

UK claim construction: return of the Protocol questions and file wrapper estoppel

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Assumptions, Actavis and Arnold J

For the 10 years since the judgment of Lord Hoffmann in *Kirin-Amgen v Hoescht Marion Roussel*,¹ it has been widely assumed that there is no file wrapper estoppel in the UK and no doctrine of equivalents either. Both these assumptions are thrown into doubt by the Patent Court's decision in *Actavis v Eli Lilly*.² The judge, Mr Justice Arnold, first applied the more or less defunct *Improver* or Protocol Questions³ in a manner that potentially opens the door to a doctrine of equivalents in all but name. The judge then held that the court should not shut its eyes to the prosecution file but should ensure a patentee did not abuse the system by accepting narrow claims during prosecution and then arguing for a broader construction in a subsequent infringement action.

Use of the file wrapper

In *Kirin-Amgen*, Lord Hoffmann said that there were good reasons why the German and English courts discouraged, if not actually prohibited, the use of patent office prosecution files in aid of the construction of claims. The reasons included the consideration that the meaning of a patent does not change depending on whether a party has access to the office file and, in any event, the file may reflect no more than a patentee's desire to get the patent granted quickly without further argument with the examiner. In short, it was a difficult and likely unproductive exercise to use the file wrapper to try to work out what the patentee meant by a claim's terms.

Taking the hint, parties and the courts made little use of file wrappers in subsequent cases with Sir Robin Jacob observing in *Eli Lilly v Human Genome Sciences*⁴ that he was not confident it was legitimate to do so even though the UK courts had yet to decide the matter conclusively. Going further, Mr Justice Floyd in *Qualcomm v Nokia*⁵ warned that it was positively counterproductive to be referred to prosecution documents as this practice alerted

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This article

- The law of patent construction in the UK has been largely settled since the 2004 House of Lords' decision in *Kirin-Amgen* which, in confirming purposive construction as the correct approach, ruled out any US-style doctrine of equivalence. It also doubted the utility of the Protocol Questions, despite their regular application by the UK courts and the adoption of similar questions in other EU jurisdictions.
- The law on file wrapper estoppel, the use of a patent's prosecution history to estop the patentee from arguing a different construction during litigation, has been settled for even longer. The UK courts have felt strongly that it should not be necessary to read the prosecution history in order to determine a patent's scope. Germany and Canada concur with the UK's approach, however, the US courts take the opposite stance with file wrapper estoppel providing a counterbalance to its doctrine of equivalents.
- Mr Justice Arnold's judgment in *Actavis v Eli Lilly* has reopened both these issues. Arnold J not only applied the previously defunct Protocol Questions in construing Eli Lilly's Alimta patent but then used the patent's prosecution history in deciding that its claim did not extend to cover Actavis's variant. This comes close to the US approach criticized by Lord Hoffmann in *Kirin-Amgen* and may lead to a resurrection of the Protocol Questions as a doctrine of equivalence, even if not explicitly recognized as such.

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¹ *Kirin-Amgen v Hoescht Marion Roussel* [2005] RPC 9.

² *Actavis v Eli Lilly* [2014] EWHC 1511 (Pat).

³ From *Improver v Remington Consumer Products* [1990] FSR 181: in brief, as guidance on arriving at a purposive construction of a claim, the Questions

ask whether a variant has a material effect on the way an invention works, whether this was obvious at the patent's publication date and whether strict compliance with the primary meaning of the claim is nonetheless essential.

⁴ *Eli Lilly v Human Genome Sciences* [2013] RPC 22.

⁵ *Qualcomm v Nokia* [2008] EWHC 329 (Pat).

the tribunal to the fact that there might be something to be said for the alternative construction.

The approach in the UK can be contrasted with that of the US courts, where file wrapper estoppel provides a counterbalance to the doctrine of equivalents in construing a patent by ensuring that a patentee cannot argue a narrow claim construction on validity during prosecution but then seek to expand the scope of protection via the doctrine of equivalents in subsequent litigation on infringement. In contrast, the Canadian courts follow a doctrine of purposive construction with extrinsic evidence being inadmissible. Accordingly, file wrapper estoppel has been rejected by the courts there.⁶ This position also prevents a patentee from relying on a file wrapper to show consistency of construction before a patent office and in the courts.

Doctrine of equivalents

Returning to *Kirin-Amgen*, having first confirmed that the *Catnic*⁷ principle of purposive construction was firmly in accordance with the Protocol on the construction of Article 69 of the European Patent Convention (EPC), Lord Hoffmann addressed the question of equivalents:

It seems to me that both the doctrine of equivalents in the United States and the pith and marrow doctrine in the United Kingdom were born of despair. The Courts felt unable to escape from interpretations which ‘unsparing logic’ appeared to require and which prevented them from according the patentee the full extent of the monopoly which the person skilled in the art would reasonably have thought he was claiming.

He reasoned that if literalism stood the way of construing patent claims in such a way as to give fair protection to the patentee then there were two options available:

- (i) to adhere to literalism in construction but evolve a doctrine which supplements the claims by extending the protection of the patent to equivalents; or
- (ii) to abandon literalism altogether (as the House of Lords did in *Catnic*).

Lord Hoffmann found that Article 69 of the EPC had shut the door on any doctrine (and in particular any ‘structured’ approach) which extended scope of protection beyond the claims. But he stopped short of dismissing the concept of equivalents in its entirety; instead, he acknowledged that equivalents could be an important part of the background that would affect the skilled person’s understanding of a claim. His conclusions in that

respect were entirely consistent with Article 2⁸ of the Protocol on the Interpretation of Article 69, which states that, in balancing the literal and purposive construction of a patent’s claims, due account should be taken of ‘any element which is equivalent to an element specified in the claims’. He then specifically addressed the Protocol Questions, doubting their usefulness in reaching a purposive construction and in particular highlighting the difficulties of applying the second question to new technology. In conclusion he said that there was in reality only one question which was compulsory: what would a person skilled in the art have understood the patentee to have used the language of the claim to mean?

What has followed since *Kirin-Amgen* has not been unexpected; the Protocol Questions have seldom been used in UK patent actions, judges and practitioners shunning the structured approach in favour of asking Lord Hoffman’s compulsory question: ‘what would a person skilled in the art have understood the patentee to mean?’ In *Smith & Nephew v Convatec Technologies*,⁹ it was even questioned whether a 1992 decision on infringement of a numerical limitation would have been decided the same way following *Kirin-Amgen* as it had been using the Protocol Questions. This apparently settled state of the law on construction is now reopened by Mr Justice Arnold’s decision in *Actavis v Eli Lilly*.

Actavis v Eli Lilly

Actavis concerned Eli Lilly’s European patent protecting the formulation of its cancer treatment, Alimta. The patent claims the active ingredient, pemetrexed disodium, in combination with vitamin B12 and, optionally, a folic protein binding agent. Actavis sought declarations that its proposed generic version of Alimta, which would contain one of pemetrexed diacid, pemetrexed dipotassium or pemetrexed dimethamine, did not infringe this patent. If granted, the declarations would mean that once Eli Lilly’s Supplementary Protection Certificate, based on an earlier and now expired patent for pemetrexed alone, also expired on 10 December 2015, its path to market would be clear. This was not just the position in the UK but in other European jurisdictions too: since Actavis was not challenging validity, it was allowed to seek declarations of non-infringement under the French, Italian and Spanish designations of the patent as well as the UK designation. Originally, Actavis had sought a declaration in relation to the German designation of the patent too but the claim

6 *Free World Trust v. Electro Santé Inc.* [2000] 2 SCR 1024, 2000 SCC 66 (CanLII).

7 *Catnic Components Ltd v Hill & Smith* [1982] RPC 183—the speech of Lord Diplock (with which the other members of the House Lords agreed) in *Catnic* is considered to be the starting point of the modern approach to

patent construction and in particular purposive construction of patent claims.

8 As added to the Protocol by the Munich Act of 29 November 2000 which revised the EPC.

9 *Smith & Nephew v Convatec Technologies* [2013] EWHC 3955 (Pat).

was eventually dropped after Eli Lilly filed an infringement action in the Düsseldorf Regional Court.

In his judgment, Mr Justice Arnold carefully reviewed the case law on both use of file wrappers and the doctrine of equivalents. On the latter, he identified three main classes of case in which patentees resort to arguments on equivalents, namely where:

- (i) the patent has been poorly drafted (as in *Improver*);
- (ii) technology has moved on significantly since the patent was filed (as in *Kirin-Amgen*); and
- (iii) the patentee regretted a decision taken during the course of prosecution.

He considered *Actavis* to be a clear example of the third category. Eli Lilly had attempted to broaden its claims in prosecution to cover ‘pemetrexed’, failed and accepted the narrower claims to pemetrexed disodium. It had reserved the right to file a divisional application, but did not do so. Several years on, faced with a competing product, it clearly wished it had broader claims in order to catch *Actavis*’s product on infringement. But there was ‘no reason why the law should be sympathetic to the patentee’, which not only had the benefit of skilled professional advice but also had the opportunity to appeal against adverse decisions by patent examiners. Further, from a policy point of view, to allow examiners’ decisions effectively to be overturned by the courts on claim construction would undermine their important role in balancing the monopoly granted with the disclosure given. Against this background, Mr Justice Arnold made use of the prosecution history as one of several reasons why Eli Lilly’s broad construction, that pemetrexed disodium encompassed other salts because the important pemetrexed anion was present irrespective of the cation used, should be rejected.

Further, it is significant that Mr Justice Arnold choose to use the Protocol Questions when construing the scope of the claims. He noted that the Questions had fallen out of fashion since *Kirin-Amgen*, which he regarded to be unfortunate as, despite their shortcomings, they provided a structured approach to the question of equivalents and had been influential across Europe. Other factors influencing the judge’s decision to use the Protocol Questions were that there was no dispute that the alleged infringement was not within the primary, literal meaning of the claim and that the parties themselves had used the Questions for consistency of their submissions on the non-UK designations. What is also significant about this choice is that Mr Justice Arnold chose to resurrect the Protocol Questions when there were other (and better-trodden) routes he could have taken to reach the same destination should he have wished. As with all first instance

decisions, it is now a matter of waiting for the Court of Appeal’s decision to see if the Protocol Questions do indeed have a new lease of life as a means of introducing a form of equivalence and whether file wrapper estoppel is here to stay.

Meanwhile, in Düsseldorf, the District Court granted an interim injunction against *Actavis* finding infringement of the German designation of the patent by its threatened dealings in pemetrexed dipotassium and on the basis of equivalence rather than literal infringement of the patent’s claims. As an aid to construction the German courts use a set of questions which at first read are not dissimilar to the Protocol Questions but that arguably give greater scope for a finding of equivalence (particularly in the third question which considers the technical effect of the equivalent means rather than circling back to the language of the claim as in the Protocol Questions). This approach is not generally counter-balanced by reference to a patent’s prosecution history and was not in this instance.

Construction, caveat and caution

Mr Justice Arnold observed that the US has a doctrine of equivalents with a doctrine of file wrapper estoppel to counterbalance it. Recent case law suggested the UK had neither. The judge’s considered use of the Protocol Questions and file wrapper estoppel (albeit only in the case of the regretful patentee) in his judgment suggests that the status quo could be changing. As could be expected he issued a caveat regarding his use of file wrapper estoppel, cautioning that the use of prosecution history should only be when it is short, simple and shows clearly why the claims are in their granted form and not broader.

As regards the Protocol Questions, they merely fell out of favour after *Kirin-Amgen*. Lord Hoffmann may have shut the door on doctrines that explicitly extended the protection outside the claims but he left it ajar in terms of the Protocol Questions. Mr Justice Arnold clearly felt this was one of the cases where the Questions were useful—but applying them where there is plainly no literal infringement comes very close to Lord Hoffmann’s description of the US approach, ie ‘to adhere to literalism in construing the claims and evolve a doctrine which supplements the claims by extending protection to equivalents’. Even if not explicitly recognized as a doctrine of equivalence, the decision may therefore lead to a resurrection of the Protocol Questions by patentees effectively arguing just that. The decision may also see a renewed use of the Protocol Questions as an aid to construction generally but it seems unlikely to return to the time when every ambiguity in a claim was routinely put through them.