



ACTAVIS V ELI LILLY – SHOULD WE HAVE SEEN IT COMING?

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There are a number of important aspects to the Supreme Court decision in *Actavis v Eli Lilly*¹, but the most surprising, and indeed radical, was undoubtedly the advent in English law of a doctrine of equivalents.

The possibility that courts might consider the prosecution history of a patent has been discussed on and off over the years. Indeed, Arnold J's judgment in the first instance case appeared to open the door, at least a little, to some form of (the arguably linked) "file wrapper" estoppel. However, the continual rebuttal of the existence of a doctrine of equivalents in English law had been one of the most consistent aspects of the jurisprudence, certainly over the last 20 years. With this, apparently, was a rebuttal of any need for a form of file wrapper or "prosecution history" estoppel.

But was the Supreme Court's judgment in *Actavis v Eli Lilly* really such a surprise? Have there been clues that it was on the cards, and indeed should judges have got to this place much earlier?

A UK doctrine of equivalence was a possibility in the late 1990s, following *Warner-Jenkinson*

Way back in 1998 the issue was under consideration, in part because of the judgment of the US Supreme Court in *Warner-Jenkinson v Hilton Davis*². At the time this was the definitive statement on the doctrine of equivalents in the USA. In short, the US Supreme Court said that equivalents should not be limited to those identified in the patent.

This prompted a flurry of speculation as to whether, with such a definitive statement from the USA, and with the German position established after their version of the *Improver* case (on which see below), the time had come for a reconsideration of the position in England and Wales.

The established UK law at the time of the *Warner-Jenkinson* decision was the principle of purposive construction, derived from the decision of the House of Lords in *Catnic v Hill & Smith*³, in which Lord Diplock gave the only reasoned judgment, and applied using the three part test set out by Hoffmann J (as he then was) in *Improver v Remington*⁴.

However, there remained debate. In *Glaverbel v British Coal*⁵, a case in which the Court of Appeal's reasoning was concerned with validity not infringement, Staughton LJ set out seven propositions regarding claim construction which he said were common ground or well-founded. These included (from Lord Diplock's instruction in *Catnic*) that: "the interpretation of a patent, as of any other written document, is a question of law and so evidence of what the patentee intended is not admissible", and that the court must adopt a "purposive construction rather than a purely literal one". The *Improver* approach was not referred to or applied.

In *PLG v Ardon*⁶, the Court of Appeal cast some doubt on the applicability of the *Improver* test. Millett LJ asserted that the UK law was, by then, dictated by the European Patent Convention and the Protocol on the Interpretation of Article 69. Considering the Protocol and the *Improver* questions he said:

“If the two approaches are the same, reference to Lord Diplock's formulation is unnecessary, while if they are different it is dangerous.”

He did not indicate whether he felt they did amount to the same test, but concluded that it did not matter.

In reaching that decision Millett LJ overturned a first instance decision of Aldous J, as he then was.

Aldous J's cementing of purposive construction employing Hoffmann J's *Improver* approach

Shortly afterwards, Aldous J was elevated to the Court of Appeal (so becoming Aldous LJ), and took the opportunity to express a more elevated view in *Kastner v Rizla*⁷. He found that the Court of Appeal was bound to follow *Catnic*, and that it would take a decision of what was then the House of Lords to stipulate that there was any discrepancy between the application of the *Improver* questions and the requirements of the Protocol.

That became the norm. In a series of decisions at first instance and Court of Appeal levels, the *Improver* questions were deployed and approved. There was a background buzz of dissent from academics and other commentators that the questions were internally inconsistent and that the whole formulation was effectively circular⁸.

1. Actavis UK Limited & Ors v Eli Lilly and Company [2017] UKSC 46

2. Warner-Jenkinson Co. Inc. v Hilton Davis Chemical Co., 520 U.S. 17 (1997), which elaborated on the statement of the principle in *Graver Tank & Manufacturing Co Inc v Linde Air Products Co* 339 US 605, 607 (1950)

3. *Catnic Components Limited & Anr v Hill & Smith Limited* [1982] R.P.C. 183

4. *Improver Corporation & Ors v Remington Consumer Products Limited & Ors* [1990] F.S.R. 181

5. *Glaverbel SA v British Coal Corp & Anr* [1995] R.P.C. 255

6. *PLG Research Ltd & Anr v Ardon International Ltd & Ors* [1995] R.P.C. 287

7. *Kastner v Rizla Ltd & Anr* [1995] R.P.C. 585

8. For example "Purposive Construction: Seven Reasons why *Catnic* is Wrong" – Jonathan D C Turner. EIPR [1999] 531 and [1999] CIPA 700

However that did not affect the way the courts were dealing with the issue.

The year after the *Warner-Jenkinson* decision, Aldous LJ expressed the English approach most assertively in *Auchinloss v AVF*⁹, when he said:

“The correct approach to construction is not in doubt. The patent with its claims must be construed as a whole according to the guidelines given in the Protocol on the Interpretation of Article 69 of the European Patent Convention. The correct approach is purposive construction as stated in authorities such as *Kastner v Rizla*”¹¹.

He expressed the same sentiment with equal force and more colourful language in *Hoechst Celanese Corporation v BP Chemicals*¹⁰ when he said:

“It follows that the court must look at the claims, with the aid of the specification, to ascertain whether there is infringement. To do that attention must be paid to the Protocol which states that a strict literal construction should be avoided as should the use of the claims as a guideline. The correct approach is to arrive at the middle ground which provides fair protection and reasonable certainty.

It is now settled in this court (see *Kastner v Rizla Ltd* [1995] R.P.C. 585) that purposive construction as propounded by Lord Diplock in *Catnic Components v Hill & Smith Ltd* [1982] RPC 183 and as explained by Hoffmann J in *Improver Corp. v Remington Consumer Products* [1990] FSR 181 is the correct means of navigating between Scylla, the rock of literal construction; and Charybdis, the whirlpool of guided freedom as required by the Protocol. It enables the court to arrive at a result which gives fair protection to the patentee with a reasonable degree of certainty for third parties.”¹¹

Aldous LJ was never afraid to approve his own judgments.

Aldous LJ's further cementing of the *Improver* test as the established law defining and equating issues of extent of protection (i.e. infringement) and construction came in 2000, in *Wheatley v Drillsafe*¹¹. Aldous LJ said that “literal construction is outlawed by the Protocol”. The task of the court being to ascertain objectively what the meaning of the words used were intended to convey, this was best achieved with the aid of the *Improver* questions, which were “better called the Protocol questions”. There it was, at a stroke – problem solved. The *Improver* questions were, on this test, just a way of applying the underlying principles in the Protocol.

Three weeks later, in *AHP v Novartis*¹², Aldous LJ firmly shut down a minor first instance rebellion by Laddie J. At his most schoolmasterly, Aldous LJ said “This court has explained in a number of cases the correct approach to construction”. Adopting his approach in *Wheatley v Drillsafe* by referring again to the “Protocol questions”, he retrospectively applied them to the case in question in what seemed like a mild rebuke to Laddie J.

First instance dissent by Neuberger J and Laddie J

In his first instance judgment in *AHP v Novartis*¹³, Laddie J had observed that, per Lord Diplock's reasoning in *Catnic*, the language of the claim was “not supreme”; and he had concluded that although the claims in issue were expressed only in terms of the use of the compound rapamycin, the inventive contribution of the patent was broader than this such that Novartis' SDZRAD compound, a derivative of rapamycin, would infringe.

Immediately following the Court of Appeal's judgment in *AHP v Novartis*, the relatively junior first instance judge, Neuberger J, dutifully applied the Protocol questions in *Rohm & Haas v Collag*¹⁴. However, the following year, in another first instance decision, *Kirin-Amgen v Roche*¹⁵, Neuberger J, as he then was, expressed his own reservations about the Protocol questions. He said:

“It may be that the way in which these questions were expressed would seem to be a little narrow to those who practise in jurisdictions where there is a sharp demarcation between construction and infringement (for instance in Germany, where those issues are tried separately, indeed by different courts). In a sense,

9. *Auchinloss v Agricultural & Veterinary Supplies Ltd* [1999] R.P.C. 397

10. *Hoechst Celanese Corporation v BP Chemicals Limited* [1999] FSR 319, 323-4

11. *Wheatley v Drillsafe Ltd* [2001] R.P.C. 7

12. *American Home Products Corporation & Anr v Novartis Pharmaceuticals UK Limited* [2000] EWCA Civ 231

13. *American Home Products Corporation & Anr v Novartis Pharmaceuticals UK Limited & Anr* [2000] R.P.C. 547

14. *Rohm & Haas Co. v Collag Ltd* [2001] F.S.R. 28

15. *Kirin-Amgen Inc v Roche Diagnostics GmbH* [2001] EWHC 518 (Pat)

by tying oneself down to construction, it might be said that one was concentrating more on form than on substance. I suspect that, free from the binding constituents of *Catnic*, the questions might not have been expressed in terms of construction. After all, the claim in *Improver* referred to a “helical spring”¹⁶: as a matter of language that could scarcely include a “rubber rod”, as Hoffmann J recognised. Yet *Catnic* enabled him to conclude that a rubber rod could be within the claim. It may be that, shorn of authority, the question should be characterised as whether the rubber rod infringed the claim bearing in mind the technical contribution of the patent and not merely the words of the claim¹⁷.

He went on to say in the next passage:

“While, particularly at first instance, it would be brave or worse to depart from the three questions, I do not find it entirely easy to accept that it can be right that, where there is no infringement on a literal construction, the Court is in every case to be forced into the straightjacket of answering the three specific questions in order to decide issues of construction or even issues of infringement”¹⁸.

Neuberger J’s *Kirin-Amgen v Roche* decision was the first instance judgment in the case that eventually reached the House of Lords, leading to Lord Hoffmann’s 2004 judgment in *Kirin-Amgen v Hoechst*¹⁶. Interestingly, Neuberger J’s judgment addressed validity and then infringement. Before considering validity, he cited and abbreviated Staughton LJ’s “seven propositions” for the interpretation of patents. He then construed the relevant claims of *Kirin-Amgen*’s patent by interpreting them in a contextual way, and considering whether the conclusion he reached was in accordance with the Protocol. His consideration of the Protocol questions was in the context of his infringement analysis, with the explanation:

“As a matter of principle, questions of construction of a claim in a patent, and questions of infringement of that claim are separate. Indeed, there are obvious dangers in determining issues of construction of the

claims of a patent while having regard to the issues of infringement. At least on the face of it, what the patent means should not be influenced by the existence or nature of an alleged infringement. Apart from anything else, the alleged infringement will normally have arisen sometime after the patent has been applied for, and will therefore be something which occurred after the date by reference to which the patent is to be construed. However, some issues of construction in a patent action only arise because of the nature of the alleged infringement, and sometimes an issue of construction can hardly be understood without reference to the alleged infringement which gives rise to the issue of construction.

Furthermore, in many cases there is something of an overlap between construction and infringement issues. In many infringement actions, where the alleged infringement is not within the literal wording of a claim, it is now well established that the court has to ask itself the three questions which Hoffmann J set out in *Improver*, and which were recently cited with approval, as being in accordance with the Protocol, by Aldous LJ in *Wheatley*. The reasoning of Hoffmann J was based on the approach of Lord Diplock in *Catnic* and that of Aldous LJ was based on the Protocol. Accordingly, at least on the face of it, there is a powerful case for saying that, ultimately, when considering the three questions, the court is really posing a composite issue of interpretation. This view is supported by Hoffmann J’s statement in *Improver* that:

“In the end..... the question is always whether the alleged infringement is covered by the language of the claim.”¹⁹

It nonetheless remains the case that the three *Improver* or Protocol questions are directed to infringement, indeed to a specific alleged infringement - note the approach of the Court in *Improver*. At least in this case, it

16. *Kirin-Amgen Inc. & Ors v Hoechst Marion Roussel Limited & Ors* [2002] EWCA Civ 1096

seems to me that these *Improver* or Protocol questions, to the extent that it is necessary to deal with them, are more conveniently considered under infringement, rather than under construction.¹⁷

In the context of infringement, Neuberger J applied the Protocol questions, concluding that both Roche and TKT/Hoechst infringed. TKT's technology, he said, drew upon the inventive concept of the patent to a significant extent (question 1). He was prepared to assume that the notional reader of the patent was told that TKT's variant worked (question 2), and he considered that the fact that TKT's variant (homologous recombination) did not exist at the date of Kirin-Amgen's patent meant that it could not be argued that it was the patentee's apparent intent to exclude the variant from the extent of protection.

In my own comments on Neuberger J's judgment at the time I said:

“Sooner or later the current Patents Court judges will start working their way through the ranks of the appellate Courts, and when they do, I do not think that we should assume that *Improver* is sacrosanct beyond review¹⁷.”¹⁷

Whether or not prompted by Neuberger J's words, the other judges started to express their own doubts. Christopher Floyd QC, sitting as a deputy judge in *Deutsche Institute fur Textil v Fibreguide*¹⁸, described the Protocol questions as “simply an aid to construction”. Laddie J, in *SABAF v MFI*¹⁹, used language which appeared to cast doubt on the universal applicability of the Protocol questions.

Aldous LJ and Jacob LJ's suppression of rebellion

When the *Kirin-Amgen* case got to the Court of Appeal²⁰ (which again included Aldous LJ), Neuberger J's conclusion that TKT/Hoechst infringed Kirin-Amgen's patent was overturned. In the combined judgment, the Court of Appeal said that while there could be no doubt that at the heart of the invention was the discovery and sequencing of the gene that produced erythropoietin, the claim language was to a DNA sequence which had been made suitable for use in a host cell to produce EPO. This was, in effect, a claim to an exogenous DNA sequence suitable for expressing EPO when introduced to a host cell,

whereas the variant was an endogenous DNA sequence not suitable for expressing EPO until after introduction of the construct. This meant there were “real differences” between the claimed invention and the variant such that Kirin-Amgen's claim for infringement fell at the first Protocol question. The Court of Appeal also disagreed with the judge's application of the second question, on the basis that in light of the evidence, it could not have been obvious to the skilled addressee, at the time the patent was filed, that that the variant would work in the same way. Concluding, the judgment said:

“Having answered the Protocol question[s] in a way that indicates a conclusion of non infringement, it is appropriate to stand back and consider whether that conclusion is consistent with the broad principles laid down in the Protocol¹¹”.

There was no rebuke to Neuberger J for the structure of his first instance analysis i.e. of applying the Protocol questions in the context of his infringement analysis rather than in the context of pure construction. The Court of Appeal said that this was “consistent with practice”, but then said that this was because “the ambit of the claim must be the same whatever the issue” (i.e. conflating the issues of construction and infringement).

At times, the courts relaxed a little the application of the Protocol questions. The extent of movement away from their strict application was perhaps best demonstrated in the judgment of Jacob J, as he then was, in *Tickner v Honda*²¹ where he said:

“So I turn to construction. There is no dispute as to principles. The basic rule is that the monopoly is determined by the terms of the claims and that the description and drawings shall be used to interpret these, EPC Art. 69. The Protocol on the Interpretation of Article 69 directs the Court to eschew on the one hand a strict literal meaning out of context or on the other a mere guideline approach. A position between the two extremes, combining fair protection for the patentee with a reasonable degree of certainty for others is called for. The Courts of England and Wales have developed a series of well-known questions (the so called Protocol questions) to assist in the inquiry:

17. “Carry on Patents – The Year 2001 in the Patents Courts” – Gordon Harris

18. *Deutsche Institute fur Textil und Faserforschung Stuttgart v Fibreguide Limited* 2001 WL 395221

19. *SABAF SpA v MFI Furniture Centres Limited & Anr* 2001 WL 825163

20. *Kirin Amgen Inc. & Ors v Hoechst Marion Roussel Limited & Ors* [2002] EWCA Civ 1096

21. *Tickner v Honda Motor Company Limited & Ors* [2002] EWHC 8 (Patents)

these are a “useful tool to arrive at the middle ground” per Aldous LJ in *Pharmacia Corpn. v Merck*... No-one suggests they are, or could be, the be-all and end-all of the matter. The whole approach goes by the sobriquet “purposive construction”. You learn the inventor’s purpose by understanding his technical contribution from the specification and drawings. You keep that purpose in mind when considering what the terms of the claim mean. You choose a meaning consistent with that purpose – even if that involves a meaning which, acontextually, you would not ascribe to the word or phrase. Of course in this exercise you must also be fair to the patentee – and in particular must not take too narrow a view of his purpose – it is the widest purpose consistent with his teaching which should be used for purposive construction.”

Although this was, to some extent, a departure from the *Improver* orthodoxy of the time, it still conflated the issues of construction and infringement – in other words it did not go as far as the answer tentatively postulated by Neuberger J in the *Kirin-Amgen v Roche* decision.

In the case of *City Technology v Alphasense*²², the Court of Appeal rejected a submission that the skilled reader would have understood that the patentee intended strict compliance with the primary meaning. In the only reasoned judgment, Aldous LJ said:

“Nowhere in the specification or the claims does the patentee indicate that strict compliance was a requirement... There is nothing in the specification or claims which indicates that fair protection envisaged by the patentee should be confined to a literal interpretation.”

It is not hard to see that the courts were getting in something of a tangle at this time. Also, in *Sara Lee v Johnson*²³, the Court of Appeal (Aldous LJ) appeared to place the burden of defining the scope of the inventive concept on the patentee, saying:

“If the variant is not obviously immaterial, it would normally be wrong for the public to be prevented from making that variant. It is the patentee who chooses the words of the claims.”

However, in the *City Technology* case Aldous LJ’s judgment appeared to indicate that the onus lay with the alleged infringer to demonstrate that strict compliance was a requirement, and consequently that a variant did not amount to an infringement.

The interplay between the UK Courts and the US Courts on the question of patent construction came into operation again following the US Supreme Court decision in the *Festo Corporation*²⁴ case, and the UK case of *Celltech v Medimmune*²⁵. The *Festo* decision put a limitation on the US doctrine of equivalents. That limitation took two forms, known respectively as amendment estoppel and argument estoppel. The two can easily be summarised as that if a patentee amends their patent, or makes an argument before the examining patent office which might constitute a limitation on interpretation, then, faced with a variant which is along the lines of the pre-amended form of the patent, the doctrine of equivalents cannot apply to allow for infringement to be found. In the *Celltech* case, a Court of Appeal bench which did not include Aldous LJ approved the *Festo* decision, and found that both argument estoppel and indeed amendment estoppel were present. This decision in itself may be seen as a precursor to the adoption of some form of file wrapper estoppel as ultimately approved by Lord Neuberger in the *Actavis v Eli Lilly* decision.

In April 2004, in *Rockwater v Technip*²⁶, Jacob LJ provided an 11-point summary of the principles of construction, which included the following:

“Art 69 says that the extent of protection is determined by the terms of the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.

It follows that the claims are to be construed purposively – the inventor’s purpose being ascertained from the description and drawings.

22. *City Technology Limited v Alphasense Limited* [2002] EWCA Civ 347

23. *Sara Lee Household & Body Care Ltd v Johnson Wax Limited* [2001] EWCA Civ 1609

24. *Festo Corp. v Shoketsu Kinzoku Koguo Kabushiki Co.* 535 U.S. 722 (2002)

25. *Celltech Chiroscience Ltd v Medimmune Inc.* [2003] EWCA Civ 1008

26. *Rockwater Ltd v Technip France SA & Anr* [2004] EWCA Civ 381

... there is no general “doctrine of equivalents.” Any student of patent law knows that various legal systems allow for such a concept, but that none of them can agree what it is or should be. Here is not the place to set forth the myriad versions of such a doctrine. For my part I do not think that Art. 69 itself allows for such a concept – it says the extent of protection shall be determined by the terms of the claims. And so far as I can understand, the French and German versions mean the same thing. Nor can I see how the Protocol can create any such doctrine.”

The views of the French and German courts, as to whether Article 69 and the Protocol permitted a doctrine of equivalents, were not considered in the judgment.

Lord Hoffmann's cementing of purposive construction in *Kirin-Amgen*, and Jacob LJ's gloss

The next major development was the decision of the House of Lords in the *Kirin-Amgen* case²⁷, later in October 2004.

Lord Hoffmann took the opportunity to step back and review the whole question of patent construction from the bottom up. He noted the most important legislative provision as being article 69 of the EPC and its Protocol. He also said:

“Although article 69 prevents equivalence from extending protection outside the claims, there is no reason why it cannot be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean. That is no more than common sense. It is also expressly provided by the new article 2 added to the Protocol by the Munich Act revising the EPC, dated 29 November 2000.”

Lord Hoffmann reviewed many of the judgments of the courts which followed the *Catnic* decision, and took the opportunity to rebut some of the principles which appeared to have emerged since then.

For example, in *Rockwater v Technip*, Jacob LJ had said that one must use “the widest purpose consistent with his teaching” in order to achieve the fairness sought by the Protocol. Lord Hoffmann said that this confused the purpose of the utterance with what it would be understood to mean. He went on to explain:

“The purpose of a patent specification...is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one uses to ascertain the meaning. But purpose and meaning are different. If, when speaking of the widest purpose, Jacob LJ meant the widest meaning, I would respectfully disagree. There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.”

He elaborated on the meaning of purposive construction saying:

““Purposive construction” does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean, and for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly.”

Lord Hoffmann went on to review the US decisions, culminating in the Supreme Court's ruling in the *Festo* case. His conclusion was quite specific:

“There is often discussion about whether we have a European doctrine of equivalents and, if not, whether we should. 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.

27. *Kirin-Amgen Inc & Ors v Hoechst Marion Roussel Limited & Ors* [2004] UKHL 46

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 that he was claiming.”

He elaborated further saying:

“If literalism stands in the way of construing patent claims so as to give fair protection to the patentee, there are two things you can do. One is to adhere to literalism in construing the claims and evolve a doctrine which supplements the claims by extending protection to equivalents. That is what the Americans have done. The other is to abandon literalism. That is what the House of Lords did in the *Catnic* case... The solution, said Lord Diplock, was to adopt a principle of construction which actually gave effect to what the person skilled in the art would have understood the patentee to be claiming.”

Finally, he turned his attention to the Protocol questions, and returned to basic principles, saying that everything which had followed derived from the *Catnic* case, and should therefore be identified as the “*Catnic* principle”.

He explained his view saying:

“When speaking of the *Catnic* principle it is important to distinguish between, on the one hand, the principle of purposive construction which I have said gives effect to the requirements of the Protocol, and on the other hand, the guidelines of applying that principle to equivalents which are encapsulated in the Protocol questions. The former is the bedrock of patent construction, universally applicable. The latter are only guidelines, more useful in some cases than in others. I am bound to say that the cases show a tendency for Counsel to treat the Protocol questions as legal rules rather than guides which will in appropriate cases help to decide what the skilled man would have understood the patentee to mean.”

Lord Hoffmann accepted that there is no perfect test to ascertain meaning. He said that the vast majority of patent specifications are perfectly clear, and as a consequence never come to court. In borderline cases interpretation which strikes one person as fair and reasonable, may strike another as unfair to the patentee or unreasonable to third parties. He concluded:

“That degree of uncertainty is inherent in any rule which involves the construction of any document. It afflicts the whole of the law of contract, to say nothing of legislation. In principle it is without remedy.”

Turning to Neuberger J's first instance judgment, the conceptual dichotomy is apparent from Lord Hoffmann's criticism of it:

“Having thus construed the claims, the judge described his construction as “literal” and moved on to the Protocol questions. In what sense could the construction have been literal? The first difficulty about the application of the Protocol questions is to decide what is meant by a “primary, literal or acontextual meaning”. The judge's construction could not possibly be described as acontextual. It was entirely dependent on context and reflected the evidence of how the claim would have been understood by men skilled in the art.”

As noted above, Neuberger J had construed the claims by interpreting the words used in their context, and only applied the Protocol questions in the context of his infringement analysis.

Where we appeared to have got to after Lord Hoffmann's judgment was that the first two limbs of the *Improver* test had effectively been dropped and we were left with question three. Lord Hoffmann's approach was to ask what the skilled reader would have thought the patent was intended to mean, and the effect of any limitations which appear in the wording of the patent.

As regards the other minor controversy of construction, the question of file wrapper estoppel, Lord Hoffmann was fairly decisive. He said that “life is too short” to read the file wrapper!

The Court of Appeal's gloss on the *Kirin-Amgen* decision came in the following year in the case of *Mayne Pharma v Pharmacia*²⁸. Lord Justice Jacob noted with interest that, in effect, Lord Hoffmann had approved his (Jacob LJ's) previous judgments, and in particular the analysis of the method of construction he had set out in *Rockwater v Technip*. Jacob LJ took the opportunity to reiterate his own multi-part approach to construction and, subject to minor amendments which Jacob LJ made himself in the case of *Virgin v Premium*²⁹ a few years later, the approach to construction has been consistent since then. The question is whether that was right, or whether, all along, the changes which have now been introduced by Lord Neuberger should have been evolving.

Lord Hoffmann's empire

Throughout the evolution of the UK courts' approach to construction, from the *Catnic* case through to the *Mayne Pharma* formulation, the underlying theme was that, whatever formulation was adopted, it needed to reflect the approach set out in the Protocol on the Interpretation of Article 69 of the European Patent Convention. Although there was an appreciation that the *Catnic* and *Improver* decisions were effectively "old law", applying to patents granted before the European Patent Convention came into force, the underlying approach was still right, and so the *Improver* questions were simply renamed the Protocol questions because they amounted to nothing more than a device for applying the principles in the Protocol.

In December 2007, a new version of the Protocol came into effect. The main body of the text remained intact, but a new Article 2, headed "Equivalents", was introduced. It read:

“For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.”

Its introduction is discussed in more detail below. My own comment at the time was:

“It is hard to see how this strong position against the consideration of equivalents can be squared with the

amendment to the Protocol on the Interpretation of Article 69.”³⁰

However, English judges clearly considered themselves more beholden to Lord Hoffmann in the House of Lords than to any amendment to the Protocol, and there was little development between 2007 and June 2017. Lord Hoffmann's judgment in *Kirin-Amgen* had been quoted with great frequency. There had been no major revision of the underlying principles. It remained the leading authority in the UK, defining the law in respect of claim construction (which of course impacts validity issues also) and infringement.

The decline of the empire

When article 2 of the Protocol was adopted, there were those who were very keen to say that the change had no real meaning, and took the law no further forward. That was, in many ways, a strange position to adopt. After all, in the *Kirin-Amgen* case, Lord Hoffmann said that "plain words should have a plain meaning". On the face of it, there was an entirely new paragraph in the Protocol which included the word "equivalents". What is more, when the changes were being discussed, way back in 2000, the UK delegation to the diplomatic conference published comments saying:

“It was an interesting proposal which consisted of a radical change to the legal position in the United Kingdom and still required in depth examination and consultation of the interest groups involved.”

Their official paper went on to say:

“The office compared the legal position in the United Kingdom with the proposed arrangement. UK law did not apply the classical doctrine of equivalents, instead dealing with issues of equivalence by applying the principle of “purposive construction” developed in the House of Lords’ “*Catnic*” decision”.

The *Improver* case was widely discussed in the diplomatic conference in 2000 because the English method of construction had led to a different result being achieved in the United Kingdom to that which occurred in Germany. The Swiss delegation to the conference said

28. *Mayne Pharma Pty Ltd & Anr v Pharmacia Italia SPA* [2005] EWCA Civ 137

29. *Virgin Atlantic Airways Limited v Premium Aircraft Interiors UK Limited* [2009] EWCA Civ 1062

30. "When is a Patent not a Patent? The year 2007 in the Patents Courts" – Gordon Harris

of the *Improver* case that it was “a striking demonstration of how equivalents were treated differently in individual contracting states”. They went on to say that there was an urgent need for legislation, and supported the basic proposal which came to pass in the revised version of the Protocol.

The final published version of the additional paragraph 2 was amended from its original draft. The original wording said:

“A means shall generally be considered as equivalent if it would be obvious to a person skilled in the art that using such means would achieve substantially the same result as that achieved through the means specified in the claim.”

In a special edition of the Official Journal in 2003, the following was stated by way of explanation:

“The changes to Article 69 of the EPC are likewise purely clarificatory and editorial. The same is true of the addition made to the Protocol on the Interpretation of Article 69 of the EPC as part of the revision. In one form or another, patent practice in all the contracting states has long accepted that equivalents should be taken into account in determining the extent of protection of the European patent. The Protocol’s new Article 2 neither gives a binding definition of equivalents nor specifies exactly how they are to be taken into account. The new provision is thus intended not to change the existing legal situation but to formalise the elements underlying it.”

It is hard to accept an assertion that, in 2003 in the United Kingdom, it had been “long accepted that equivalents should be taken into account”.

There was no such indication in the judgment of Lord Hoffmann in *Kirin-Amgen*, in 2004.

Nevertheless, this did not stop Sir Hugh Laddie, who had given the first instance judgment in *AHP v Novartis*, from explaining to the world why the House of Lords’ judgment in *Kirin-Amgen* was wrong. A case comment³¹ attributed to Sir Hugh was published in the

International Review of Intellectual Property and Competition Law (a Max Planck Institute journal), in early 2009, shortly after his death. Sir Hugh Laddie had resigned from the High Court in 2005.

In a review spanning over four hundred years of English patent law, Sir Hugh explained why, in his view, Lord Hoffmann had been wrong to describe the law in the UK before *Catnic* as an “old English literalism” (meaning acontextual literalism) from which the “pith and marrow” doctrine was “born of despair”. First, for 200 years there were no patent claims, and second, once claims came into existence, they were always construed in context. It appeared instead that the pith and marrow doctrine and associated doctrines grew up independently of claims, could be traced back to a time when claims did not exist, and continued to be applied up until *Catnic*.

So, for example, in 1977 in *Beecham v Bristol*³², a product claim to the antibiotic Ampicillin (which contained an amino group) was infringed by Bristol’s dealings in its Hetacillin medicine. When Hetacillin was put in water or ingested it would revert to Ampicillin with the release of acetone (i.e. de-protecting the amino group). This was infringement on the pith and marrow basis as a “colourable evasion” of the Beecham claims. Sir Hugh noted that the House of Lords clearly considered that Hetacillin took, in substance, the Ampicillin inventive concept, and that this was what counted, even though Hetacillin did not fall within the terminology of the claims.

After asking how the House of Lords could have got the history so wrong, Sir Hugh suggested that their Lordships “fell into the error of assuming that old English literalism which had existed in relation to the interpretation of commercial documents in general until the sea-change in the mid-1970s had also existed in relation to the interpretation of patent claims”. In any case, in Sir Hugh’s view, far from being a liberalising decision, *Catnic* was better regarded “as the penultimate step on the road to the adoption of a narrow, unforgiving approach to the determination of the scope of protection”.

Nevertheless, with the House of Lords’ *Kirin-Amgen* decision guiding the way, it was virtually impossible for first instance judges, or the Court of Appeal, to question or vary the approach to construction which had become so rooted in the jurisprudence of England and Wales. At first instance in the *Actavis v Eli Lilly* litigation³³, Arnold J gave a hint of possible changes to come by opening the door, albeit only slightly, to the possibility of file wrapper estoppel. When

31. *Kirin-Amgen - The End of Equivalents in England?* (2009) 40 IIC 3

32. *Beecham Group Ltd v Bristol Laboratories Ltd* [1978] R.P.C. 153

33. *Actavis UK Limited & Ors v Eli Lilly & Company* [2014] EWHC 1511 (Pat)

considering whether the prosecution history was admissible as an aid to construction, Arnold J said that he considered reasoning of Robert Walker LJ in the Court of Appeal's decision in *Rohm and Haas v Collag*³⁴ (confirming Neuberger J's first instance judgment) to be persuasive. Robert Walker LJ had drawn upon the judgment of the Supreme Court of the Netherlands, *Ciba-Geigy v. Optics* (January 13, 1995), which said:

“Article 69, paragraph 1 of the EPC as interpreted in accordance with the Protocol relating thereto does indeed purport (among other things) to ensure reasonable certainty for third parties, but it does not follow that the information from the granting file that is available to third parties may never be used in support of the interpretation given by the patentee to his patent. The requirement of reasonable certainty for third parties does, however, call for restraint in using arguments derived from the granting file in favour of the patentee. Consequently, a court will only be justified in using clarifying information from the public part of the granting file, when it holds that even after the average person skilled in the art has considered the description and the drawings, it is still open to question how the contents of the claims must be interpreted. In this connection one must also take into consideration that the risk of any ambiguities due to careless wording of the patent specification must in principle lie with the patentee.”

However, the door appeared to be slammed fairly firmly shut again by Lord Justice Floyd in the Court of Appeal³⁵. And so we move to the Supreme Court, and what was Lord Neuberger's last substantive intellectual property decision.

The fall of the empire and rise of a doctrine of equivalents

In his judgment, Lord Neuberger covered much of the ground which I have explored above, and I do not propose to analyse his description of the history in full. After a detailed consideration of the position in

a range of European jurisdictions, he got to the heart of the matter in paragraph 53:

“Any patent system must strike a balance between the two competing factors referred to at the end of article 1 of the Protocol, namely “a fair protection for the patent proprietor [and] a reasonable degree of legal certainty for third parties”. The balance cannot be struck on an *ad hoc* basis without any guiding principles, as that would mean there was no legal certainty. On the other hand, striking a balance by adopting a normal approach to interpretation would risk depriving patentees of a proper measure of protection.”

Lord Neuberger emphasised repeatedly that the Protocol is not intended to be a guide to document construction. It is rather a means to assist in the assessment of the question of infringement from case to case. He said that the question of infringement is, in his view, best approached by addressing two issues, each to be looked at through the eyes of the notional addressee:

“Those issues are: (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? If the answer to either issue is “yes”, there is an infringement; otherwise, there is not.”

He asserted that issue (i) self-evidently raised the question of interpretation, whereas issue (ii) needed to be resolved by reference to facts and expert evidence. His assessment of the decisions of Lord Hoffmann in *Improver* (when he was still Hoffmann J) and *Kirin-Amgen* was that they effectively conflated the two issues, and indicated that the conflated issue involved a question of interpretation. This Lord Neuberger described as “wrong in principle” and likely to “lead to error”, the problem being that it may be thought of as sufficient to put an end to the patentee's infringement argument on facts such as those in *Improver*, and there would seem to be little purpose in going through the three questions in that case. Interestingly, this was the same argument he had deployed back in 2001, in his *Kirin-Amgen v Roche* judgment.

34. *Rohm and Haas Co & Anr v Collag Ltd & Anr* [2001] EWCA Civ 1589

35. *Actavis UK Limited & Ors v Eli Lilly & Company* [2015] EWCA Civ 555

By analogous reasoning, it may be that the outcome in *Beecham v Bristol* would not have been a finding of infringement, had it been assessed in accordance with purposive construction/the *Improver* questions.

Perhaps the underlying reason for Lord Neuberger's approach can also be found in *Kirin-Amgen v Roche*. In that case Neuberger J abbreviated the first of Staughton LJ's "seven propositions" (in *Glaverbel v British Coal*) to "the interpretation of a patent is a question of law, and therefore the question of construction itself is not a matter for evidence".

With that in mind, how could the issue of equivalence ever be properly considered by the court, if the assessment of infringement was one based purely on the construction of the patent? To achieve the balance required by the Protocol to give a fair degree of protection to the patentee, it seems clear that one must be able to look at evidence, including expert evidence, in assessing equivalents for possible infringement. To be able to do that one must move away from an approach which ties the assessment of infringement to the construction of the patent in a way which invokes the *Glaverbel* rules. The very fact that what Jacob J described as the sobriquet, purposive construction, has that name, ties the process to the principles of patent construction.

Briefly considering the amendment to the Protocol introduced in 2007, I have described above the initial views of the UK delegation to the diplomatic conference and the stated views of some other delegations. Yet in the English jurisprudence, it was pretty much ignored. In his *Actavis v Eli Lilly* judgment, Lord Neuberger did not make a great deal of it, but clearly considered that article 2 needed to be paid a little more heed than his fellow judges had to date. He said:

“It is apparent from article 2 that there is at least potentially a difference between interpreting a claim and the extent of the protection afforded by a claim, and, when considering the extent of such protection, equivalents must be taken into account, but no guidance is given as to precisely what constitutes an equivalent or how equivalents are to be taken into account.”

It is interesting also that Lord Neuberger also turned to the 2009 Sir Hugh Laddie article discussed above to support his view in *Actavis v Eli*

Lilly, expressed originally in 2001, that the Protocol is not concerned with the rules of construction, but rather with determining the scope of protection. While Lord Neuberger acknowledged that the first limb of his two part test is all about interpretation of the claims, the second part relates to the scope of the inventive concept – the technical contribution of the patentee.

Lord Neuberger is always keen to return to the “helical spring/slotted rubber rod” dilemma, which under-pinned the *Improver* decision, which in turn influenced so much of what has followed. In his *Actavis v Eli Lilly* judgment, he drew an analogy in the subject matter of the case before him:

“In the present case there is no doubt that, according to normal principles of interpreting documents, the Actavis products do not infringe the Patent, as in no sensible way can pemetrexed free acid, pemetrexed ditromethamine, or pemetrexed dipotassium mean, ie be said to fall with the expression, “pemetrexed disodium” in claim 1 of the Patent, any more than a slotted rubber rod can be said to be within the expression “a helical metal spring” in the claim in the *Improver* patent. According to normal principles of interpreting documents, then, this would be the end of the matter”.

What he said next referred back to his 2001 *Kirin-Amgen v Roche* judgment:

“It may be that, shorn of authority, the question should be characterised as whether the rubber rod infringed the claim bearing in mind the technical contribution of the patent and not merely the words of the claim.”

That was his precursor to the second limb of his two part test – does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial? This approach focuses on the inventive concept, not the specific words of the claims.

It is very interesting that, for assistance in answering the question he poses himself – what is it that makes a variation immaterial? – he turns to the *Improver* questions as a first point of reference. In doing so he is acknowledging his own assertion that, “[t]he balance cannot be struck on an *ad hoc* case-by-case basis without any guiding

principles, as that would mean there was no legal certainty". His starting point for establishing "guiding principles" is the *Improver/Protocol* questions, but that comes with a caution that they were, in his view, wrongly conceived because they had an emphasis on how the invention works as opposed to the inventive concept – the problem underlying the invention.

After analysing the three *Improver/Protocol* questions, he reformulated them in these terms:

- i) 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, ie the inventive concept revealed by the patent?
- ii) 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?
- iii) 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?

The least altered of the three questions is the last, though even that comes with provisos. Lord Neuberger asserted that, in applying the third question, due consideration should be given to the specification (and presumably the drawings, though he does not make reference) as well as the knowledge and expertise of the notional skilled person. He was at pains to emphasise that just because the wording of the claims does not cover the variant is not enough to justify holding that the patentee does not satisfy the third question. We should not be surprised by that assertion – it is the whole basis on which any doctrine of equivalents is founded.

It is worth just reflecting here on one short passage from Lord Hoffmann's judgment in *Kirin-Amgen*. Lord Hoffmann acknowledged that the specification of the patent may portray an inventive concept at one level, but that the patentee may, for whatever reason, have chosen specifically to claim a monopoly which is more limited than the entire teaching of the patent. Lord Hoffmann said, "there is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables". It is arguable

that this is the case with nearly every granted patent. Will such "under-claiming" create a form of estoppel which limits the scope of the potential boundaries of infringement for variants? How specific must a patentee be to achieve limitations on the claims which might, for example, be chosen to avoid dangers of invalidity as against pre-existing variants?

One obvious example of an instance where strict compliance might be inferred is the case of numerical limits. The courts have been quite clear about this over the years – if the patentee sets numerical book-ends, they act as a strict delimitation on the scope of the claims subject only to the principles of mathematical rounding.

Perhaps the most significant alteration is to the second question. As amended, it acknowledges that the obviousness of the variant is being assessed at the date of infringement, not the priority date. This, as Lord Neuberger put it, imbues the notional addressee "with rather more information than he might have had at the priority date". Whilst the patent is deemed to be read at the priority date, the assessment of the variant is done through the eyes of a notional addressee at the date of the alleged infringement. This precisely adopts the passage from paragraph 197 of the 2001 *Kirin-Amgen v Roche* decision of Neuberger J (as he then was) which I have quoted above. It was there all the time if we had looked for it.

Drawing the threads together, it is also worth just reflecting on the approach to the file wrapper history as considered by Lord Neuberger in *Actavis v Eli Lilly*. This is one area where he appears to have changed his mind. In his 2001 *Kirin-Amgen* decision Neuberger J (as he then was) said:

"If, when construing a patent, one could take into account what was said on behalf of the patentee at any opposition proceedings, then, it seems to me, one always would have to take into account what was said at opposition proceedings. It cannot be a matter of choice. Accordingly, no patent agent or lawyer could sensibly advise an interested third party as to the meaning and effect of a European patent without studying a transcript of the opposition proceedings (if any)."

He went on to refer to the *Glaverbel* principles, acknowledging that file wrapper estoppel was not itself an issue in the *Glaverbel* case, but nonetheless finding support for his position from Staughton LJ's judgment in which he rejected an attempt to rely upon other documents containing statements by the patentee relating to the alleged invention.

However, in 2017 in *Actavis v Eli Lilly*, Lord Neuberger concluded that:

“In my judgment, it is appropriate for the UK courts to adopt a sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file of a patent should be referred to when considering a question of interpretation or infringement, along substantially the same lines as the German and Dutch courts.”¹¹

Identifying circumstances where it might be appropriate he said:

“While it would be arrogant to exclude the existence of any other circumstances, my current view is that reference to the file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored. The first type of circumstance is, I hope, self-explanatory; the second would be exemplified by a case where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.”¹²

To me this seems like an acknowledgement that, if one is to adopt an evidence based assessment of infringement in the second limb of his test, it would be wrong to operate a rule which effectively excluded a class of evidence from the consideration, even if there might be some skepticism as to its relevance. His example of the second appropriate case probably falls within the concept of “argument estoppel” as identified in the *Festo* case.

Lord Neuberger's legacy

It would be fair to say that Lord Neuberger's judgment in *Actavis v Lilly* is significant to the extent of being radical. As a judgment of the Supreme Court it is binding until another bench of the same court addresses the issues again, and after such a comprehensive judgment that may not happen any time soon.

However, although its impact is indeed significant, it would be wrong to say that the opinions which underpin it have not been expressed in the years since the *Catnic* and *Improver* decisions in various fora. Lord Neuberger has a habit of having the last word. In *Virgin v Zodiac*³⁶ he joined Lord Sumption in giving a judgment which supported his own minority judgment in the Court of Appeal in *Coflexip v Stolt*³⁷ and overturned many intervening judgments, most notably that of Jacob LJ in *Unilin v Berry*³⁸. In that case he waited only nine years to correct his errant colleagues on the question of *res judicata* and the interaction of the High Court and the EPO. This time it has taken 16 years since his judgment in *Kirin-Amgen v Roche*, which foreshadowed almost every aspect of the *Actavis v Eli Lilly* decision. In the meantime Lord Neuberger will have had his views strengthened by the amendment to the Protocol.

We could, and should, have seen this coming. Lord Hoffmann, Lord Justice Aldous and Sir Robin Jacob - the generation of judges which cemented Lord Diplock's judgment in *Catnic*, a case under the UK's 1949 Patents Act, as establishing that purposive construction was the correct approach to construction and infringement according to the European Patent Convention - have ended their judicial careers. *Actavis v Eli Lilly* was the first opportunity for Lord Neuberger to consider, in the Supreme Court, the issue on which he (and fellow rebel Laddie J) had so eloquently expressed their dissent. In truth it was always likely that, given such a chance, he would want to tidy up an area in which he has clearly long thought that all was not in order.

Another reason why we might have seen this coming is that it with the anticipated opening of the Unified Patent Court in 2018, the transition to a harmonized law of patent infringement will be eased with the UK more in line with the approach taken in other leading European jurisdictions, most notably Germany. It is also arguable that, notwithstanding the significance of the Protocol, before and after amendment, all Lord Neuberger has done is return to some principles which guided the assessment of infringement before

36. *Virgin Atlantic Airways Limited v Zodiac Seats UK Limited* [2013] UKSC 46

37. *Coflexip SA v Stolt Offshore MS Ltd (No 2)* [2004] FSR 708

38. *Unilin Beheer BV v Berry Floor NV* [2007] FSR 635

Catnic, and which are common across many different legal systems. The language may have changed, but the principles are remarkably familiar.

So we now have a doctrine of equivalents in the UK. We are also, in some circumstances, permitted to adduce evidence from the prosecution history, particularly where it might affect the assessment of equivalence. We have a two part approach, dealing first with an assessment of infringement by reference to the words and drawings in the patent on the basis of document construction, but then, if necessary and appropriate, moving on to an evidence-based assessment of infringement by equivalents. Further, we know that to provide a framework for dealing with that second limb in a manner which can provide at least some degree of certainty, we have a reformulation of the *Improver* questions, arguably aligned with the doctrine of equivalents in Germany.

We have what seems to be an assessment of infringement which may move over time, as equivalents are evolved, and we certainly have a degree of uncertainty as to the extent to which this new method of considering equivalents for the purposes of assessing infringement might read on to the assessment of prior art for the purposes of assessing obviousness.

It will, as ever, be interesting to see how the judges at first instance and in the Court of Appeal set about dealing with this significant change in approach. One of the first issues to consider is how claims should be construed for the purpose of an assessment of validity: is there now a gap between the scope of the claim which must be inventive and supportive, and its reach for infringement purposes? Many of the current patent specialists honed their advocacy skills in the cases discussed above.

What does seem clear is that in the areas of construction and infringement, Lord Neuberger seems finally, in 2017, to have dragged UK patent jurisprudence in to line with the EPC and much of Europe.

GORDON HARRIS – SEPTEMBER 2017

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