Following the Supreme Court's decision in Actavis v Lilly, is there a gap between the interpretation of a patent claim for validity purposes and its reach for infringement purposes? If so, what are the practical implications?

In a landmark decision (Actavis v Eli Lilly [2017] UKSC 48), the UK Supreme Court has re-steered the law of patent infringement in the UK, stating that there is a doctrine of equivalents. Effectively, Lord Neuberger said that by conflating the issues of construction and infringement, the leading authorities were wrong.

The implications of this reasoning may be felt across swathes of patent law in the UK. It raises questions that go to the heart of the policy for permitting the grant of limited term monopolies by the grant of patents. One of the most interesting questions is whether, now, the reach of a patent claim for infringement purposes may be wider than its scope for validity purposes. To best consider this question, it is necessary to understand the background to Lord Neuberger’s decision, so that is where we begin.

What was the position before Actavis v Eli Lilly?

Construction ≡ Infringement

In 1980, in Catnic v Hill & Smith [1982] RPC 183, the House of Lords (Lord Diplock) ruled that a
patent specification should be given a "purposive construction" rather than a purely literal one. He said that the question in each case was whether the skilled addressee would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee.

In Improver v Remington [1990] F.S.R. 181, Hoffmann J (as he then was) built upon Catnic by suggesting the use of a series of three questions as a guide, when considering whether a feature embodied in an alleged infringement fell outside the "primary, literal or acontextual meaning of a descriptive word or phrase in the claim", nevertheless fell within the scope of the claims.

There remained, for a time, debate as to whether, in some circumstances, a doctrine of equivalents could apply, extending the protection of the patent beyond the language of the claims as construed. This was suggested, for example, by Laddie J in AHP v Novartis [2000] RPC 547 and by Neuberger J (as he then was) in Kirin-Amgen v Roche [2001] EWHC 518. As explained in a paper attributed to Sir Hugh Laddie after his death ((2009) 40 IIC 3), earlier English case law had permitted such extension in appropriate cases, by a doctrine described as being infringement by use of the "pith and marrow" of the invention, "colourable evasion" or a "doctrine of equivalents". A notable and (relatively) modern example was Beecham v Bristol [1978] RPC 153.

However, the possibility of there remaining any doctrine of equivalents following the coming into force of the European Patent Convention was firmly shut down by the House of Lords in Kirin-Amgen v Hoechst [2004] UKHL 46.

In Kirin-Amgen, Lord Hoffmann said that issues of infringement should be resolved by adopting a 'purposive' construction of the language of the patent claim(s), so giving effect to "what the person skilled in the art would have understood the patentee to be claiming". In Lord Hoffmann's judgment, the EPC, and in particular Article 69, firmly shut the door on any doctrine which extended protection outside the claims. Equivalents could be an important part of the background of facts known to the skilled man which could affect what he understood the claims to mean. For this purpose the so-called Improver questions (by now re-named the "Protocol questions") remained a useful guide for the purpose of construing the scope of a patent claim. But their lordships' emphasis was that the extent of protection should correspond with the level of generality in which the invention was defined in the claims.

The approach of the first instance judge (Neuberger J) in the Kirin-Amgen case was firmly criticised by Lord Hoffmann. He had construed the claims by a process that was dependent on their context (i.e. the specification) and which reflected the evidence of how the claim would have been understood by the person skilled in the art. Lord Hoffmann said that he did not
consider this to be a "literal" construction as contemplated by the Protocol questions. The judge’s approach of subsequently considering the Protocol questions "could only cause confusion" and was, essentially, superfluous. Once the judge had construed the claims as he did, he had answered the question of infringement.

In the years since Kirin-Amgen, the law regarding the interpretation of a patent claim and the assessment of infringement had remained relatively settled.

**The context of patent law in England and Wales**

England and Wales is a common law jurisdiction in which issues of infringement and validity are almost always considered together in a single substantive trial. This has some notable consequences. One is that patent law is developed by the jurisprudence, in which policy principles may be drawn upon, as well as by the legislature. Another is that 'squeeze' arguments are commonly employed in litigation, which leads to the judicial consideration and development of guiding principles which are drawn upon when considering the application of the legislative provisions.

One principle of English patent law is that the extent of the monopoly claimed by the patent must correspond to the technical contribution made (see Biogen v Medeva [1997] RPC 1, Generics v Lundbeck [2009] RPC 13). In Biogen, the House of Lords drew upon reasoning from the European Patent Office (EPO), in particular in Exxon/Fuel Oils (T 409/91).

Where issues of construction and infringement are conflated, this means that the extent of the monopoly conferred by a patent must be justified by the technical contribution to the art (Generics v Yeda [2013] EWCA Civ 925). The disclosure must enable the invention to be performed to the full extent of the monopoly claimed (Kirin-Amgen). In Generics v Yeda, the Court of Appeal also drew upon reasoning from the EPO, in particular AgrEvo/Triazoles (T 939/92). The EPO, however, is never called upon to consider issues of infringement.

In Gillette Safety Razor Co v Anglo-American Trading Co (1913) 30 RPC 465 (House of Lords), Lord Moulton said that the alleged infringer "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". This has given rise to the so-called Gillette defence, which is a defence under the common law to an allegation of patent infringement. It is not a direct challenge to the validity of the patent but is consistent with a finding of non-infringement of the patent if the patent is valid. Similarly, "Arrow" and "Fujifilm" type declaratory relief enable, essentially, a finding under the common law of non-patentability (and therefore non-infringement) in respect of the claimant’s own product or
The correlation between issues of novelty and infringement was considered in Synthon v SKB [2006] RPC 10, in which the novelty of Synthon’s patent was in issue in the House of Lords. Lord Hoffmann reasoned ([22]):

"...the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention.... It follows that, whether or not it would be apparent to anyone at the time, whenever subject-matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied."

What is the position now?

**Construction ≠ Infringement**

In the Supreme Court in Actavis v Eli Lilly, Lord Neuberger gave the only reasoned judgment. He drew a clear distinction between the concepts of construction and infringement, emphasising that the Protocol on the interpretation of Article 69 of the EPC (set out in full in our introductory article here) is a means to assist in the assessment of infringement from case to case, not a guide to document construction.

Lord Neuberger said that a problem of infringement is best approached by addressing two issues ([54]):

"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."

Our commentary on what this approach means in practice is provided in our introductory article, with more detailed articles focussing respectively upon the "limb (i)" and "limb (ii)" issues. When assessing whether there is infringement under limb (ii) (also referred to as the 'doctrine of equivalents'), Lord Neuberger said that the reformulated Improver questions provide helpful assistance. Of particular note is the second of the reformulated questions, which asks:
Lord Neuberger said that the time of assessment is the priority date of the patent, but with a significant caveat: the notional addressee is imbued with the knowledge that the variant works to the extent that it actually does work. In the real world, such 'knowledge' may not exist until many years after the patent has been granted. It means that later technological developments, which enable the achievement of substantially the same result in substantially the same way as is revealed by the patent, but without falling within the literal meaning of the claim, may still infringe the patent pursuant to the doctrine of equivalents.

There is logic behind this. It means that a patent, granted as it is in exchange for the disclosure of the invention, can remain commercially valuable even if a later development enables an unforeseen work-around which still draws upon the inventive concept underpinning the patent. Lord Neuberger said:

"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?" (emphasis added)

It is of course possible for a later invention to infringe an earlier patent, 'selection inventions' being a prime example.

How should a patent be construed for the purposes of assessing a challenge to validity?

Lord Neuberger did not address how a patent should be construed for the purposes of assessing a challenge to its validity. The validity of Eli Lilly's patent was not in issue. However, analysis of the reasoning gives pointers towards the approach now likely to be adopted by the courts in the UK.

Lord Neuberger introduced his reasoning on infringement by referring to the "question of how far one can go outside the wording of a claim to enable the patentee to enjoy protection against
products or processes which are not within the ambit of the actual language, construed in accordance with ordinary principles of interpretation”. He said that issue (ii) of his infringement test "squarely raises the principle of equivalents". Later, dismissing an argument by Actavis that a statement made by Eli Lilly to the patent examiner should limit the extent of protection conferred by the patent, Lord Neuberger said:

"I do not consider that that consideration can have any bearing on the question whether any pemetrexed salts other than pemetrexed disodium should be within the scope of the patent pursuant to the doctrine of equivalents. The whole point of the doctrine is that it entitles a patentee to contend that the scope of protection afforded by the patent extends beyond the ambit of its claims as construed according to normal principles of interpretation."

The authors’ view is that when construing a patent for the purpose of assessing a challenge to its validity, it would be incorrect to employ limb (ii) of his infringement test.

Should limb (i) be employed?

Lord Neuberger said that consideration of the limb (i) question ("does the variant infringe any of the claims as a matter of normal interpretation") "self-evidently raises a question of interpretation", which is "familiar to all lawyers concerned with construing documents". He cited Wood v Capita [2017] UKSC 24 a leading UK authority on commercial document interpretation.

Analysis of the principles of English commercial document interpretation suggests that "normal interpretation" requires patent claims to be considered in their context (i.e. in the context of the description and drawings), to establish their objective meaning through the eyes of the notional addressee of the patent. As is discussed in our article titled "Actavis v Eli Lilly - Should We Have Seen It Coming?", this would appear both "purposive" (in the English contractual sense, because of the contextual reading) and contextual literal (because the words of the claim are not merely a guide). However, Lord Neuberger’s reasoning suggests that 'normal interpretation' does not entail consideration of the Improver questions (in their original form or as reformulated), and so the approach - while close - is not fully aligned with the "purposive construction" permitted by Kirin-Amgen. Nor may the interpretation of the claim be confined to the "strict" or "acontextual" literal meaning (i.e. the dictionary meaning) of the words used unless this is appropriate in the context (i.e. of the specification).

It is perhaps notable that in his first instance decision in the Kirin-Amgen case (Kirin-Amgen v Roche [2001] EWHC 518 (Pat)), Neuberger J (as he then was) seems to have taken exactly this approach, construing the relevant claims of the patent by interpreting them in the context of
the teaching of the specification, and considering whether the conclusion he reached was in accordance with the evidence and the Protocol. His consideration of the Improver (by that time re-named as the "Protocol") questions came much later in his judgment, after his assessment of the challenges to validity, in the context of the issues of infringement.

In four recent decisions, the Patents Court and the Court of Appeal have attempted to address how patent claims should be interpreted for the purpose of assessing a challenge to validity following Actavis v Eli Lilly.

In Generics v Yeda [2017] EWHC 2629 (Pat) (26 October 2017), Arnold J expressed the view that it remained the law that a patent claim should be given a "purposive construction", but without addressing whether the old Improver questions could or should be employed in this context.

Shortly following, in Actavis v ICOS [2017] EWCA Civ 1671 (1 November 2017), the Court of Appeal (Kitchin L.J) observed that the correct approach to the construction of the claims in issue was what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. Although this was not an issue between the parties to the case, the Court of Appeal observed that nothing in the Supreme Court's decision in Actavis v Eli Lilly affected the application of this approach in the context of the dispute in the case.

A week later, in Fisher & Paykel v ResMed [2017] EWHC 2748 (Ch) (10 November 2017), deputy judge Mr Richard Meade QC made a notable contribution to the debate. He was of the view that following Actavis v Eli Lilly, it is not satisfactory to proceed on the basis of Kirin-Amgen and then to ask how Actavis changes the position. Instead, the courts should consider and apply Actavis, which is now the law. In determining the "normal" meaning of a claim, the court is not limited to the literal meaning of the claims and may consider the broader teaching in the specification where the patentee asserts what has been accomplished. The deputy judge proceeded to apply this approach when construing the scope of the claims of ResMed's patent for the purpose of assessing their validity. (For good measure, in case he was wrong on this, he also ruled as to the "literal" meaning of contested claim integers and by both approaches he concluded that the patent was invalid).

Most recently, in Illumina v Premathia [2017] EWHC 2930 (Pat) (21 November 2017) Henry Carr J agreed with Arnold J that "normal interpretation" involved interpreting words in context and that the context must include "the very purpose for which the document exists, namely to describe and claim an invention". Henry Carr J's view was that "normal interpretation means purposive interpretation",

In light of the above, the lower courts appear to be reaching a view that "normal interpretation"
means a purposive interpretation of the claim language. However, they do not appear to have addressed whether the "purposive construction" of Kirin-Amgen, which would permit consideration of the Improver questions, remains good law. Further guidance from the Supreme Court would be welcomed.

However, in the authors' view, when interpreting a patent claim for the purposes of assessing a challenge to validity, Lord Neuberger's limb (i) should be employed. "Normal interpretation" is essentially purposive construction, but without the employment of the Improver questions. Such an approach would appear to be consistent with Lord Neuberger's reasoning in Actavis v Eli Lilly and also with the comments of Arnold J, Kitchin LJ and Mr Richard Meade QC in their judgments referenced above.

The remaining analysis in this article is founded upon this assumption.

**Is there a validity gap?**

The above suggests 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 scope of the claim for the purposes of infringement and the scope of the claim for the purposes of validity (referred to below as a "validity gap").

What does this mean in practice?

**Is there conceptual alignment between novelty and infringement?**

In Generics v Yeda, Arnold J noted Lord Hoffmann's reasoning in Synthon v SKB that in order to anticipate, the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. He observed that the House of Lords "had not been considering the question of anticipation by equivalents, because at that time it was not possible to infringe by virtue of a doctrine of equivalents if the alleged infringement fell outside the claim on its proper interpretation".

Arnold J expressed the view that it will "require another decision of the Supreme Court" to supply a definitive answer to the question of whether, subsequent to Actavis v Eli Lilly, there can as a matter of law be anticipation by the application of the doctrine of equivalents to the disclosure(s) of the prior art. For the purposes of resolving the dispute before him, Arnold J proceeded on the basis that there is no anticipation by equivalents; a patent claim would only
lack novelty if the prior publication disclosed subject-matter which fell within the claim on its "proper interpretation" (yet another form of words to describe construction!).

In Fisher & Paykel v ResMed, deputy judge Mr Richard Meade QC agreed on the need for higher court guidance. As matters stood, he considered that he should follow Arnold J.

Most recently, in Illumina v Premaitha, Henry Carr J considered Lord Hoffmann's statement in Kirin-Amgen that "the disclosure must enable the invention to be performed to the full extent of the monopoly claimed". After considering the Court of Appeal's reasoning in the Kirin-Amgen case, which he concluded that Lord Hoffmann had not disapproved of, Henry Carr J said ([139]):

"The principle of enablement across the breadth of the claim is of considerable importance, but it is not absolute. It does not require a patentee who has claimed a principle of general application to anticipate inventive improvements which make use of that principle, nor future advances in technology, which would be an impossible task."

With reference to Lord Neuberger's second reformulated Improver question (which may be drawn upon in the limb (ii) test for infringement), Henry Carr J said ([144]):

"It would not make sense if...the patent was found to be insufficient solely because such an inventive variant, which it did not enable, fell within the scope of its claims".

Although this does not address the issue of alignment between novelty and infringement, it would seem to indicate that a validity gap is permissible as a matter of law.

In this context, the authors make some further observations.

First, it is worth noting that in Synthon v SKB, Lord Hoffmann said that in order to anticipate, a prior publication must necessarily infringe if done afterwards. As noted by Arnold J in Generics v Yeda, Lord Hoffmann did not consider the position in the event that, contrary to his own judgment in Kirin-Amgen, there was no longer alignment between the scope of a claim for the purposes of validity and infringement.

Second, in Gillette v Anglo-American, Lord Moulton's judgment indicated the squeeze defence as applying to that which "differs from that which has been done of old only in non-patentable variations, such as ... mechanical equivalents ...". There is an interesting alignment here with the reach of Lord Neuberger's doctrine of equivalents, described in paragraph 53 of his judgment by the limb (ii) question: does the variant nonetheless infringe because it varies from
the invention in a way or ways which is or are immaterial?

Lord Moulton's Gillette test was framed decades before Catnic, when the common law recognised that a patent could be infringed by matters falling outside the literal meaning of the claims. It has since been developed to apply in cases where the invalidity challenge is of obviousness. Arguably this provides a counter in the common law to prevent the application of the doctrine of equivalents extending the extent of a patent monopoly into the remit of unpatentable subject-matter. However, differences in the knowledge imbued to the skilled person at the relevant dates (as discussed below) means that the Gillette defence may not fully close the gap.

**When will a validity gap make a difference in practice?**

It is worth re-iterating the authors' view that (on the assumption set out above) a validity gap may only exist where infringement is not established under Lord Neuberger's limb (i) (normal interpretation) but is established under limb (ii) (doctrine of equivalents).

In some cases, resolution of the uncertainties in the law, following Actavis v Eli Lilly, regarding the operation of a Gillette defence and the extent of conceptual alignment between anticipation and infringement (as discussed above) will be critical. In particular, in cases in which 'novelty-only' prior art is relied upon, an obviousness case on such prior art cannot be run in parallel and so a judicial position on the reach of the Gillette defence and/or an anticipation/infringement squeeze may be necessary.

Further, in many cases, the 'common general knowledge' of the skilled addressee of the patent will change between the date at which validity is assessed and the date of alleged infringement. This may lead to a validity gap existing in practice in some cases in which infringement is established pursuant to limb (ii) (the doctrine of equivalents).

An obviousness challenge is assessed as at the priority date of the patent. For this purpose the skilled addressee of the patent is imbued with the 'common general knowledge' at that date, but not with later knowledge. The skilled person is therefore not imbued with knowledge of any later technological developments following which it would be obvious to the skilled person that a variant would work in the same way as the claimed invention. However, for the purposes of the infringement assessment under the doctrine of equivalents, the skilled person is informed that the variant does work (to the extent that it does). Consequently, the knowledge with which the skilled person is imbued at the priority date of the patent is likely to be different for the purposes of the assessments of inventive step and infringement.
It would seem to follow from this that any product or process that infringes only pursuant to the doctrine of equivalents would not, if it had been made available to the public before the priority date of the patent, necessarily have rendered the claimed invention obvious.

So on the assumption of the existence of a validity gap, there is no conceptual alignment between the doctrine of equivalents and the test for inventive step. Whether there is in fact alignment of this nature in any particular case will depend upon the circumstances of the case.

Let us consider also the position in a case in which the sufficiency of the patent is challenged. Such a challenge is assessed at the filing date of the patent (Biogen v Medeva [1997] RPC 1), which may be up to a year after the priority date. The skilled person's common general knowledge for the assessment of sufficiency is as at the filing date of the patent. Again, where infringement is established pursuant to limb (ii) (the doctrine of equivalents), there is potential for a gap.

If the patentee has chosen broad claim language, at the level of the perceived inventive contribution and encompassing contemplated variants, the claim may not be considered plausible across its breadth at the filing date of the patent. It may therefore be susceptible to an invalidity challenge, even if the perceived invention can in fact be performed. Examples of patents being found invalid for lack of plausibility include Warner-Lambert v Generics [2016] EWCA Civ 1006, where the efficacy of pregabalin across the claimed "neuropathic pain" indication was later established but was found not to have been plausible at the date of filing of the patent application, and Idenix v Gilead [2016] EWCA Civ 1089, in which a claim encompassing over 50 billion compounds by use of a Markush formula covered classes of compounds that would not plausibly have had the relevant anti-viral activity.

On the other hand, if the patentee has chosen claim language at a level of specificity which is perhaps narrower than the perceived inventive contribution, the claim may be less vulnerable to an insufficiency challenge. With the application of the doctrine of equivalents, it may yet still be capable of exerting a monopoly over immaterial variants which do in fact work. The Actavis v Eli Lilly case is one such example - Lord Neuberger noted that Eli Lilly's inventive concept was concerned with the pemetrexed anion generally, not just its disodium salt form, and although the claim language was to the disodium salt the monopoly conferred by the patent was extended to pemetrexed diacid, pemetrexed ditromethamine and pemetrexed dipotassium pursuant to the doctrine of equivalents i.e. to reflect the inventive contribution.

The conclusion of all this is that the validity gap, if it does in fact exist, can and will make a difference in practice in some disputes regarding the infringement and validity of granted patents covering the UK.
More significantly, patentees with an understanding of the existence of a doctrine of equivalents and the potential for a validity gap in the UK may use this understanding of the law to maximise their chances of obtaining commercially valuable and robustly defensible patent filings.

What applicants and patentees should do now

The authors’ view is that Lord Neuberger’s doctrine of equivalents, and any associated validity gap, would in practice only have made a difference to the outcome of a very small proportion of the cases which reached the UK courts in recent decades.

However, depending on the nature of the claims sought and asserted by patentees, this will not necessarily be reflected in the profile of future patent disputes.

The most high profile UK cases in which Lord Neuberger’s doctrine of equivalents assisted, or would most obviously have been of assistance to the patent owner in recent decades, are arguably the following: Beecham v Bristol, Improver v Remington, American Home Products v Novartis, Kirin-Amgen v Hoechst and Actavis v Eli Lilly. In each of those cases, a judge (at first instance or otherwise) expressed an understanding that the inventive concept of the patent was broader than the level of generality at which the claim in issue was particularised.

Patent owners should be aware of this, when prosecuting an application and when considering whether to seek amendment of a granted patent.

Securing claim language at a level of particularity (for example, ‘pemetrexed disodium’) which is more narrowly defined than the level of the invention (for example, ‘pemetrexed anion’) may provide meaningful commercial protection while maximising the strength of the patent in the face of a validity challenge.

However, in the prosecution of a European patent, it is not just the law in the UK and the practice of the UK courts that needs to be born in mind by patentees. This is because in the current European patent litigation system, issues of validity and infringement may reach the courts of each country for which the European patent is designated, and each court would apply its own relevant national law and practice.

Provided the examiner is satisfied that the criteria are met, the options of broad versus narrow claim drafting are not mutually exclusive. In the conventional way, dependent claims may progressively narrow the claimed invention, providing a fall back option in the event broader claim language is found invalid.

Accordingly, in view of the need to keep in mind the potential for future litigation in many different countries, patentees would be well advised to give particular attention to ensuring that
dependent claims at appropriate level(s) of specificity are chosen, to provide, simultaneously, as much comfort as possible on validity and scope for a commercially valuable monopoly.

Since any claim to priority may need to be defended, an appreciation of the need for a graduated and independently defensible claim structure should be reflected in the drafting of any patent filing, anywhere in the world, which may later be relied upon in order to claim priority in a European or international patent application.

Stakeholders should also bear in mind that for patents currently in examination, it may be twenty years or more (if a supplementary protection certificate is granted) until issues regarding their infringement and validity are tested. By that time, UK law may have swung away from a doctrine of equivalents, whether by reason of the views of the most senior justices at that time or as a result of the emergence of a unified patent litigation system in Europe.

**What stakeholders may also wish to consider if considering litigation in the UK**

The Supreme Court's judgment in *Actavis v Eli Lilly* undoubtedly makes a difference to the day to day practice of litigation in the UK courts, in particular in the way pleadings and evidence are structured and drafted. How often it results in a significant change remains to be seen, however.

In some cases, the doctrine of equivalents will be drawn upon and infringement established under limb (ii). In some of those cases, a validity gap may emerge. This begs questions regarding the principle in the English jurisprudence that the extent of the monopoly conferred by the grant of a patent must be justified by the technical contribution to the art (*Generics v Yeda*). For example, would the technical contribution of the pemetrexed anion have satisfied this principle?

Of wider expected relevance, the Supreme Court's judgment in *Actavis v Eli Lilly* demands consideration of the law regarding patent claim interpretation for validity purposes. Savvy litigators may take the opportunity of apparent tension in the English patent jurisprudence to seek a broader review of the law. In particular -

The word 'plausible' does not appear in the UK's Patents Act 1977. Nevertheless, drawing upon reasoning of the EPO Boards of Appeals and the principle that the extent of the monopoly must be justified by the technical contribution, the UK courts have incorporated it in the legal tests applicable to the interpretation of legislative provisions regarding entitlement to priority, novelty, inventive step and sufficiency.

Noted above are examples of two cases (*Warner-Lambert v Generics* and *Idenix v Gilead*) in
which a patent has been found by the Court of Appeal to be invalid for lack of plausibility.

Recently, a similar sort of concept, the Canadian "promise doctrine", derived from old English law (pre-1977), was discarded by the Supreme Court of Canada as having no place in the assessment of whether a patent had ‘utility’. Although the legislative contexts are different, there is some alignment of the high level principles in issue, and English patent lawyers would be well advised to consider the judgment in in *AstraZeneca v Apotex 2017 SCC 36*.

In light of the Canadian Supreme Court's insights, it may be appropriate for the UK Supreme Court to consider not just the interpretation of claim language for validity purposes and whether the existence of a validity gap is consistent with a requirement that the scope of the monopoly conferred by the grant of a patent justified by the technical contribution made, but also whether the concept of plausibility, as it is currently being employed by the lower courts, is consistent with the Supreme Court's jurisprudence.

The case of *Warner-Lambert v Generics* appears to present the Supreme Court with an opportunity to grapple with claim interpretation and plausibility. Lord Neuberger is expected to return and sit as one of the justices. Following *Actavis v Eli Lilly*, the judgment is now of interest to all patent stakeholders.

Finally, as the introduction of a doctrine of equivalents is expected to make a difference to the outcome of questions of infringement in some cases, it will also impact some assessments of risk in respect of freedom to operate. Where commercial decisions have been taken on the basis of a freedom to operate assessment, it would be prudent for stakeholders to revisit the legal analysis to consider whether the patent(s) identified could benefit from the application of the doctrine of equivalents, and whether this could impact the assessment of risk of infringement of a valid claim. Such analysis will require a view to be reached as to the technical contribution made by the patent, and therefore an assessment of the material disclosed in the specification.

It has always been the case that the scope of the monopoly conferred by a patent covering the UK is assessed in the context of the specification as a whole. Confining any patent review to claim language has never been the recommended course. In this respect, the exercise of assessing freedom to operate has not been impacted by the Supreme Court's judgment in *Actavis v Eli Lilly*. However, in some cases, review of the prosecution history may now also be appropriate in respect of the UK.
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