The scope of protection of patent claims in Europe and the UPC

Paul England*

The author

- Paul England is a senior associate and PSL at Taylor Wessing. He is the editor of the forthcoming book *UPC: A Practitioners' Guide to the New European Patent Litigation System* (Hart Publishing, 2016) and the consulting editor of *Intellectual Property in the Life Sciences* (Globe Law and Business, 2015).

This article

- Article 69 of the European Patent Convention links the scope of protection conferred by a patent to its claims. The Protocol on Interpretation of Article 69 EPC clarifies that courts should interpret the claims adopting an approach that combines a fair protection for the patentee with a reasonable degree of certainty for third parties. In this perspective, the claims should not be interpreted strictly, nor should they be treated as mere guidelines.
- National courts have taken different paths towards the application of Article 69 EPC. This article examines the approaches taken by courts in the UK, Germany, France and the Netherlands, highlighting their similarities and differences and examining the outcome of two parallel cases.
- The UPC will need to build a coherent approach, seeking common grounds between the various national approaches and identifying appropriate solutions for areas of divergence.

Article 69 of the European Patent Convention (EPC) states that the extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims, using the description and the drawings to interpret the claims. Article 69 is to be interpreted according to the Protocol on Interpretation of Article 69 of the EPC (the 'Protocol'). Article 1 of the Protocol states:

> Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European Patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.

The Protocol requires a middle way to be found between the two extreme approaches that it describes. These extremes are based on different philosophies: the first adopts a literal approach where the words used in the patent are restricted to their literal meaning, as interpreted by the patent and surrounding circumstances (contextual), or alternatively 'the meanings assigned to the words by a dictionary and to the syntax by a grammar'[1] (acontextual). According to this philosophy, the words used by the patent draftsman are intended to mark out the claims of the patent precisely. This approach provides a reasonable degree of certainty for third parties, as required by the Protocol, but also risks an injustice to the patentee if something he thought he had claimed is excluded by a strict and unforgiving construction of the language of the claim.

The second approach is more liberal. According to this approach, the wording of the claims is only taken as a guideline, to be read together with the specification and drawings. It aims to identify the 'inventive concept' that the patent protects. This approach will provide a fair protection for the patentee, but it leaves third parties in doubt as to the activities that may infringe.

The difficulty that has been encountered in applying the Protocol is finding the middle way between these two approaches:

> Like the hippopotamus, the median position is difficult to define but the hope is that the man skilled in the art will recognise it when he sees it.[2]

* Email: P.England@taylorwessing.com.

1 H. Laddie, 'Kirin Amgen – the end of equivalents in England?' (2009) 40(1) IIC 3.

2 Ibid, 30.

doi:10.1093/jiplp/jpw116

A particular concern with the literal approach is that it is likely to exclude immaterial variants—so-called 'equivalents'.[3] An equivalent is generally understood to be a small variation to a product or process, which enables it to effectively use the patented inventive concept, without literally infringing the language of the patent claim—the product or process lies outside the claim, strictly construed. To expressly address equivalents, the Protocol was revised to add Article 2[4]:

> [. . .] 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.

How 'due account' is given to immaterial variants in a clear and structured way goes to the central issue of how patent scope should be determined.

With the Unified Patent Court (UPC) expected to come into force in 2017, this article examines the approach taken to these issues in four jurisdictions experienced in patent litigation—France, Germany, the Netherlands and the UK—and addresses whether there is any common ground shared between them that might guide the UPC on this issue.

France

General principles

Article 69 of the EPC, as amended by the EPC 2000, is codified in French law by Article L.613-2 of the Intellectual Property Code. The doctrine of equivalents is not codified but has been widely adopted and understood by the courts to mean that the scope of protection of claims includes variants that have the same function and achieve the same result as those embodiments within the express language of the claim.

Whether the doctrine of equivalents applies depends on whether the claims in question are drafted broadly to cover general means (*moyens généreaux*) or narrowly to cover particular means (*moyens particuliers*). For the doctrine to apply to *moyens particuliers*, the court must first assess the function of that means to establish whether it is new. If it is new, a variant that has the same function and achieves the same result will be equivalent. On the other hand, if the means is already known to the art, the scope of protection is limited to the means presented in the claim. An example is the claim to detect HIV with a particular DNA fragment probe, using a specific means of DNA/RNA hybridization.[5] The function of this specific means was known to the art at the priority date. It followed that the claim could not be interpreted as protecting other methods of hybridization that are not claimed but achieve the same function.

Role of the prosecution file

In the French approach to the scope of protection of claims, the prosecution file will form part of the general factual context by which scope is determined. It has an additional significance for claims that were narrowed during prosecution, especially when the claims were narrowed in order to secure the grant of the disputed patent. In these cases, a non-ambiguous claim with narrow scope cannot be given a general scope through interpretation, in particular when the patentee has been forced, in order to distinguish the invention from the prior art, to limit the scope of the claim in the context of the granting process.[6]

The UK

General principles

The specific mention of equivalents in Article 2 of the Protocol was a source of interest in the UK because a 'doctrine of equivalents' had never been considered part of English law. However, even before the provision came into force in the UK, the House of Lords held in *Kirin-Amgen* that Article 69 EPC 'shuts the door on any doctrine which extends protection outside the claims'.[7] Thus, any determination of patent scope must be limited by the extent of the claims and no further[8]:

> Although art. 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 art. 2 added to the Protocol by the Munich Act revising the EPC [. . .]

Since *Kirin-Amgen*, the Court of Appeal has sought to organize the principles laid down by the House of Lords in a list of eleven guidelines.[9] The ninth item on

3 For the purposes of this paper, the terms are used interchangeably.

4 Munich Amendment Act to the European Patent Convention dated 29 November 2000.

5 Cour de Cassation, Appeal S 09-15668 *Institut Pasteur v Chiron Healthcare* of 23 November 2010. Compare Cour de Cassation, Appeal No. 06-17915 *B2M Industries v Acome* of 20 November 2007, in which a means was found to be equivalent to a novel integer because it performed the same function and produced the same result as that claimed in the patent.

6 Cour d'Appel, Paris, Case No. 08/00882 *Hewlett Packard GmbH v Agilent Technologies Deutschland GmbH* of 27 January 2010.

7 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd.* [2004] UKHL 46; [2005] RPC 9.

8 Ibid, para 49.

9 The Court of Appeal modified these principles to take into account the amended language of the EPC 2000.

the list expressly states that there is no doctrine of equivalents. However, the Court of Appeal has more recently stated that the fact that English courts do not apply a general doctrine of equivalence to the const ruction of patent claims does not mean that the existence of equivalents which have no material effect on the way the invention works has no bearing on the proper, purposive interpretation of a patent claim. Instead, the court stated, it has long been the law that such equivalents form part of the background of facts, known to the skilled reader, which would affect what he understands the claim to mean.[10] The Court of Appeal went on to say that English law recognizes the impact of equivalents in the Protocol Questions,[11] which at the time had been little considered for ten years. The Protocol Questions are as follows:

> If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim ('a variant') was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:

1. Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?
2. Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes?
3. Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim. On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class.

Therefore, while the UK courts do not recognize a doctrine of equivalents as such, there remains the possibility, in rare cases, that a claim may be construed to include an immaterial variant.

Role of the prosecution file

Although it is not inadmissible, the courts are skeptical about the application of evidence from the prosecution file when determining the scope of protection of a patent. The Court of Appeal, in *Actavis*,[12] provided two sets of considerations that explain this scepticism:

1. using evidence from the prosecution file assumes that the skilled reader will always read the prosecution history even when it is recognized to have limited value, and
2. more importantly, cases in which the story told by the prosecution history will assist the court in preventing abuse of the system will be very rare. Unless the acceptance of a restriction in a claim is to operate as an estoppel against an argument for wider claims (rejected, for example, in *Bristol Myers*,[13] at least at first instance), there will be an issue about whether the applicant *needed* to accept the restriction, regardless of whether they did so. This limits the light that the prosecution history can shed on construction.

The Court of Appeal, therefore, did not regard it useful to go to the prosecution history in order to discover whether the patentee accepted a restriction to their claim. It is open to the patentee to say that the apparent concession made in prosecution was not actually necessary and wrongly made. However, the court left open the possibility that, should this argument not be open to the patentee, then the prosecution history may have interpretative value.

Germany

General principles

The principles developed by the Federal Supreme Court of Germany (Bundesgerichtshof) place the claims as the decisive basis for determining claim construction—the extent of protection must align with the claims.[14] However, since claims must include equivalents, further to Article 2 of the Protocol, it is not possible to provide the optimum of certainty for third parties in the way that would be provided by literal attention to the language of the claims. Therefore, it is necessary to adjust the extent of protection achieving an appropriate scope of protection of claims. The objective person skilled in the art must, against the background of his skills and knowledge, determine what in his view is the scope of

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

11 *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181.

12 *Actavis* (n 10).

13 *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc.* [1999] RPC 253.

14 P. Meier-Beck, 'The scope of protection – the test for determining equivalence' (2005) 36(3) ICC 339.

protection. In simple terms, this scope extends to those variants that, having regard to the patent claim, are obvious to a person skilled in the art.[15]

Whether the variant is obvious is determined according to the approach exemplified by *Schneidmesser I*.[16] This requires a positive answer to be given to each of the following three steps (sometimes referred to as the '*Schneidmesser* Questions')[17]:

1. Does the modified embodiment solve the problem underlying the invention with means that have objectively the same technical effect?
2. Was the person skilled in the art, using his specialist knowledge, able to find the variant at the priority date as having the same effect?
3. Are the considerations which the skilled person takes into account for the variant in the light of the meaning of the invention close enough to the considerations taken into account for the literal solution protected by the claims, such that the skilled person will consider the variant as a solution which is equal/equivalent to the literal one.[18]

For those rare cases in which a positive answer to the first three questions extends the scope of protection to a variant which is obvious or lacks novelty with regard to the prior art, a fourth question (the '*Formstein*[19] objection') is applied—this must be answered in the negative in order to guard against over-extending the scope of the claim:

4. Does the variant, having regard to the state of the art, lack novelty or is the variant obvious to a person skilled in the art?

It has been noted that the *Schneidmesser* Questions resemble the UK Protocol Questions,[20] in particular as regards the similarity of the second step to the second Protocol Question:

> [...] at least if we understand the word 'obvious' in the Improver test as we understand it in Art. 56 EPC, i.e. meaning that no inventive step is needed. For, just like applying Art. 56, we have to exclude those cases where an inventive step is necessary to find the modified means as having the same effect.[21]

The German courts have placed limitations on the doctrine of equivalents. The Bundesgerichtshof, in *Okklusionsvorrichtung*/'occlusion device'[22] and in *Diglycidverbindung*/'diglycidyl compounds',[23] strengthened the applicant's responsibility to clearly formulate the patent claims and defined tighter requirements for patent infringement under the doctrine of equivalence. In particular, the Bundesgerichtshof pointed out that, in case of contradictions between the claim language and the patent description, in particular where the claim language specifically selects only one embodiment out of several embodiments described in the patent specification, the person skilled in the art will consider this selection when assessing equivalence under *Schneidmesser* Question 3. Hence, whilst Germany is considered to have a doctrine of equivalence, it is a restricted one. However, the above approach should be contrasted with the Federal Supreme Court in the pemetrexed case (*Eli Lilly v Actavis, 14 June 2016) where it was not apparent on the facts that a specific selection had been made.

Role of the prosecution file

In Germany, it is not permitted to use the prosecution file as a means to construe the scope of protection of claims.

The Netherlands

General principles

Historically, in the Netherlands, the scope of claims was determined following the approach set out by the Supreme Court (Hoge Raad) in *Philips v Tasseron*.[24] Here, the Hoge Raad held that the scope of protection of a patent must be based on the 'essence of the invention' ('het wezen van de vitvinding'). This approach allowed the scope of protection of a claim to be broader than the wording of the claim itself. The effect was to

15 Ibid, 341.

16 Indeed, the decision 'Schneidmesser I' is only one of a series of Bundesgerichtshof decisions that were delivered at the same time and that identically phrased the questions. The decisions are 'Kunststoffrohrteil' (GRUR 2002, 511), 'Schneidmesser I' (GRUR 2002, 515), 'Schneidmesser II' (GRUR 2002, 519), 'Custodiol I' (GRUR 2002, 523) and 'Custodiol II' (GRUR 2002, 527). 'Schneidmesser I' is usually (inter alia by judges P. Meier-Beck and K. Grabinski) regarded as the lead decision.

17 See e.g. P. Meier-Beck, GRUR 2003, 907 and K. Grabinski, GRUR 2006, 716.

18 *Schneidmesser 1* as translated into English by P. Meyer in F. Van Helsen et al., 'Europe's courts converge on non-literal infringement' (*Managing Intellectual Property*, Life Sciences Focus, Supplement, 2005); P. Meier-Beck, ibid, at 343 offers a different translation: '[a]re the considerations that the person skilled in the art had to apply oriented to the technical teaching of the patent claim in such a way that the person skilled in the art took the variant into account as being an equivalent solution?'

19 Decision 98 BGHZ 12, 1986 GRUR 803, 18 IIC 795 (1987) – *Formstein*.

20 The reason for the similarities is that, in formulating this approach, the German court was to some extent influenced by the English cases of *Catnic Components Ltd v Hill & Smith Ltd* [1981] FSR 60 and *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181, and was consciously making a step towards an approach concerned as much with claim language as with pure inventive concept.

21 P. Meier-Beck (n 14) 342 and 343.

22 GRUR 2011, 701 extracts published in English translation in IIC 2011, 851

23 GRUR 2012, 45.

24 20 June 1930, (NJ 1930/1217).

make it difficult for third parties to rely on the wording of the claims to know whether they were working within their scope of protection and therefore infringing. Despite the introduction of the EPC and Article 69 and the Protocol, the Dutch courts remained reluctant to move away from placing the essence of the invention at the heart of their method of assessing the scope of protection.[25] This changed, only to a limited extent, in *Ciba-Geigy vs Oté Optics*,[26] in which the Hoge Raad shifted its emphasis from the essence of the invention to the 'inventive concept behind the wording of the claims' ('de achter de woorden van de conclusies liggende uitvindingsgedachte' Four factors, according to the Hoge Raad, must be used to assess the scope of protection:

1. in interpreting the terms of the claims, the court is to determine the essence of the invention; in other words, consider the inventive concept behind the wording of the claims;
2. this interpretation then needs to be corrected to give a reasonable degree of certainty for third parties, which may sometimes justify a restricted, literal interpretation of the wording of the claims;
3. the skilled person may—with restraint—use the prosecution history file for the purpose of claim interpretation;
4. all other circumstances of the case are to be taken into account, including the possible breakthrough nature of the invention (justifying a broader scope). When considering factors 2 and 3, poor drafting of the patent may be construed to the patentee's disadvantage.[27]

This continues to be the approach of the Hoge Raad, although the court has more recently clarified that the essence of the invention is a 'viewpoint', rather than the 'starting point' by which scope of claims must be determined.[28] However, the decision in *Medinol*[29] demonstrates that this viewpoint may nonetheless be the dominant factor in the assessment. The essence of the invention, in the *Medinol* case, was the solution to the problem that out-of-phase stents shorten when expanded, which was not perceived as a problem for in-phase stents at the priority date. Therefore, the Hoge Raad held that the in-phase variant could not be included within the scope of the claim. The District Court of The Hague (Rechtbank den Haag) has since explained the Hoge Raad's reasoning in *Medinol* as follows:

> [T]he scope of protection of a European patent is established on the basis of the skilled person's perspective on the first [priority/filing] date in view of [...] aforementioned principles (also named the contextual interpretation). Equivalents already known at that moment will be involved in this interpretation. The question to be answered thereafter, whether a product or method should be considered infringing, takes, in principle, place on the basis of the scope of protection on the first date, as established by the contextual interpretation. The possibility of additional protection by equivalence will be limited, as equivalents known to the skilled person have already been involved in the contextual interpretation on the first date Such a possibility only seems to exist in case of equivalents which were not foreseeable at the first date, which can then be involved in the infringement question and, if appropriate, brought within the scope of protection.[30]

In practice, however, the lower courts have tended towards an approach that distinguishes literal infringement from non-literal infringement by equivalents.[31] To assess non-literal infringement, the courts use the 'function-way/means-result' test[32]—does the non-literal variant fulfil the same *function* as the patented one, by using similar *means*, leading to a similar *result*, or the insubstantial differences test (more easily applied to chemical and biochemical cases), which assesses whether the differences between the allegedly infringing article or process and the claim are material.[33] In applying these tests, the courts take care that any protection outside the literal wording of the claims does not go outside the invention (and as such the approach remains in line with the Hoge Raad case law). However, concerns about providing certainty for third parties have persisted and it has become rarer to see cases in which infringement is held on the basis of equivalence.

Role of the prosecution file

The Hoge Raad has held that third parties are entitled to assume that any limitations in the wording of a patent claim were intended by the patentee, if this is supported by the specification in the context of, among

25 *Meyn/Stork* (NJ 1989/506).

26 (NJ 1995/391) as discussed in Van Helsen (n 18).

27 The approach is clarified by the Hoge Raad in *Van Bentum/Kool* (NJ 2002/530) to say that the skilled person can only assume that the patentee has surrendered a part of the patent protection if there is a 'proper ground' to do so—see Van Helsen (n 18).

28 Hoge Raad: *Lely v Delaval*, 7 September 2007; *AGA v Occlutech*, 25 May 2012; *Medinol v Abbott*, 4 April 2014.

29 *Medinol v Abbott* (n 28).

30 *MBI Co. Ltd. v. Shimano Inc et al*, District Court The Hague, 18 June 2014, Case No. HA ZA 13-745.

31 Van Helsen (n 18).

32 Hoge Raad, *Dreizler v Remeha*, 13b January 1995, NJ 1995, 392.

33 For example, in assessing molecular variants—see Van Helsen (n 18).

other things, the prosecution file.[34] However, reasonable doubt must exist as to what the claims cover.[35] While a defendant may rely on the prosecution file in respect of scope of protection, the Dutch courts will only accept with reluctance arguments that are in favour of the patentee based on the prosecution file.

Case comparisons

The decisions of national courts in parallel actions allow some practical comparison between the approaches they take to the scope of claims, subject to evidential and other procedural differences. Two sets of parallel decisions from recent years are those in the litigation between Occlutech and AGA Medical concerning stent devices, and between Actavis and Eli Lilly concerning a combination therapy for tumour growth inhibition that includes pemetrexed disodium.

The Occlutech stent cases

In the parallel actions involving Occlutech and AGA Medical Corporation, the Dutch, German and English courts had to decide whether Occlutech's stent device for the occlusion of blood vessels and other body lumens infringed a patent owned by AGA Medical. The patented device used a metal fabric formed of braided metal strands, clamped at opposite ends of the device. Occlutech's device was also made from metal wire, but differed in that the metal strands were welded together at only one end.

Central to the infringement analysis in the English Patents Court[36] was the construction of the words 'clamps' and 'the strands at the opposite ends of the device'. The Court of Appeal[37] reviewed the authorities and reiterated that, while a patent specification operates as a contextual aid to construction, it is not necessarily determinative of the scope of the claims on its own. In particular, the court considered whether Occlutech devices achieved the same effect as the patented devices by equivalent means, so far as permitted by Kirin-Amgen.[38] The court held that there was no infringement, on the basis that the skilled person would understand the clamp—not welding—to be the primary and effective means of securing the strands of metal at their ends. It was also held that the words 'opposite' and 'clamps' would be understood as meaning that the device must be clamped at both opposite ends, not just one of them.

In the Dutch case, the doctrine of equivalence was also employed to argue that the means used to secure the meshes in both devices is equivalent. However, the Rechtbank den Haag, followed by the Court of Appeal of The Hague (Gerechtshof den Haag), held, like the English Patents Court, that the requirement that the devices be clamped at both ends was an essential element of the claim and that this could not be interpreted more broadly.

In the German case, the Düsseldorf Oberlandsgericht came to the opposite view.[39] Relying on a statement from the specification, it held that there was infringement, because the skilled addressee would understand that the function of the clamp was to hold together the ends of the metal strands, and that doing so at only one end fell within the embodiments of the invention. On appeal to the Bundesgerichtshof, the decision was overturned.[40] The upper court found that there was neither literal infringement nor infringement by equivalence. The Bundesgerichtshof held that the patent description is admissible as a guide to construction only in so far as it explains the claimed subject matter. The description must not be used to correct the language of the claim, for instances where there is an inconsistency between the claim and the description, infringing equivalent solutions must be based on the claim.

The pemetrexed cases

The UK patent

Actavis sought declarations that its proposed pemetrexed diacid, pemetrexed dipotassium and pemetrexed ditromethamine products would not infringe Lilly's European patent EP 1 313 508 (the '"'508 Patent'), which essentially claims the use of pemetrexed disodium in combination with vitamin B12 and, optionally, folic acid, for inhibiting tumour growth. The focus of the case was on the meaning of the expression 'pemetrexed disodium'—does the scope of the claim extend to pemetrexed dipotassium, pemetrexed diacid or pemetrexed ditromethamine?

In the English Patents Court,[41] there was no dispute that pemetrexed diacid is not pemetrexed disodium

34 *Meyn/Stork* (n 25).
Hoge Raad in *Ciba Geigy v. Oté Optics* (NJ 1995/391) and *Van Bentum/Kool* (NJ 2002/530).

36 [2009] EWHC 2013 (Ch).

37 [2010] EWCA Civ 702.

38 [2005] RPC 9.

39 OLG Düsseldorf, decision of 22.12.2008 – I-2 U 65/07.

40 *AGA Medical v Occlutech*, 10 May 2011, Case No. X ZR 16/09.

41 *Actavis UK Ltd & Ors v Eli Lilly & Company* [2014] EWHC 1511 (Pat). The finding of non-infringement by Arnold J in respect of the UK patent was later overturned by the Court of Appeal on unusual factual grounds: the drug in question was accompanied by instructions to reconstitute in saline (sodium chloride), thus forming pemetrexed disodium in solution.

according to its 'primary, literal or acontextual meaning'. The court used the Protocol Questions[42] to determine whether the alternative pemetrexed compounds could be deemed to be variants of the potassium compound.

As regards the first Protocol Question, the parties accepted that the difference between pemetrexed diacid, dipotassium and ditromethamine on one hand, and disodium, on the other, had no material effect. This is because from the point of view of the skilled oncologist, the active anti-cancer principle in an aqueous solution of pemetrexed disodium for intravenous admin istration is the pemetrexed anion, the source of which is immaterial. From the perspective of a chemist, pemetrexed diacid, dipotassium and ditromethamine are all pharmaceutically acceptable and sufficiently soluble.

Resolving the second Protocol Question depended on the meaning of 'the way in which the invention works', and the level of generality at which that is assessed. The problem is the same, the judge commented, if one asks whether the variant solves the problem underlying the invention by means that have the same technical effect. From the oncologist's perspective, it would be obvious that, provided the diacid yielded a sufficient concentration of pemetrexed anions in solution and did not introduce side effects, using the diacid would have no material effect on the invention. However, the evidence of the skilled chemist was that it did not know if there was no material effect until the alternative compound was tested. The chemist would not be confident of success before testing (in particular because of the potential toxicity of potassium given the quantities of pemetrexed required). This was far from the level of confidence required for an affirmative answer to the second Protocol Question.

As regards the third Protocol Question, it was necessary to consider overall which construction of the expression 'pemetrexed disodium' combined fair prote ction for the patentee and reasonable certainty for third parties under the Protocol. On this, there was nothing in the specification or the common general knowledge of the skilled team to suggest the expression 'pemetrexed disodium' meant anything other than its conventional sense.[43] The court held that the claim was limited to the use of pemetrexed. This would provide fair protection, without the risk of the '508 Patent being invalidated on the grounds of added matter and/or insufficiency. Construing the claim as extending to (at least) any form of pemetrexed which is pharmaceutically acceptable and sufficiently soluble would not provide a reasonable degree of certainty for third parties. Any other conclusion would fail to give effect to the Protocol and would be tantamount to treating the claims as a mere guideline.

The French patent

The pemetrexed case is unusual in that the issue of non-infringement of the French part of the '508 Patent was also decided by Arnold J in the English Patents Court. It is common ground in respect of the French validation that none of pemetrexed diacid, dipotassium and ditromethamine were within the scope of the claims of the patent on a literal interpretation. The issue was again whether, according to the French approach, these compounds were within the scope of the claims when applying the doctrine of equivalents. In Arnold J's judgment, they were not. This was for two main reasons:

(i) the doctrine of equivalents does not apply in a case of this kind, because pemetrexed disodium is a *moyen particulier*. The judge found that the function of pemetrexed disodium in inhibiting tumour growth was already known at the date of the patent. Therefore, the expression 'pemetrexed disodium' must be interpreted as being limited to the particular compound specified by that expression;

(ii) the prosecution history showed that the claims were deliberately limited to pemetrexed disodium in order to secure grant. In those circumstances,

This decision does not challenge the approach to determining scope of claim using the Protocol Questions adopted by the judge. At the time of writing, the case was subject to appeal to the Supreme Court.

42 The judge makes the observation that patentees resort to arguments about equivalents in three main classes of case: i) where, with the benefit of hindsight, it can be seen that the patent was unfortunately drafted, whether because of poor instructions from the inventor or poor drafting by his patent attorney or a combination of these things. The law recognizes that drafting patent claims is a difficult and imprecise art and that third parties should not be allowed to exploit infelicities of drafting where it is reasonably clear that those infelicities should not affect the scope of the claim. This is in order to provide 'fair protection for the patent proprietor'. However, the law also recognizes that there must be 'a reasonable degree of legal certainty for third parties'. The courts have to strike a balance in this regard; ii) where technology has moved on since the priority or filing date of the patent, the law is sympathetic to the proposition that third parties should not be able to avoid infringement merely by employing new technical means to implement the invention. However, the drafting of a claim may be inescapably tied to the old technology; and iii) where the patentee now regrets a decision taken during the course of prosecution of the patent application, whether by himself or by the examiner, and is trying to avoid the consequences of that decision. There is no reason why the law should be sympathetic to the patentee. Not only do applicants generally rely on skilled professional advice, but also they can appeal against adverse decisions of examiners during the course of prosecution if they consider that those decisions are wrong.

43 In this respect the judge was influenced by the prosecution history showing that the claims had been deliberately limited to pemetrexed disodium, although the Court of Appeal has since doubted whether such reliance on the prosecution file is permissible; see *Actavis* (n 10).

the judge held, it would not be appropriate to interpret the claims as having a broader scope.

The German patent

Lilly brought proceedings against Actavis for threatened infringement of the German designation of the patent in question before the Düsseldorf Regional Court (Landgericht).[44] Again, assessing whether pemetrexed dipotassium would fall within claims to the use of the disodium compound, the court first considered literal infringement. Neither the patent claim nor the patent description provided an indication to the skilled person that the term pemetrexed disodium encompassed the use of other pemetrexed compounds and so there could be no literal infringement.

As regards equivalent infringement, the court used the approach in *Schneidermesser*. In the first step, the court held at first instance that the use of pemetrexed dipotassium in the context of the combination therapy together with vitamin B12 has the same effect as the use of pemetrexed disodium—it solves the problem of the patent with modified, but objectively equal-acting, means. Differing from the English court, the Landgericht held, in the second step, that the skilled person would be able to find, without any inventive effort, that pemetrexed dipotassium is an alternative equal-acting means for pemetrexed disodium.

Under the third step, the court came to the conclusion that an equivalent infringement could not be ruled out merely because the '508 Patent specification only explicitly identifies pemetrexed disodium, but not other pemetrexed derivatives, in particular pemetrexed dipotassium; the skilled person would think that the substitution of pemetrexed disodium with pemetrexed dipotassium complies with the meaning of the teaching of the patent and that pemetrexed dipotassium thus constitutes an equal solution.

The finding of non-infringement at first instance was overturned by the Düsseldorf Court of Appeal (Oberlandesgericht).[45] This court emphasized that it does not suffice for the person skilled in the art to recognize a teaching as having technically equivalent effect to the teaching formulated in the claims, based on his expert knowledge. Instead, his assessment must focus on the claim—'orientation on the claim'. This requires that the claim not only forms the starting point in all its characteristics, but also the decisive basis for the considerations of the person skilled in the art. The first instance court had not considered that the patent in its entirety suggests to the skilled person that the applicant had consciously decided in favour of the use of pemetrexed disodium. If the technical teaching of the claim is taken seriously, there is no equivalent way of substituting the pemetrexed disodium taught with pemetrexed dipotassium, despite the fact that the invention could be successfully realized with either. In turn, the Federal Supreme Court has now overturned the Court of Appeal on the basis that because pemetrexed disodium is the only specific embodiment in the description, it cannot be said to have been deliberately selected in the claim. In the light of this, the case has been referred back to the Court of Appeal for re-examination.

Common ground for the UPC?

What common ground can the UPC judges draw from these national approaches to determining the scope of protection of the claims, to assist them when developing their own application of the Protocol?

Although parallel cases can be found in which the Dutch, French, German and UK courts have come to different decisions, the unanimous finding that there was no infringement in the *Occlutech* and pemetrexed cases suggests that the approaches taken in these jurisdictions are not far apart (currently subject to re-examination by the German appeal court). This can be seen by looking at the common principles that the systems share in their approaches to Article 69 and the Protocol.

The Hoge Raad test in *Ciba-Geigy*, whilst focused on the inventive concept itself, shares the characteristic of the English, French and German tests, as it allows determination of whether a third-party product or process is a variant of those within the scope of the claim. The Hoge Raad has been content to accept the use by the lower courts of function-way/means-result and insubstantial difference tests. This approach has the effect of defining the invention as a collection of variants with the same function-way/means-result in common. Similarly, in France, the underlying question is whether variants have the same function and achieve the same result as those claimed, with the exception that variations of means that were known at the priority date are not covered by the claim. In Germany, the *Formstein* objection ensures that variants that lack novelty or are obvious to a person skilled in the art are not included within the scope of protection of the patent. In the Netherlands, a variant can be included within the scope

44 LG Düsseldorf, 03.04.2014 - Az. 4b O 114/12. A jurisdictional challenge by Actavis, on the basis that the UK Court was first seized, was rejected. At the time of the Landgericht decision, the patent covering pemetrexed disodium had expired, but the active substance remained subject to a German SPC.

45 OLG Düsseldorf, 05.03.2015 - I-2 U 16/14.

of the claim only if it solves a problem that was known at the priority date of the patent.

The English and German tests are more complex in presentation, but at their heart there is the same analysis. In Germany, the question is: does the modified embodiment solve the problem underlying the invention with means that have objectively the same technical effect? This approach is concerned with the variant producing the same *result*, using basically similar *means*. In the UK, under the Protocol Questions, the question asked—does the variant have a material effect upon the way the invention works?—similarly links the variants to a common technical result.

Concern remains in the UK that the *Kirin-Amgen* approach is too unforgiving for patentees, as they cannot be expected to predict what future technological developments might be made, and should not pay the penalty for slips by the claims draftsman.[46] By contrast, the courts in many European jurisdictions have recognized the fallibility of patentees and have come to their aid when it is thought that defendants have taken the essence of the invention even if they have avoided the wording of the claims. Most European courts and experts agree that the scope of patent protection may, in some cases, be extended beyond the claims to equivalent solutions of the technical problem underlying the invention.

Some form of extension of the scope of protection is consistent not only with the wording of the legislation but also with the history of the negotiations that led to Article 69 EPC and the Protocol. However, in practice, despite the above recognition of a doctrine of equivalents, many courts have to a large degree moved towards an approach that places the claim language at the centre of the infringement analysis and in which the application of the doctrine of equivalents is something of a last resort to avoid an inequitable result. As the pemetrexed cases illustrate, the finding that a variant that lies outside the literal scope of a claim is nonetheless protected under the doctrine of equivalents, will be relatively rare in the national courts. The UPC, in which many of the judges will be drawn from the same national courts, might be expected to follow a similar approach.

An open question, at present, is the extent, if any, to which the UPC will be willing to take the prosecution file into consideration when determining the scope of the claims. In a system that commonly uses the doctrine of equivalents, use of the prosecution file can be important to prevent the unfair situation where a claim is construed to cover an embodiment that was deliberately excluded in prosecution. It might be expected that the prosecution file should feature less when the doctrine of equivalents is relied on rarely, although there is no clear relationship between the two in the countries described above: Germany, which can employ the doctrine of equivalents, does not rely on the prosecution file at all; France and the Netherlands appear more willing to take the prosecution file into consideration. In the UPC, it will take some time for the court to settle on the correct role of the prosecution file, and in the meantime decisions will be influenced by the national experience of the judges concerned. However, where it is relevant, parties can be expected to try to introduce the prosecution file into cases when asking the court to make decisions about the scope of patent claims.

46 Ibid, at 37.