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Salt limitation leads to sweet and sour Court of Appeal judgment

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The **Actavis v Eli Lilly** UK litigation concerning pemetrexed (sold by Eli Lilly under the brand Alimta(®) has already been widely reported in light of Actavis' innovative application to the English court for declarations of non-infringement (DNIs) of national designations of a European Patent in addition to the UK designation. The latest instalment concerns the Court of Appeal's judgment in the appeal on the merits. In summary, the Court of Appeal refused to grant the declarations sought by Actavis. This overturned the decision of Mr Justice Arnold in the Patents Court, who had held that each of the UK, French, Italian and Spanish national designations of Eli Lilly's European patent were not infringed by the pharmaceutical products that Actavis intended to sell in each of those countries. The Court of Appeal agreed with the trial judge's conclusion that the patents were not directly infringed but overturned his decision on contributory infringement. The Court of Appeal's judgment, with the leading judgment given by Lord Justice Floyd, raises several points of wider interest, in particular in relation to claim construction, second medical use patent claims and the procedural requirements to seek DNIs of foreign patents before the English court.

Claim construction

At first instance, the Patents Court had relied on the prosecution history as a guide to construction of the patent claim. During prosecution, the patentee had amended the wording of the claims sought in response to an office action from the EPO that the claims previously sought were contrary to Article 123(2) of the European Patent Convention. The Court of Appeal strongly disagreed that the prosecution history was useful and should be used in this manner on this occasion. Indeed, the judgment from the Court of Appeal suggests that if either party had contended that the prosecution history was inadmissible as a matter of law it is likely that the Court would have agreed.

In so finding, the Court noted that the person skilled in the art does not always read the prosecution history, particularly as it is often of limited value. Nor does reviewing the basis on which amendments have been made guard against potential abuse of the system (the reader will be familiar with the Angora cat analogy) unless an amendment during prosecution creates a kind of estoppel against arguing for wider claims, a proposition that the English courts have previously rejected. In this case, the Court of Appeal therefore declined to consider the prosecution history, albeit that the Court came to the same conclusion on scope of protection as the trial judge had.

The Court also considered the application of the *Improver* or *Protocol* questions in construing the patent claims. The questions have fallen out of favour in the UK following the seminal decision of the House of Lords on claim construction in the **Kirin Amgen** case in 2005, but were applied by the judge at first instance in this case. As Actavis were also seeking declarations under certain foreign patent laws where the questions, or variations of them, are used more frequently it is possible that the judge was persuaded to do so as a one-off, and this is not the beginning of a novel trend towards their reintroduction. Nevertheless, the Court of Appeal endorsed their application on this occasion.

Second medical use claims

The relevant second medical use claims of the patent in suit were in both Swiss-type and EPC 2000 form. The Court of Appeal held that the claims were not directly infringed by Actavis' proposed products, as the scope of protection was restricted to the claimed pemetrexed disodium salt and did not extend to other salts of pemetrexed. However, pemetrexed disodium was construed to extend to a solution of pemetrexed and sodium ions in a concentration of at least 2 to 1 in favour of sodium ions, on the basis that the person skilled in the art would not construe the claims as being limited to pemetrexed disodium salt in a solid pharmaceutical composition. As Actavis' products were indicated for use by injection after dissolution in saline, Eli Lilly argued that Actavis indirectly infringed by supplying means relating to an essential element of the invention. In reaching this conclusion on construction, the Court made a number of interesting findings.

First, the Court was of the view that as second medical use claims must involve the step of manufacturing a medicament for treating a disease (otherwise they would be to a method of treatment), a formulation chemist would generally have to be part of the team that forms the person skilled in the art. Moreover, the Court held that a second medical use claim includes a requirement that the manufactured medicament is to some extent effective for treating the disease.

Second, in this case the Court held that the dissolved lyophilisate that Actavis proposed to sell could be the medicament referred to in a second medical use claim, and thus that the manufacture of that medicament could take place by the physician rather than just the manufacturer of the medicinal product placed on the market. That is likely to open up more manufacturers of generic pharmaceutical products to liability for contributory infringement of second medical use claims where the requisite knowledge can be demonstrated.

Third, the Court said that the means supplied by the defendant did not have to constitute a free-standing feature or element of the claim but only means relating to an essential element. In this case, a means for releasing pemetrexed ions into the solution for injection related to an essential element of the invention, as it was the presence of pemetrexed ions in the solution which gave efficacy. It did not matter that the specific pemetrexed salts in the Actavis products were not an element or feature of the claim.
As Actavis had conceded that it intended for its products to be dissolved in saline, the Court held that it would infringe the UK patent. As it was common ground between the parties that there was no detectable difference in the laws of France, Italy and Spain regarding the approach to contributory infringement. The court therefore held that Actavis' products would also infringe the three non-UK patents in suit and thus refused to make any of the DNIs sought.

Declarations of non-infringement of foreign patents

Whilst the Court of Appeal refused to grant the injunctions sought on the basis that Actavis' products infringed the patents in suit under contributory infringement, the Court gave an *obiter* ruling on which country's procedural requirements an applicant must satisfy before commencing an action before the English courts to obtain a DNI. It was noted by the Court that English law took the most relaxed attitude amongst the four relevant states of what a party must show before it can apply to the court for a DNI, and that Actavis had satisfied that requirement under the *lex fori*, i.e. English law. However, Eli Lilly had argued that an applicant should be required to satisfy the law of the national designation of the European patent, the *lex causae*. In the Court's view, the rules at issue were conditions of admissibility of rights rather than rules concerned with the substance or content of the parties' rights. Or in other words: "*They are all concerned with whether the court should hear a dispute about substance. They are not concerned directly with the substance itself*". Such rules would traditionally be considered, for private international law purposes, as procedural and not substantive and thus subject to the *lex fori* and not the *lex causae*. Therefore, only if the exceptions in the Rome II Regulation applied should the Court not apply the *lex fori*. The Regulation states that it shall not apply to evidence and procedure (Article 1(3)), which Actavis relied on to argue that private international law should apply rather than the Regulation. However, Eli Lilly argued that the requirements to start a DNI were within or closely analogous to the matters specified in Article 15 and therefore that the rules are those found in the law applicable to the non-contractual obligation, i.e. the law of the national designation in question of the European patent. According to the Court, none of the exceptions in Article 15 was apt to encompass the rules for admissibility of a DNI. Therefore, had Actavis been entitled to the DNIs as a matter of patent construction/infringement, the Court would have granted them.

Prior to handing down judgment, Actavis also requested that the case be remitted for further trial in the Patents Court in relation to a proposed new product for reconstitution with dextrose rather than saline. The Court of Appeal has allowed this request to determine whether and to what extent there will be infringement in those circumstances if some persons administering the products reconstitute them in saline rather than dextrose (we refer to the recent and ongoing case of **Actavis v Warner-Lambert** for the latest jurisprudence on the infringement of second medical use claims). Therefore although the judgment represents sweet success for Eli Lilly, the subsequent trial may sour the dish.

At a subsequent hearing on 30 June, Actavis was refused permission by the Court of Appeal to appeal the case to the Supreme Court. A further option is for Actavis to petition the Supreme Court directly. If Actavis chooses to petition the Supreme Court, it will be several months before the Supreme Court indicates whether it is prepared to hear the appeal or not.

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