



## The arrival of the Doctrine of Equivalents

Following the *Actavis* decision, practitioners had speculated on how the new doctrine was to be applied in practice

The 2017 Supreme Court decision in *Eli Lilly v Actavis UK* reformulated the test used to determine patent infringement in the UK by introducing a Doctrine of Equivalents. It also provided extensive guidance on the role of prosecution history in litigation. Following the *Actavis* decision, practitioners had speculated on how the new doctrine was to be applied in practice. While a number of subsequent judgments have provided commentary on the *Actavis* decision, the Court of Appeal's decision in *Icescape v Ice-World* is the highest authority to apply the reformulated *Actavis* test and provided useful guidance both on how the Courts should apply the doctrine and the role of prosecution history. In this article we summarise the *Actavis* and *Icescape* decisions, and identify the key takeaway points.

### Actavis

Lilly was the owner of a European patent directed to a dosage regimen involving co-administration of the anti-cancer drug pemetrexed (marketed as Alimta) with vitamin B12. The claims specifically recited "pemetrexed disodium". *Actavis*' proposed generic versions of the product included the free acid or different salts (pemetrexed diacid, ditromethamine and dipotassium).

The dispute started in 2012 when *Actavis* sought a declaration for non-infringement in the UK and other jurisdictions. Earlier decisions found for *Actavis* where salts other than disodium did not directly infringe the patent, but findings of indirect or contributory infringement, partly because *Actavis*' products would form the disodium product when reconstituted in saline.

The Supreme Court decision focused on direct infringement.

### New test for infringement by equivalents

Unlike the US and several other European jurisdictions, the UK courts have historically not adopted a "doctrine of equivalents". *Actavis* emphasised the importance of assessing scope of protection in two stages: (i) considering infringement under normal interpretation; and (ii) infringement by immaterial variation. It was accepted that under "normal interpretation" the proposed *Actavis* products did not infringe.

The decision reset the questions used to determine whether a variation is 'immaterial' in the following terms (the 'Pemetrexed Questions'):

- a) 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? If yes:
- b) 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 yes:
- c) 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 show infringement within limb (ii), a patentee would have to establish that the answer to questions (a) and (b) was "yes" and that the answer to question (c) was "no".



The court found Actavis' proposed products to satisfy the newly adopted test and therefore to infringe, with the following technical rationale:

- i. Actavis' compounds worked in substantially the same way as pemetrexed sodium, e.g. because they provided the pemetrexed anion;
- ii. knowing that Actavis' compounds worked, it would have been obvious that they do so by providing the pemetrexed anion; and
- iii. while the language of the claim was clearly limited to disodium, it was not clear that the patentee intended to cover only disodium salts; for instance, the description suggested the invention would work with any anti-folate compound.

## File wrapper estoppel

The decision also looked at the relevance of prosecution history when assessing scope of protection.

Looking at the file contents has typically been discouraged by the UK courts. The Supreme Court set out the two situations where it would be appropriate: (i) if the point at issue is unclear based on the specification, and the file unambiguously resolves the point, or (ii) if it would be contrary to the public interest to ignore the file, e.g. where a patentee has stated previously that it would not enforce the patent against a particular variant.

The Supreme Court found that the contents of the file did not justify departure from the above conclusion on infringement. The limitation from any anti-folate compound down to pemetrexed disodium was made to address formal objections against the broader scope under Article 123(2) EPC. The Supreme Court suggested that this might have been different if the amendment had been made to address prior art.

## Icescape - determining infringement post-Actavis

The decision of Lord Kitchin (now in the Supreme Court) sitting in the Court of Appeal, provided guidance both on the application of the Doctrine of Equivalents and also on prosecution history estoppel.

## Background to the case

The appellants, Ice-World, made a system for cooling mobile ice rinks and leased them to third parties, including the respondent. They also owned a European patent to the ice rink in question. When Icescape's business relationship with Ice-World ended, Icescape designed, made and began to operate its own mobile ice rink.

Ice-World wrote to Icescape (as well as Icescape's actual and potential customers), asserting that its mobile ice rink infringed Ice-World's patent. Icescape issued proceedings seeking damages for groundless threats of patent infringement, a declaration of non-infringement and an order that the patent be revoked. The appellants counterclaimed, asserting that the patent was valid and infringed.

## The Decision

### Validity of the patent

The Court of Appeal upheld the trial judge's findings and the patent was invalid and had to be revoked.

### Infringement

Kitchin LJ acknowledged that, following Actavis, the problem of infringement is best addressed by two issues, considered through the eyes of the "notional addressee" (i.e. the anticipated audience for the patent):

- 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.

Kitchin LJ explained the approach taken in Actavis to state that (ii) was to be determined by three Pemetrexed Questions.

As to question (a), Icescape's system had a parallel rather than a series connection between the manifolds which was said to possibly confer advantages but was determined to have nothing to do with the 'inventive core' of the patent. The concept of equivalent features applied here is quite broad and it is not a simple drop-in replacement of one component for another but instead taken as a wholesale configuration. Therefore, the answer to (a) was yes.

The same logic applied for question (b): because the variant did not affect the inventive core, it would be obvious to the skilled person that Icescape's system achieves substantially the same result as the invention and does so in substantially the same way. Therefore, the answer to (b) was also yes.



On question (c), the fact that the language of the claim did not cover the variant was not enough to find that Ice-World intended strict compliance with the literal meaning of the claim. As the variants were outside the inventive core, these variants were not an essential requirement of the invention. The answer to question (c) was no.

Floyd LJ added that there was nothing to suggest that the patentee regarded a series connection as essential in any relevant sense. In practice this means that, to assess the scope of the claims for infringement, it is necessary to identify the 'inventive core' of the patent. This is non-trivial for third parties.

### Prosecution history estoppel

The prosecution history was considered in the case. During examination, Ice-World responded to an objection of the Examining Division by deleting one claim said to lack novelty, providing a new claim comprising additional integers. Icescape argued that certain features of the granted claim could then not be asserted as inessential parts of the invention, but this was rejected by Kitchin LJ.

It was impossible to determine if the objection raised at the EPO was sound and to discern from the correspondence that Ice-World were surrendering any ability to argue the features were inessential or accepting a limitation of the scope of the claims. The correspondence fell well below the threshold set in Actavis and was a good illustration of why it is generally so unprofitable to explore the prosecution history.

### Key takeaways

1. The new Actavis approach will make it more likely that immaterial variants will fall within the scope of protection and will be binding on the lower Courts.
2. When faced with an alleged claim of patent infringement to fully assess the scope of the claims it is necessary for parties to identify the 'inventive core' of the patent.
3. In patent infringement cases the prosecution history is rarely likely to be taken into account by the Court when considering claim scope and patentees can be less concerned that amendments made during prosecution of the patent will limit the scope of the monopoly.

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