potentially, obtaining recognition in the UK of some type of Formstein defence as discussed below.

A possible new defence to infringement to close the validity gap?

In Technetix v Teleste [2019] EWHC 126 (IPEC), Technetix's patent to a "cable tap unit" (used in a cable TV wire network), as proposed to be amended, was invalid for anticipation and obviousness. Had it been valid, the patent would have been infringed under the doctrine of equivalents by Teleste's "Tap Bank". In case such an infringement finding had been reached in respect of a valid claim, Teleste had argued for a defence based on the Merrell Dow (or Gillette) principle. HHJ Hacon said:

"One way of reconciling the Merrell Dow principle with the doctrine of equivalents would be to say that if an accused product or process is an equivalent and for that reason is nominally within the scope of the claim, but the equivalent would have lacked novelty or inventive step over the prior art at the priority date, then it is deemed to fall outside the scope of the claim, thus providing a defence to
Judge Hacon noted that in a number of other legal systems, such a defence exists, in particular:

- In German law, as first stated in the judgment of the Federal Supreme Court in Case X ZR 28/25 Formstein GRUR 1986, 803.
- In Dutch law, as stated in Core Distribution Inc v Lidl Nederland GmbH, District Court of The Hague, 14 March 2012 (Kalden, Hensen and van Peursem).
- In US law, as stated in a judgment dated 29 September 2017 the Court of Appeals of the Federal Circuit said this in Jang v Boston Scientific Corp, Opinion no. 16-1275 (Fed. Cir. 2017) at 14-15.

Accordingly, the judge said that one route the Supreme Court or the Court of Appeal may take in due course, regarding the interplay between the scope of a claim on the one hand and novelty and inventive step on the other, is the introduction into English law of a Formstein defence. He therefore considered whether such a defence would exist on the facts of the Technetix case, concluding that it would have been obvious at the priority date to adapt the common general knowledge to create a unit the same as the Tap Bank.

In Emson v Hozelock [2019] EWHC 991, Nugee J also concluded that the patents in issue, to a new type of garden hose, were invalid for obviousness, but had they been valid they would have been infringed under the doctrine of equivalents. Again, the party alleged to infringe had argued for a Formstein defence. In view of the invalidity of the patents, the judge declined to address whether such a defence might have a place in English law but noted the judgment in the Technetix case and said that a decision on the subject should be left to a case where it would make a difference, and very probably to a higher court.

To summarise, the first instance courts have indicated that English law may provide a defence to a finding of infringement by equivalents by drawing upon the long-standing principles that a patent may not be granted which prevents a third party from doing what has been done before or that which differs to what has been done of old only in non-patentable variations.

The impact of Actavis v Eli Lilly on patent infringement law

The UK Supreme Court’s judgment in Actavis v Eli Lilly has significantly impacted the courts’ approach to the assessment of patent infringement in the UK. Analysis of the case
law indicates that in some cases, this is making a difference to the outcome of an issue of infringement.

Since the start of 2019, following the Court of Appeal's judgment in Icescape v Ice-World, judicial consideration of issues of infringement according to the two-limb process laid down by Actavis v Eli Lilly has become the norm in UK patent judgments, notably increasing the jurisprudence in the area. There is now a helpful body of guidance on the application of Lord Neuberger's test.

It is clear that the consideration of a question of infringement is a two stage process, and under the second stage (the doctrine of equivalents), the correct identification of the inventive concept of the patent is key.

Further, the impact of the Actavis v Eli Lilly judgment is not limited to the law on infringement. By (apparently) enabling a difference between the reach of the claims for the purposes of infringement and the scope of the claims for the purposes of validity, it may, in some cases (where infringement is found on the doctrine of equivalents but not on the normal interpretation), now be possible for patentees to side-step squeeze arguments between infringement and validity which formed a conventional part of patent litigation before Actavis v Lilly.

It is therefore to be expected that in coming years the courts will be called upon to better define what is meant by 'inventive concept' in the context of the doctrine of equivalents, most likely in conjunction with any emerging Formstein type defence.

Look out for future updates from Gowling WLG on these and wider IP-related issues and visit our other news and insight resources.

Footnotes:


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