

Deconstructing Actavis v Eli Lilly

Christopher de Mauny

The Supreme Court's decision in *Actavis v Eli Lilly* [2017] UKSC 48 has changed the way that the UK courts will determine the extent of protection of a patent's claim. Prior to this decision, since the House of Lords' decision in *Catnic Components v Hill* [1982] RPC 183 the UK courts has used "purposive construction" in order to establish the scope of a patent's claim. As famously explained by Lord Hoffmann in the seminal decision of the House of Lords in *Kirin Amgen v Hoechst Marion Roussel* [2005] RPC 9 the crux of purposive construction is to determine "*what the person skilled in the art would have understood the patentee to be using the language of the claim to mean*".

The purposive construction approach was adopted by the English courts in *Catnic* in a case heard under the Patents Act 1949, i.e. prior to the influence of the EPC entering English law via the Patents Act 1977. Nevertheless, as Lord Hoffmann explained in *Kirin Amgen*, the purposive construction approach was the correct approach under the EPC. Article 69 EPC requires that the "*extent of protection*" be "*determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims*". The Protocol to Article 69 explains that the extent of protection to be found between two extremes, one wherein the claims are interpreted literally using the description and drawings only to resolve ambiguities and one where the claims serve only as a guideline. The Protocol explains that Article 69 EPC should be understood as "*defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties*". Since the implementation of EPC 2000, the Protocol has contained a second article which states that "*due account shall be taken of any element which is equivalent to an element specified in the claims*".

Prior to *Actavis*, therefore, purposive construction was the lodestone that guided all aspects of determining the scope of a patent's claim. Thus, while the Patents Court would consider whether any alleged equivalent fell within the claim, this was done as part of the purposive construction exercise, using the three 'Protocol questions' first pronounced by Hoffmann J in *Improver v Remington* [1990] FSR 181, following certain passages of Lord Diplock's speech in *Catnic*. As Lord Hoffmann went on to explain years later in *Kirin Amgen*, it was important to distinguish between "*the principle of purposive construction which I have said gives effect to the requirements of the Protocol, and on the other hand, the guidelines for 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.*" Lord Hoffmann recognised in *Kirin Amgen* that the Protocol had been amended to introduce article 2, referring to equivalents, although at the time of the *Kirin Amgen* decision that amendment had not come into force.

Since *Kirin Amgen* the Court of Appeal and Patents Court have applied purposive construction in a multitude of cases. In a few cases, most notably *Virgin v Premium Aircraft* [2010] RPC 8, the Courts had found it beneficial to expand the guidance from *Kirin Amgen*. However, in all cases there was but one exercise to be performed: determining what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean.

The Supreme Court in *Actavis v Eli Lilly* has fundamentally changed how the UK courts are to determine the extent of protection afforded by a patent. In particular, as has been widely discussed,

the decision introduces a full-blown doctrine of equivalents into English patent law. Lord Neuberger, giving the judgment of the Court, stated that *"a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, ie the person skilled in the relevant art. 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?"*

Lord Neuberger then provided a reformulation of the Protocol questions in order to assisting in answering the second issue. These reformulated Protocol questions refer to *inter alia* the "literal meaning of the relevant claim(s)" and the "invention, i.e. the inventive concept revealed by the patent". It would appear, therefore, that there are at least three different exercises in construction that must in principle be performed under the *Actavis v Eli Lilly* approach:

- (1) determining the "normal interpretation" of the claim(s);
- (2) determining the "literal meaning" of the claim(s); and
- (3) identifying the "invention" or "inventive concept".

It should be noted that in paragraph 54 the Court draws a distinction between the first main issue ("normal interpretation") and the second main issue (variants, including the three sub-questions referring to the "literal meaning" and the "inventive concept") and states that *"issue (i) self-evidently raises a question of interpretation, whereas issue (ii) raises a question which would normally have to be answered by reference to the facts and expert evidence."* It is unclear whether this is intended to suggest that facts and expert evidence should play no part in answering the first issue although, as discussed below, the Court appeared to answer the first issue in this case without recourse to the facts and expert evidence.

In the remainder of this article each of these three exercises will be discussed.

Normal interpretation

The Supreme Court provides very little guidance on what it means by "normal interpretation". Indeed, it is discussed briefly in only two sentences of general applicability beyond the case before the Court:

Turning to the two issues identified in para 54 above, issue (i), as already mentioned, involves solving a problem of interpretation, which is familiar to all lawyers concerned with construing documents. While the answer in a particular case is by no means always easy to work out, the applicable principles are tolerably clear, and were recently affirmed by Lord Hodge in Wood v Capita Insurance Services Ltd [2017] 2 WLR 1095, paras 8 to 15.

The case cited by Lord Neuberger, *Wood*, is a case about a contract. Curiously, the *Wood* case itself does not contain a detailed discussion of the principles of contractual interpretation but rather confirms that the earlier Supreme Court decision of *Arnold v Britton* [2015] AC 1619 was not intended to "row back from" the principles set out in the previous Supreme Court decision of *Rainy Sky v Kookmin Bank* [2011] 1 WLR 2900. It would appear, therefore, that it is from *Rainy Sky* that the detailed principles are to be extracted. Two things should be remembered at all times, however: (1) Lord Neuberger expressly recognised in *Actavis* that the exercise of "normal interpretation" had to be *"considered through the eyes of the notional skilled addressee of the patent"*; and (2) the Supreme Court's decision provides only guidance on the statutory test embodied in Article 69 EPC (and s. 125 Patents Act 1977). This contrasts with the position of contracts (and many other legal instruments) for which the principles of interpretation are derived almost wholly from the common law, modified by statute only in certain respects.

In *Rainy Sky* the majority judgment was given by Lord Clarke. Before discussing some of the principles in further detail, he recorded in paragraph 14 that *"the ultimate aim of interpreting a provision in a contract, especially a commercial contract, is to determine what the parties meant by the language used, which involves ascertaining what a reasonable person would have understood the parties to have meant ... the relevant reasonable person is one who has all the background knowledge which would reasonably have been available to the parties in the situation in which they were at the time of the contract"*.

This approach is reminiscent of the key tenet of purposive construction expounded by Lord Hoffmann in *Kirin Amgen*, albeit expressed in terms applicable to a contract rather than a patent and, for that reason and perhaps importantly, addressed to a situation in which there is a dispute between two (or more) parties each of whom has voluntarily entered into the contract and, generally, negotiated the terms prior to agreeing them.

However, the main issue in *Rainy Sky* was how to resolve a dispute between the parties as to the meaning, in particular the role played by "business common sense" in that resolution. As Lord Clarke recorded at paragraph 21, *"the language used by the parties will often have more than one potential meaning. I would accept ... that the exercise of construction is essentially on unitary exercise in which the court must consider the language used and ascertain what a reasonable person ... would have understood the parties to have meant. ... If there are two possible constructions, the court is entitled to prefer the construction which is consistent with business common sense and reject the other."*

He went on to say, in paragraphs 23 to 24, that *"where the parties have used unambiguous language, the court must apply it. ... Where [a] result, though improbably, flowed from the unambiguous language of the clause, [the party relying on that construction] succeeded, whereas where they did not, they failed... It [is] necessary when construing a commercial document to strive to attribute to it a meaning which accords with business common sense"*. At paragraphs 29-30 he went on to quote with approval a judgment by Longmore LJ which stated that *"If a clause is capable of two meanings ... it is quite possible that neither meaning will flout common sense. In such circumstances, it is much more appropriate to adopt the more, rather than the less, commercial construction."*

Rainy Sky, approved by Wood cited in *Actavis*, does not provide a great deal of illumination for how the exercise of "normal interpretation" is to be carried out for a patent's claim. One could analogise the discussion of a business common sense to technical common sense but, generally, the dispute over construction in a patent case is not one in which either construction put forward is necessarily more or less "sensible".

There is room for the view that the exercise of "normal interpretation" should be carried out in a

similar way to the exercise of purposive construction used hitherto: seeking to determine what the relevant reader would understand the authors to have meant against the relevant background (common general knowledge in the case of the patent). However, in the context of Lord Neuberger in *Actavis* expressly departing from the *Kirin Amgen* decision in respect of how to determine the extent of protection and choosing to cite *Wood* instead of any patent case, it must be questioned whether this point of view is sustainable. The Supreme Court surely intended to do more than merely "add on" a second mandatory step of considering whether a variant was materially different to the previous exercise of purposive construction: if that was what was intended, surely the Court would have said so plainly. As is discussed further below, the Court's view of the "normal interpretation" of the relevant part of Eli Lilly's patent did not appear to involve much more than looking at the words of the claim.

We must await further guidance from the Patents Court as to how "normal interpretation" is to be performed and in particular the extent to which it differs from or is similar to the exercise of purposive construction English patent lawyers are familiar with. For now, a few comments as to the similarities and differences between the construction of contracts and patents will be made.

First, the principles used for construing contracts have arisen in a context where the contract is negotiated between the parties who later dispute its meaning. Thus while the parties' subjective intentions are ignored, those parties have (at least in principle) both been responsible for drafting the relevant clause(s) in dispute. In contrast, a patent is a unilateral statement made by the patentee and the words of the claim are of the patentees' choosing – perhaps with the occasional hint or suggestion by the relevant patent office. As Lord Diplock recognised in *Catnic*, *"a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. "skilled in the art"), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly."* The other party in patent litigation (the party seeking revocation or allegedly infringing) has had no influence on the words used.

Second, in contractual construction there are certain well-recognised principles that have not to

date had direct parallel in patent construction. For example, the rule of *contra preferendum*, while of limited application, provides for instruments to be construed against their maker where there is a doubt or ambiguity that cannot be resolved by normal principles of construction. Chitty states that the application of this rule to negotiated contracts has been "doubted" but, as noted above, a patent is not a negotiated instrument and certainly not one negotiated by the parties to a dispute concerning it. Could a rule of *contra preferendum* apply? If so, how might this be done in practice when most cases before the Courts involve at least some degree of "squeeze" between a broader extent of the claim favouring infringement and a narrower extent of claim favouring validity?¹

Third, there are some specific principles of purposive patent construction that do not appear to have a parallel in contractual interpretation. Thus, for example, the acceptance by the Court of Appeal in *Virgin* that the skilled person should be taken to know enough about the patent system to take account of divisionals does not at first sight have a parallel with any part of contractual construction. It may be the case that this falls within the scope of the "background information" that the person interpreting the document is taken to have. Indeed, in effect this is why Jacob LJ held that the skilled person should have this knowledge; however, he did so expressly on the understanding that he was following the principle from *Kirin Amgen*.

Fourth, there are certain principles of purposive patent construction that do have a parallel in contractual construction. Thus, for example, the principle that one cannot "strike out" part of a claim merely because certain words appear unnecessary, recognised in *STEP v Emson* [1993] RPC 513. In *Rainy Sky* at paragraph 23 Lord Clarke approved a judgment of Hoffmann LJ that stated that "*this robust declaration [i.e. a quotation from Lord Diplock concerning "yielding to common sense"] does not, however, mean that one can rewrite the language which the parties have used in order to make the contract conform to business common sense...*"

Fifth, there are reasons why a patentee may choose to frame his claims in a certain way that have no direct parallel with how a contract is framed – and may not be discernible from reading the document. Thus, for example, the patentee may have framed his claims more narrowly in order to get the patent granted more easily or more quickly. The patentee may have framed his claims in a certain way because he or she also had in prosecution a divisional application with a different claim set. The patentee may have been cognisant of some prior art not cited by the examiner, or of some perceived common general knowledge, which caused him or her to frame the claims more narrowly.

Sixth, if in paragraph 54 the Court did intend to limit "normal interpretation" to an exercise carried out without reference to any facts or evidence, this would be in contrast to the exercise carried out in contractual interpretation where evidence is admissible as to the background facts against which the contract is to be construed. Moreover, it would appear to draw this exercise much closer to that of determining the "literal meaning".

Seventh, contractual interpretation is the only exercise required to determine the extent of the parties' express obligations and, from them, whether any such obligation has been breached, requires enforcement, etc. There is no parallel for the second of Lord Neuberger's "issues" in *Actavis* concerning variants for any particular obligation. At best, some parallel with implied terms could be drawn.

Literal meaning

In paragraph 42 of *Actavis* the Supreme Court contrasts "*literalism*" with purposive construction when discussing *Kirin Amgen*. No further explanation is given as to what is to be done in order to find the "*literal meaning*" and we must presume that this requires, as Lord Hoffmann described it in *Kirin Amgen* at paragraph 64, the "*conventional rules for the use of language, such as one finds in a dictionary or grammar*". Lord Hoffmann there was elucidating his earlier judgment in *Improver* where the Protocol questions were to be used as an aid to interpretation where an alleged infringement was outside the "literal" meaning of the claim. In that sense it was part of the single overall exercise of purposive construction and thus there might be no need to define a "literal meaning" per se: the parties would be arguing about whether a certain word or phrase could cover something that prima facie was

¹ Other authors have commented on the validity consequences of *Actavis v Eli Lilly*; see, for example, *Kelleher, Actavis v Eli Lilly – Are we clear now? (2017)* available at <https://www.twobirds.com/en/news/articles/2017/uk/actavis-v-eli-lilly-are-we-clear-now>

not covered by its literal meaning. It would appear from *Actavis*, however that, at least in principle, a literal meaning must be determined in order to carry out the second part of the required analysis, whether an alleged variant is inside or outside the extent of protection.

It would appear that, now, the literal meaning must be established expressly, in order to answer the question of whether any variant is material. In practice it will be difficult to construe a claim wholly literally, not least since the claim must also be construed in context as a matter of "normal interpretation". However, it must be considered that in many cases there may be only a few words in the claim that will give rise to any substantial difference of meaning.

A further question arises over the use of technical words in a claim: these will of course be frequently found. A technical word may often have a different meaning literally, i.e. in a dictionary, to that meant in the relevant art. May this be taken into account as a matter of determining the literal meaning, provided the alternative meaning is one of general application in the art rather than one that arises from the context of the patent? In some cases, of course, a good dictionary may include such a meaning as an alternative in any event.

Invention

The idea of identifying the "invention" or "inventive concept" of a patent is not new: it features, for example, in the conventional approach to assessing obviousness set out in *Pozzoli*

However, hitherto the identification of the invention or inventive concept has been bound up with the exercise of purposive construction. Thus in *Pozzoli*, Jacob LJ stated:

"Identify the inventive concept of the claim in question or if that cannot readily be done, construe it..."

In *Conor v Angiotech* [2008] RPC 28, Lord Hoffmann stated at paragraph 19 that

"In my opinion, however, the invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description".

This flowed *inter alia* from s. 125 Patents Act 1977 and, of course, from purposive construction. Thus, in *Conor* the concept of the "inventive concept" was coterminous with the scope of the claim as determined by purposive construction.

In applying their new principle regarding variants to the facts, the Supreme Court in *Actavis* considered, in paragraphs 70 to 74, the kinds of arguments that could have been raised as a matter of purposive construction: indeed, they reviewed the arguments made in the Courts below where, of course, the arguments had been based on purposive construction.

Discussion

In *Actavis* the Supreme Court provides little guidance on how each of these three exercises in construction should be performed. Indeed, it does not explain the extent to which any of them are intended to be similar or dissimilar: conceivably the "normal interpretation" of the claim could also identify the "inventive concept". If this were the case, however, one would have expected the Supreme Court to have explained this, or at least used the same terminology. Looking at how the Supreme Court applied the principles it had set out to the facts, it seems clear that the "normal interpretation" of the claim does not also identify the inventive concept. The Court stated that *"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 within the expression, "pemetrexed disodium" in claim 1 of the Patent"*. Here the Supreme Court appears to treat "normal interpretation" as closer to the "literal meaning" than to the identification of the "inventive concept" which it goes on to examine, perhaps supporting an argument that the "normal interpretation" is to be determined without recourse to the facts or expert evidence (see discussion of paragraph 54, above).

However, the Supreme Court did not expressly consider the literal meaning of the claims. In considering infringement by way of a variant it went immediately to consider whether the variant achieved substantially the same result as the invention in substantially the same way. In doing so it did not expressly identify the "invention" of Eli Lilly's patent but an inference can be drawn reading the judgment in context as a whole as to what the "invention" was taken to be.

In paragraph 7 the Court stated, after beginning to review the patent in suit, that

"Although one might have thought that the actual invention should have been characterised as a disclosure that pemetrexed could be administered safely if it was combined in a medicament with vitamin B12, the claimed invention in the Patent is, as mentioned in para 4 above, the manufacture of such a medicament. This formulation was required by the then-prevailing law contained in article 52(4) of the European Patent Convention 1973 ("EPC 1973"), which prohibited from patentability any method of treatment of humans or animals. This led to inventions which otherwise might have been expected to be expressed as being new therapeutic treatments being cast as manufacturing claims."

The Court went on to quote various passages from the specification, relating to the use of an antifolate with vitamin B12. In all the quoted passages, pemetrexed disodium is either stated to be "the" antifolate or is provided as the sole example of the antifolate.

Ultimately, in applying the principles to the facts at paragraph 68 Lord Neuberger stated that:

"In my view, application in the present case of the three questions just identified results in the conclusion that the Actavis products infringe. So far as the first question is concerned, there can be no doubt but that those products work in the same way as the invention: they all ultimately involve a medicament containing the pemetrexed anion and vitamin B12. Thus, they achieve substantially the same result in substantially the same way as the invention."

Thus it would appear that the Court viewed the invention as the delivery of the pemetrexed anion with vitamin B12 notwithstanding that the passages the Court had quoted from the specification all refer to pemetrexed disodium, i.e. a pemetrexed salt containing putative sodium cations and pemetrexed anions. The Court does not explain how or why it generalised the inventive concept at this level of detail, but an inference may be made: in paragraph 6 the Court discusses the aqueous dissociation of the salt and states that *"it is the pemetrexed anion which is of interest..."*. This would appear to be on the basis that it is the pemetrexed anion which was delivering the desired therapeutic effect (see paragraph 3), alongside the vitamin B12 which alleviated side effects. It would thus appear that the

Court considered that the sodium counter-ions were not part of the inventive concept.

Conclusion

The Supreme Court's decision leaves open how the principles set out should be applied in practice. In particular, the differences between the three exercises of construction the Court identified are unclear, as are which factors the Courts should take into account for each exercise. The Court relies on many of the same facts and arguments in reaching its overall conclusion as would have been deployed for an exercise of purposive construction but does not make clear why certain such facts and arguments are relevant to one of the new principles as opposed to one of the other new principles. By considering how the Supreme Court applied the new principles to the facts before it, it would appear that "normal interpretation" and the "literal meaning" may be very similar.

Contact

Christopher de Mauny
Senior Associate, IP

Tel: +44 (0) 20 7415 6000
Christopher.deMauny@twobirds.com



twobirds.com

Aarhus & Abu Dhabi & Beijing & Bratislava & Brussels & Budapest & Copenhagen & Dubai & Dusseldorf & Frankfurt & The Hague & Hamburg & Helsinki & Hong Kong & London & Luxembourg & Lyon & Madrid & Milan & Munich & Paris & Prague & Rome & Shanghai & Singapore & Stockholm & Sydney & Warsaw

Bird & Bird is an international legal practice comprising Bird & Bird LLP and its affiliated and associated businesses.

Bird & Bird LLP is a limited liability partnership, registered in England and Wales with registered number OC340318 and is authorised and regulated by the Solicitors Regulation Authority. Its registered office and principal place of business is at 12 New Fetter Lane, London EC4A 1JP. A list of members of Bird & Bird LLP and of any non-members who are designated as partners, and of their respective professional qualifications, is open to inspection at that address.

33656784.1