

# Kluwer Patent Blog

## English Patents Court grants extra-territorial DNIs

Gregory Bacon (Bristows) · Tuesday, June 10th, 2014

Patent litigators around Europe will be taking note of the latest significant development from the English Patents Court in the case of *Actavis v Eli Lilly* [2014] EWHC 1511 (Pat) (judgment dated 15 May 2014), in which the English Court decided to grant declarations of non-infringement (DNIs) for three foreign designations of a European Patent in addition to that for the UK. The decision of Mr Justice Arnold, the most senior UK patents judge at first instance, is wide-ranging and merits careful analysis by litigators throughout Europe in light of the potential impact on cross-jurisdictional litigation strategies. Thus, the authors make no apology for this comparatively lengthy analysis or the fact they took a little time to ponder the decision before putting finger to keyboard.

The case concerns a family of patents relating to Lilly's cancer treatment Alimta®, which contains pemetrexed as the active pharmaceutical ingredient in the form of the disodium salt. Lilly's compound protection for pemetrexed expires in Europe in December 2015. However, Lilly also owns a European patent to pemetrexed disodium in combination with vitamin B12 or a pharmaceutical derivative thereof and optionally a folic protein binding agent. Alimta does not itself contain these additional ingredients, but the approved dosage regime requires the co-administration of vitamin B12. Actavis wishes to sell a generic version of Alimta on expiry of Lilly's compound patent protection for pemetrexed, in which the active pharmaceutical ingredient will be present as either the diacid, dipotassium or ditromethamine salt. It thus sought to clear the way in advance of anticipated launch, not only in the UK but also in certain other major European markets, namely France, Germany, Italy and Spain.

In summer 2012 Actavis therefore wrote to Lilly in the UK requesting DNIs in respect of the national designation of the European patent in each of the five countries in question. When these were not forthcoming, Actavis sought the DNIs from the English Court in respect of each national designation. Readers may recall that the case was previously the subject of a jurisdictional challenge by Lilly in respect of the declarations sought for the French, German, Italian and Spanish designations. That challenge had been dismissed by the Patents Court at first instance and on appeal to the Court of Appeal.

By the time it came to the substantive determination, Lilly had brought proceedings for threatened infringement before the Düsseldorf Regional Court in Germany, which had given judgment on the merits despite the English Court considering itself first seized of the proceedings. The Düsseldorf Court found in Lilly's favour – i.e. it found that use of pemetrexed dipotassium would infringe Claim 1 of the Lilly patent.

## Construction of the scope of protection

The key question in each case was whether the pemetrexed disodium integer extended to other salts of pemetrexed, in particular those that Actavis wished to commercialise, or whether it was limited to the disodium salt. In terms of the UK patent, there are two points of interest from the judgment.

The first is that the Court considered it appropriate to use the prosecution history at the EPO as an aid to construction. Although the prosecution history is admissible as a matter of principle, the English Courts are generally cautious in doing so. The judge was of the view that in the real world anyone interested in ascertaining the scope of a patent would obtain the prosecution file and consider it to see if it sheds light on the matter. The judge held that in this case it did, as during the prosecution the patentee had sought to obtain protection for pemetrexed generally during prosecution. This claim had been rejected, and the patentee had narrowed the claim to pemetrexed disodium in response.

Second, the judge applied the three “*Improver* questions” (set out in the case of *Improver v Remington* [1990]), on the basis that the three salts proposed by Actavis are variants to pemetrexed disodium. Although the *Improver* questions (or similarly worded questions) have gained some traction in other countries, they have largely been abandoned by the English Courts following the seminal (and still leading) House of Lords decision in *Kirin-Amgen v Hoechst Marrion Roussel* [2005], which adopted purposive construction as the correct approach to patent construction in the UK. Purposive construction requires the Court to assess what the person skilled in the art would have understood the patentee to mean by the words used rather than a formulaic analysis of whether variants to the literal meaning of words or terms used fall within the claim (whether under the *Improver* questions or some other formula). Furthermore purposive construction does not allow for a separate doctrine of equivalents. However, in this case (possibly because the judge then went on to consider construction in three other European countries), the judge applied the three *Improver* questions.

In conclusion, the judge concluded that the scope of the UK patent was restricted solely to the pemetrexed disodium salt. Moreover, he concluded that there was no indirect infringement by sale of other salts. Whilst the argument in favour of indirect infringement is complicated, it was said that the preparation for injection (the Actavis generic of Alimta is reconstituted prior to injection, as with the originator’s reference product) will put the invention into effect in that it would do so in exactly the same way as use of Alimta would. The judge held that there can be no indirect infringement in this case as at no point will pemetrexed disodium be used in the manufacture of a medicament, the claim in question being a second medical use claim in Swiss-type form.

As to the foreign patents, the judge first stated that it was common ground that by virtue of Article 8(1) of the Rome II Regulation the law applicable to the question of infringement is the *lex loci protectionis*, i.e. the substantive patent law of each country. Each party adduced evidence from a (local) expert on the substantive patent law of each country, and the court ordered that there be no cross-examination in relation to any of this evidence. The court equally held it was prepared to determine the question of infringement under the foreign patent law of each country, and produced a lengthy analysis in relation to each. In summary, the court construed that each of the three foreign patents did not cover pemetrexed salts other than pemetrexed disodium, and that the proposed sale of the Actavis products would not infringe the foreign patents either under direct or indirect infringement. As to the German judgment, the Court noted that judgments of the

Düsseldorf Regional Court were entitled to considerable respect and that their judgment was detailed, careful and clearly reasoned. Nonetheless, the English Court felt unable to agree with its conclusion that the scope of the German designation extended to pemetrexed dipotassium.

#### Procedural law for granting declarations

The Court held that the requirements for the grant of a DNI in the UK in relation to the UK patent were met and so made the declaration sought. As to whether to grant the foreign DNIs, the Court held that procedural rules as to when a DNI may be sought were matters of procedure falling within Article 1(3) of the Rome II Regulation and were not governed by the law applicable to the non-contractual obligation (i.e. patent infringement) in accordance with Article 15. As a result, whether or not to grant the foreign DNIs was a matter of English law.

English law allows for the grant of a DNI on a statutory basis, which requires that certain requirements be met. However, the English Courts also retain an inherent jurisdiction to grant negative declarations if it is in the interests of justice to do so. The Court held it should grant the foreign DNIs pursuant to the inherent jurisdiction of the Court because Actavis had clearly demonstrated that they had a real commercial interest in obtaining such declarations and such declarations would serve a useful purpose. In case the judge was wrong, he also considered the position on the assumption that the relevant law was that applicable to the non-contractual obligation, i.e. the procedural law of the country in question. Again relying on the written evidence from the respective experts, the judge concluded that Actavis were entitled to the DNIs under foreign law in each case, even in cases where the requirements of national procedural law were only met during the pendency of the English action(s). Lilly also raised a claim that it was an abuse of process to satisfy the requirements of French and Spanish procedural law in relation to DNIs only during the pendency of the English action(s) rather than prior to commencing those actions. This was also dismissed by the judge, who made the three additional DNIs that Actavis sought.

It is expected that the case will proceed to appeal before the Court of Appeal (at least), and the judgments on appeal are eagerly anticipated. In the meantime, however, practitioners should bear in mind the possibilities enabled should the approach adopted by Mr Justice Arnold become settled law, not least because it now appears possible to circumvent national procedural requirements for applying for a DNI in the English Court.

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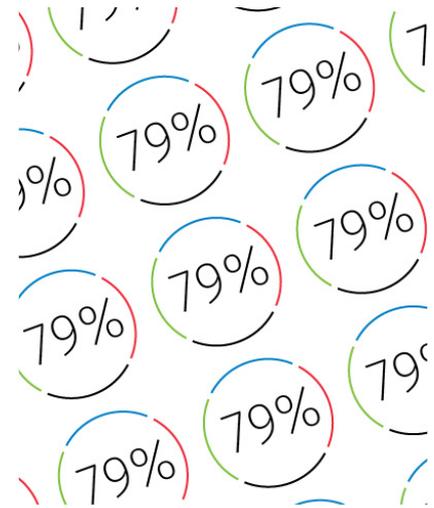
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