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PRESS SUMMARY

Actavis UK Limited and others (Appellants) v Eli Lilly and Company (Respondent)
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[2017] UKSC 48
On appeal from [2015] EWCA Civ 555 and 556

JUSTICES: Lord Neuberger (President), Lord Mance, Lord Clarke, Lord Sumption, Lord Hodge

BACKGROUND TO THE APPEAL

The appeal concerns whether three products manufactured by the Actavis group of companies (“Actavis”) would infringe a patent whose proprietor is Eli Lilly & Company (“Lilly”), namely European Patent (UK) No 1 313 508 and its corresponding designations in France, Italy and Spain.

The patent relates to the use of the chemical pemetrexed. This has therapeutic effects on cancerous tumours, but, when used on its own it can have seriously damaging side effects. The Patent discloses that these side effects can largely be avoided if a compound called pemetrexed disodium is administered together with vitamin B12. Such a medicament has been successfully marketed, under the brand name “Alimta”, by Lilly since 2004. Actavis’ proposed products (“the Actavis products”) involve pemetrexed compounds being used together with vitamin B12 for cancer treatment; however, rather than pemetrexed disodium, the active ingredient is (a) pemetrexed diacid; (b) pemetrexed ditromethamine, or (c) pemetrexed dipotassium. Actavis contend that because they intend to use the Actavis products which do not include pemetrexed disodium, the claims of the Patent would not be infringed.

At trial, Arnold J decided that none of the Actavis products would directly or indirectly infringe the Patent in the UK, or in France, Italy or Spain - [2015] RPC 6. The Court of Appeal allowed Lilly’s appeal to the limited extent of holding that there would be indirect infringement in the four jurisdictions, but agreed with the Judge that there would be no direct infringement - [2015] Bus LR 68. Lilly appeals to the Supreme Court against the holding that there would be direct infringement and Actavis cross-appeal against the holding that there would be no indirect infringement.

The appeal raises the issue of the correct approach to the interpretation of patent claims, and the requirement of the European Patent Convention 2000 (“EPC”) to take account of so-called equivalents. It also raises the issue of the extent to which it is permissible to make use of the prosecution history of a patent when determining its scope. The issue on the cross-appeal is whether the application of the law of contributory infringement would justify a finding of indirect infringement in this case.

JUDGMENT

The Supreme Court unanimously allows Lilly’s appeal and holds that the Actavis products would infringe the Patent in the United Kingdom, and in France, Italy and Spain. Actavis’ cross-appeal is unanimously dismissed, so that, if its products would not directly infringe, they would indirectly infringe as held by the Court of Appeal.

REASONS FOR THE DECISION

On direct infringement, Article 1 of the Protocol on the Interpretation of Article 69(1) EPC provides that the scope of protection afforded to a patentee is not to be limited by the literal meaning of the claims. Article 2 provides that there can be a difference between the interpreted scope of a claim and the scope of protection afforded by it, and when considering the scope of protection equivalents must be taken in to account [33-34]. Further guidance is needed to guide a court through this exercise [53].

Whether an item directly infringes a patent is best approached by addressing two questions through the eyes of the notional addressee of the patent, i.e. the person skilled in the relevant art, namely:

1. Does the item infringe any of the claims as a matter of normal interpretation; and if not,
2. Although the item may be characterised as a variant, does it nonetheless infringe because it varies from the invention in a way which is immaterial?

If the answer to either question is “yes”, there is an infringement; otherwise there is not [54].

On question 1, according to normal principles of interpretation the Actavis products do not infringe the Patent [58].

Question 2 raises the issue of equivalents and poses a more difficult question of principle [59]. The following questions should be considered by a court as a guide to the question of materiality [66]:

1. 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?
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 strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

To establish infringement where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was “yes” and the answer to the third was “no” [66].

The Actavis products directly infringe the Patent [68]. They all involve a medicament containing the pemetrexed anion and vitamin B12, and achieve substantially the same result in substantially the same way as the invention. Once he or she knew that the Actavis products achieved substantially the same result as the invention, the notional addressee of the Patent would have thought it obvious that this was so, particularly as he or she would have regarded investigating whether pemetrexed free acid, pemetrexed ditromethamine or pemetrexed dipotassium worked as a routine exercise [69]. On the third question, the Court of Appeal had placed too much weight on the words of the claim. It is 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 [70-74]. Direct infringement is also established under French, Spanish and Italian law [92-102].

Recourse to the contents of the prosecution file by a UK court will only be appropriate in limited circumstances, particularly if they clearly resolve a genuine ambiguity in the patent or it would be contrary to the public interest to disregard the file [87-88]. The contents of the file do not justify departing from the conclusion in this case [89].

In the circumstances, Actavis’ cross-appeal does not arise. However, the Supreme Court would have upheld the Court of Appeal’s determination that Actavis are liable to Lilly for indirect infringement in the United Kingdom [103-112].

References in square brackets are to paragraphs in the judgment

NOTE: This summary is provided to assist in understanding the Court’s decision. It does not form part of the reasons for the decision. The full judgment of the Court is the only authoritative document. Judgments are public documents and are available at <http://supremecourt.uk/decided-cases/index.html>