Abstract—This article discusses the recent Supreme Court decision *Actavis v Eli Lilly*, which reformulates the UK’s approach to assessing patent claim infringement and introduces a doctrine of equivalents to the UK. Three arguments are made: (1) The decision brings UK law in convergence with that of other European jurisdictions, demonstrating a structurally flawed judicial attempt to prepare for the Unified Patent Court; (2) The UK’s recognition of doctrine equivalents facilitates overly broad patentee protection, particularly if one considers numerical claims and prosecution history; and (3) Overbroad patentee protection disincentivises innovation, undermining a key aim of the patent system.

1. Introduction

The recent UK Supreme Court decision *Actavis UK Ltd v Eli Lilly and Co* ¹ reformulates the UK courts’ approach to assessing patent claim infringement and introduces a doctrine of equivalents to the

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UK. In this article, *Actavis v Eli Lilly* will be examined from three perspectives: (1) European harmonisation, (2) breadth of patentee protection and (3) effect on innovation.

(1) The decision brings UK law on patent infringement in convergence with the law of other European jurisdictions. This is part of judicial efforts to align national approaches and thereby ease the transition to the Unified Patent Court (‘UPC’). However, harmonisation via national courts is structurally flawed due to the lack of a common and supreme authority. Therefore, it lacks the legal certainty and low litigation costs that the UPC may facilitate.

(2) The UK’s recognition of a doctrine of equivalents is problematic, since the doctrine facilitates overly broad patentee protection. *Actavis v Eli Lilly* may allow a patentee to draft a very narrow claim at the patenting stage and later claim a significantly larger monopoly at the infringement stage. The problems arising from overbroad patentee protection are most apparent when one considers *Actavis v Eli Lilly*’s effect on numerical claims and prosecution history.

(3) Overbroad patentee protection disincentivises innovation, thus undermining one of the key aims of the patent system. This possibility is exacerbated by the fact that under the current approach, even equivalents requiring an inventive step are capable of infringing patent claims.

2. A brief word on patents

Before engaging with the complexities of *Actavis v Eli Lilly*, a brief word on patents is useful. A patent is a time-limited monopoly

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2 A detailed description of patents is beyond the scope of this essay. For an introduction to the subject and an overview of the key issues, see William Cornish’s 2002 Clarendon Law Lectures, ‘Intellectual
granted in return for a novel and inventive technical subject matter disclosed in a patent specification comprising claims and a description. Patent disputes are usually resolved with reference to a person or team skilled in the art, i.e. a notional addressee with common general knowledge of the technical field in question. Harmonised prosecution pathways exist at national and European levels. An applicant can apply for a patent via her national office (for example the UK Intellectual Property Office) or through the European Patent Office (‘EPO’), which offers a bundle of national patents covering those European states in which the applicant seeks recognition of her monopoly. The scope of a patent’s monopoly is interpreted by the national courts via Article 69 of the European Patent Convention (‘EPC’).

3. An overview of Article 69 EPC and Actavis v Eli Lilly

Article 69 and its Protocol are key to understanding Actavis v Eli Lilly. The provision states that the extent of European patent protection is determined by the claims, which are interpreted using the description and drawings. Article 1 of the Protocol on the Interpretation of Article 69 (‘the Protocol’) elaborates further that the extent of protection is not confined to the ‘strict, literal


4 Article 69 EPC.
meaning of the wording of the claims’. Nonetheless, the claims are not to serve as a mere ‘guideline’ either. Instead, Article 69 ‘is to be interpreted 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.’ Article 69 therefore embodies a compromise between what have been termed the ‘fence post’ and ‘sign post’ approaches. The ‘fence post’ approach marks the outer limits of the patentee’s monopoly, while the ‘sign-post’ approach indicates, but does not determine, the monopoly’s scope.

More controversially, Article 2 of the Protocol states that ‘due account shall be taken of any element which is equivalent to that specified in the claims’ when assessing the patent’s scope of protection. This provision was adopted with the aim of furthering a harmonised European approach to the treatment of equivalents. The term equivalents refers to variants of protected inventions that still fall within the scope of the patent. The notion is illustrated well by the facts of Catnic Components Ltd v Hill & Smith Components Ltd. In this case, a patent directed to a builders’ lintel specifying that the plates should ‘extend vertically’ was infringed by lintels with plates 6° and 8° off the vertical. The infringer had drawn on the patentee’s observation that the plates

5 Article 1 (General Principles) of the Protocol on the Interpretation of Article 69 EPC.
6 Ibid.
8 Ibid.
9 Article 2 (Equivalents) of the Protocol on the Interpretation of Article 69 EPC.
10 Basic Proposal for Revision of the EPC 59.
12 Ibid 188 line 29.
13 Ibid 244 lines 26-29.
bear the greatest load when vertical. Therefore, the infringer produced lintels that were roughly vertical and could still bear heavy loads. In recognising that patents should be given a ‘purposive construction’, 14 Catnic demonstrates that patent claims, which are supposed to set out the patentee’s monopoly, should not be construed too rigidly upon interpretation. Indeed, Lord Hoffmann, in Kirin-Amgen Inc v Hoechst Marion Roussel Ltd, compared the approach in Catnic with that used to interpret commercial contracts, frequently also referred to as purposive construction. 15

Actavis v Eli Lilly centred on the chemical pemetrexed, an antifolate which inhibits cancerous tumour growth. However, if taken on its own, the chemical carries potentially lethal side effects. Lilly discovered that the side effects can be largely avoided if pemetrexed disodium is administered with vitamin B12. They subsequently applied for a patent claiming the manufacture of this new medicament. The specification contained both general statements about antifolates and references to pemetrexed disodium in particular. 16 During prosecution at the EPO, the claims were narrowed to pemetrexed disodium. 17 Later, Actavis proposed generic products involving pemetrexed compounds combined with vitamin B12 for cancer treatment but using the variants pemetrexed dipotassium or pemetrexed ditromethamine (i.e. compounds not expressly referred to in Lilly’s patent claims). Delivering the unanimous judgment, Lord Neuberger held that Actavis’ proposed products would directly infringe Lilly’s patent in the UK, France, Italy and Spain. 18 In doing so, Lord Neuberger set out what the Court of Appeal has recently termed a ‘markedly

14 ibid 243 lines 3-5.
15 Kirin-Amgen (n 7) [34].
16 Actavis v Eli Lilly (n 1) [17].
17 ibid [80].
18 ibid [112].
different’\textsuperscript{19} approach to infringement than that put forth by Lord Hoffmann in the earlier House of Lords decision \textit{Kirin-Amgen}.\textsuperscript{20} Lord Neuberger held in \textit{Actavis v Eli Lilly} that infringement should now be approached via two questions: \textsuperscript{21}

1. Does the variant infringe any of the claims as a matter of normal interpretation; and, if not

2. Does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

Question 1 raises the issue of interpretation, whereas question 2, which would reach so-called equivalents, must be answered with reference to facts and expert evidence. Lord Neuberger argued that Lord Hoffmann had conflated these separate issues in \textit{Kirin-Amgen}, treating them incorrectly as a single question of interpretation.\textsuperscript{22} Furthermore, Lord Neuberger opined that the Protocol questions formulated by Hoffmann J (as he then was) in the 1990 judgment \textit{Improver Corp v Remington Consumer Products Ltd}\textsuperscript{23} are helpful in assessing question 2, but only if reformulated. Thus, the Protocol questions now read:\textsuperscript{24}

1. 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, i.e. the inventive concept revealed by the patent?

\textsuperscript{19} \textit{Icescape Ltd v Ice-World International} [2018] EWCA Civ 2219 [59].

\textsuperscript{20} \textit{Kirin-Amgen} (n 7).

\textsuperscript{21} \textit{Actavis v Eli Lilly} (n 1) [54].

\textsuperscript{22} ibid [55].

\textsuperscript{23} \textit{Improver Corp v Remington Consumer Products Ltd} [1990] FSR 181.

\textsuperscript{24} \textit{Actavis v Eli Lilly} (n 1) [66].
2. 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?

3. 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?

There is an important shift between the original Improver Corp formulation of the Protocol questions and the Actavis v Eli Lilly approach. In Improver Corp itself, the Protocol questions led Hoffmann J to conclude that a patent for an epilator which worked by trapping hairs in a rotating coiled helical spring was not infringed by an epilator that used a slotted rubber rod to achieve the same effect. In light of the new approach, Lord Neuberger has suggested extra-judicially that the case may have been decided differently today. This is because the slotted rubber rod epilator would now fall under Lord Neuberger’s second question, namely whether the variant infringes because it varies from the invention (the rotating coiled helical spring epilator) in an immaterial way.

Actavis v Eli Lilly also establishes a ‘sceptical, but not absolutist’ approach to correspondence between the patent applicant and the patent examiner during the examination process.

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25 See Improver Corp (n 23) 7 for the original Protocol questions.
26 ibid 12.
28 Actavis v Eli Lilly (n 1) [87].
– in other words the prosecution history. In *Actavis v Eli Lilly* itself, the correspondence revealed that Lilly’s claims were narrowed from antifolates to pemetrexed and finally to pemetrexed disodium, 29 but Lord Neuberger considered this irrelevant to his finding of direct infringement. 30 The prosecution history is, however, relevant in two scenarios: 31 first, if the point in question is truly unclear when confined to the specification and claims of a patent, and the file unambiguously resolves the point; second, if it would be contrary to the public interest to ignore the file’s contents.

4. European harmonisation

A. Judicial alignment

*Actavis v Eli Lilly* signals the UK’s broad alignment with a Continental European approach to Article 2 of the Protocol, as seen through a comparison with Germany, the Netherlands, Italy 32 and Switzerland. Lord Neuberger explicitly discussed the first three jurisdictions in his judgment, and although Switzerland was not mentioned, it is relevant as an EPC state that has recently followed the UK’s ruling in *Actavis v Eli Lilly*.

The German Federal Court of Justice (Bundesgerichtshof, or ‘BGH’) set out its approach to equivalents in *Schneidmesser I* 33, citing the UK decision *Improve Corp* as an

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29 ibid [76]-[80].
30 ibid [89].
31 ibid [88].
32 Lord Neuberger discusses these three jurisdictions as well as Spain and France in *Actavis v Eli Lilly* (n 1) at [44]-[52].
example of ‘harmonised law’. The BGH held that an equivalent may fall within the scope of patent protection, setting out three questions that are similar but not identical to Hoffmann J’s Protocol questions. The Schneidmesser I questions are summarised lucidly by Meier-Beck (one of the BGH judges who decided Schneidmesser I) as follows: 36

1. Does the modified embodiment solve the problem underlying the invention by means which have objectively the same effect? If the answer is no, the equivalent falls outside the patent’s scope. If yes, the second question is:

2. Was the person skilled in the art enabled by his expertise on the priority date to find the modified means as having the same effect? Again, if the answer is no, there is no infringement. If the answer to both questions is yes, the third question is:

3. While answering question 2, are the considerations that the person skilled in the art applies drawn from the technical teaching of the patent claim (so that the person skilled in the art took the modified embodiment into account as being an equivalent solution)?

34 ibid [23]. This is an odd conclusion, since the product in question, an epilator, was held to infringe in Germany: see Improver Corp (n 23) 12-13. This divergence may be due to Germany recognising a doctrine of equivalents at the time, whereas the UK did not.


36 ibid 291-293.
**Actavis v Eli Lilly** aligns the UK approach more closely with that of Germany, since both now recognise and use similar tools to assess equivalents. As Widera notes, 37 although the Schneidmesser I and Protocol questions are similar, one distinction remains: under Lord Neuberger’s approach, equivalents requiring an inventive step are able to infringe, 38 whereas this is not the case in Germany. 39 It is argued below that this is a significant difference, and that the UK stance hinders innovation.

The current UK approach is also similar to that of the Netherlands, which applies the doctrine of equivalents if (i) the variant is foreseeable at priority date, (ii) the inventive concept covers the variant, (iii) the variant makes use of the inventive concept and (iv) reasonable legal certainty is not unduly compromised. 40 Factors (ii) and (iii) in particular align with Lord Neuberger’s first reformulated Protocol question.

In Italy, a variant infringes if (i) it reproduces the inventive core of the patent and (ii) it is obvious, although (iii) the fact that the variant includes some non-obvious modifications or does not include all elements of the patent claim does not prevent infringement. 41 Factors (i) and (ii) again resemble the corresponding Actavis v Eli Lilly Protocol questions.

Lord Neuberger clearly attempted to align the UK approach with that of other European jurisdictions. He discussed the approach of other EPC states at length 42 and referred to Germany, the Netherlands and Italy in particular in connection

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38 Actavis v Eli Lilly (n 1) [64].
39 ibid.
40 ibid [51].
41 ibid [48].
42 ibid [44]-[52].
with the reformulated Protocol questions. Furthermore, the UK Supreme Court judgment purports to decide the issue of infringement not just as regards the UK patent, but also as regards the French, Italian and Spanish designations of the patent. This has had a significant effect, as Actavis v Eli Lilly has indeed been followed by the Court of Milan and the Swiss Federal Supreme Court, despite the fact that Lord Neuberger did not comment on Switzerland.

The Court of Milan found infringement by clarifying the role of prosecution history, stating that it can only be ‘completely secondary and ancillary, and may at most provide merely circumstantial evidence as to the patent holder’s willingness to exclude or not certain solutions from the scope of protection.’ Thus, Lilly’s amendments did not restrict the scope of protection so as to exclude equivalents of pemetrexed disodium, meaning that Actavis’ proposed products fell within the patent. Similarly, the Swiss Federal Supreme Court’s finding of infringement related closely to its conception of prosecution history, which the Court held is ‘generally not determinative of the patent claims’ and therefore does not determine the scope of protection either.

This demonstrates judicial alignment across the EPC states in anticipation of the UPC. The UPC will constitute a

43 ibid [62]-[64].
44 ibid [92]-[102].
47 Eli Lilly v Fresenius Kabi (n 45) 9.
48 Eli Lilly v Actavis Switzerland AG (n 46) 4.3.
centralised authority that has exclusive competence over European patents 49 and facilitates the granting of such patents with unitary effect 50 (as opposed to the bundle of national patents currently issued by the EPO). As Fisher notes, ‘by ultimately tethering the interpretation of the grant to a single judicial body much of the twisting and turning, the conceptual gerrymandering and inconsistent treatment that are cited as reasons for the revision of Art.69 and the Protocol, may have been avoided.’ 51 This is because once the UPC is in place, a European patent can be enforced in multiple states via a single infringement action before the UPC. It will therefore be less expensive for patentees to enforce their rights: instead of having to bring separate infringement actions before national courts, the patentee can rely on one judgment issued by the UPC. Furthermore, since all participating states will be bound by the judgment of the UPC, 52 national courts will be prevented from reaching different conclusions. The UPC will therefore both lower costs and protect legal certainty. 53 There is currently no legislative provision which requires alignment, but the national courts are nonetheless choosing to follow each other’s reasoning. Such judicial efforts to harmonise will ease the transition to a unified regime.

49 Articles 1, 32 and 34 UPCA.
50 Article 1 UPCA.
52 Article 32 UPCA.
B. Challenges facing the UPC

However, the UPC currently faces two significant challenges. First, a constitutional complaint has been filed against German ratification of the UPC Agreement (‘UPCA’) on the grounds that it breaches a constitutional requirement that adoption of legislation amounting to a transfer of sovereign power to European institutions must be decided by a two-thirds majority in the Bundestag (federal parliament) and the Bundesrat (council representing the sixteen federal states). 54 Second, the UK’s imminent withdrawal from the EU poses a challenge to its membership of the UPCA, which only extends to EU Member States 55 (although the UK ratified the agreement whilst still within the EU). 56 These are both serious obstacles, since the UPCA requires the participation of a minimum of thirteen Member States to come into force, including the three Member States with the highest number of European patents in effect in ‘the year preceding the year’ in which the UPCA was signed. 57 The Protocol to the UPCA clarifies that these three Member States are Germany, France and the United Kingdom. 58

There are differing views on whether the UK could remain party to the agreement after withdrawing from the EU. Some legal practitioners argue that the UK’s membership is essentially a political question dependent on the will of other Member States to amend the UPCA in the UK’s favour. 59 Others

54 This requirement is derived from Articles 23(1) and 79(2) of the Grundgesetz (Basic Law for the Federal Republic of Germany).
55 Article 2 UPCA.
56 In April 2018, after the Brexit referendum but before formal withdrawal from the EU.
57 Article 89 UPCA.
58 Article 3 of the Protocol to the UPCA on provisional application.
suggest that there is a pragmatic interest in retaining UK involvement, since this could prevent strategic patenting effects between the UPC and the UK courts. 60 Whichever view one takes, Germany’s non-participation is the more immediate challenge, as its refusal to ratify the UPCA could bring the project to a halt even if the UK is allowed to participate.

In light of this uncertainty, it could be argued that individual EPC Member States should continue taking all the steps they can to unify their approaches independently. However, such judicial harmonisation will remain a flawed effort. It cannot ensure full harmonisation, as noted by Lord Neuberger in Schütz (UK) Ltd v Werit (UK) Ltd: ‘complete consistency of approach between different national courts of the EPC states is not a feasible or realistic possibility at the moment.’ 61 There is no ultimate arbiter to ensure consistency, meaning that the benefits that a UPC would usher in (legal certainty and lower litigation costs) can only be partially realised through piecemeal harmonisation. The distinction between the UK’s recognition of inventive equivalents and Germany’s rejection of them 62 comes to mind as an irreconcilable difference that is unlikely to ever be settled by national courts. The current mode of alignment is therefore necessarily limited.

5. Breadth of patentee protection

A second issue emerging from Actavis v Eli Lilly is breadth of patentee protection. Broad patent scope is best understood as protection outside of what Lord Neuberger terms the ‘normal

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61 Schütz (UK) Ltd v Werit (UK) Ltd (Nos 1 to 3) [2013] UKSC 16 [40].
62 Actavis v Eli Lilly (n 1) [64].
interpretation’ of a patent. The danger of this is indicated by Lord Neuberger’s extra-judicial comments. He has argued that Lilly’s patent would only have been limited to the claims if they had been phrased ‘for pemetrexed disodium and nothing else.’ The onus is therefore on the patentee to explicitly limit her monopoly at the drafting stage. If she does not do so, there is always the possibility of claiming a wider monopoly at the infringement stage. This is problematic, as becomes clear when one considers Actavis v Eli Lilly’s effect on numerical claims and prosecution history in particular. In both cases, Actavis v Eli Lilly privileges patentees at the expense of legal certainty for third parties.

It is conceded that the finding of infringement in Actavis v Eli Lilly itself may be justified on the basis that the person skilled in the art would appreciate that Actavis’ products would work in the same way as pemetrexed disodium when combined with vitamin B12. Furthermore, the person skilled in the art would appreciate that salt screening tests to determine whether a variant of pemetrexed disodium would work were routine. However, the UK’s recognition of a doctrine of equivalents still allows patentees to draft a very narrow claim at the patenting stage and claim a significantly wider monopoly at the infringement stage, thus resulting in overbroad patentee protection. This facilitates the creation of monopolies that do not correspond to the scope of the claim.

A. Numerical claims

One situation in which patentees actively discount areas of patent protection is in making strict numerical claims and thereby

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63 ibid [54].
64 The UCL Faculty of Laws discussion (n 27).
65 Actavis v Eli Lilly (n 1) [69].
excluding other numerical values. At a recent panel event, Lord Neuberger conceded that he was ‘attracted’ by the point that where a patentee ‘bookends’ her claims with an upper and lower numerical limit, there is a clear indication that she does not want her monopoly to extend beyond the chosen values. Other speakers at the panel event agreed that, in general, there is not much room for a doctrine of equivalents in relation to strict numerical claims. Germany’s BGH judge Meier-Beck approved Jacob LJ’s comment in *Rockwater Ltd v Technip France SA* that ‘if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.’ Meanwhile, O’Malley, a judge on the US Court of Appeals for the Federal Circuit, noted that the patentee often has a very good reason for including numerical limitations in her application, namely to avoid the prior art.

The difficulty in reconciling strict numerical claims with the UK’s doctrine of equivalents has come to the fore in *Regen Lab SA v Estar Medical Ltd*, a recent Patents Court decision applying Lord Neuberger’s new approach. The patent in question concerned a method of producing platelet rich plasma (‘PRP’). Hacon J explained the technical background as follows: ‘platelets are small unucleated cells contained in blood plasma, responsible for blood clotting and tissue repair. PRP is plasma in which the platelet count is higher than would be found in the plasma of untreated blood. It is used by clinicians to promote the healing of wounds. There are also non-clinical diagnostic uses of PRP.’ At the priority date, different centrifugation methods

66 The UCL Faculty of Laws discussion (n 27).
67 ibid.
68 *Rockwater Ltd v Technip France SA* [2004] RPC 46 [41].
69 The UCL Faculty of Laws discussion (n 27).
71 ibid [8].
were used to separate the platelet fraction to obtain the PRP. Regen, the patentee, claimed a process for centrifugation using a thixotropic gel. Regen’s method can be summarised in three steps: (1) centrifuging whole blood from a patient in a separator tube containing a thixotropic gel and an anticoagulant; (2) removing half of the platelet poor plasma from the top of the tube; and (3) re-suspending the remaining plasma and buffy layer to produce PRP. Claim 1 of the patent mentioned two strict numerical limits: it specified that the separator tube be either a glass tube containing thixotropic gel and 0.10M sodium nitrate (an anticoagulant) or a polyethylene terephthalate separator tube containing a highly thixotropic gel formed by a polymer mixture and an anhydrous sodium citrate at 3.5mg/ml.

Although the patent was found invalid for lack of novelty and inventive step, Hacon J went on to consider the issue of infringement. The alleged infringer, Estar, used an anticoagulant molarity of 0.136M, instead of the 0.10M specified in Regen’s patent. The relevant question for present purposes is whether Estar’s chosen molarity nevertheless infringed Regen’s patent. Applying Lord Neuberger’s reformulated Protocol questions per *Actavis v Eli Lilly*, Hacon J found, with respect to question 1, that the inventive concept of claim 1 was ‘the preparation of PRP for solely therapeutic use by employing a thixotropic gel wherein (a) there is only one centrifugation and (b) after centrifugation about half the supernatant is removed and the platelets are then re-suspended in the enriched plasma.’ Moving on to question 2, Hacon J concluded that it would be obvious to the skilled person

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72 ibid [10].
74 *Regen Lab v Estar* (n 70) [25].
75 ibid [197].
76 ibid [212].
77 ibid [235].
that Estar’s variant achieved substantially the same result as Regen’s invention in substantially the same way. However, most of the discussion centred on question 3. Hacon J held that the Regen would only intend that strict compliance with the literal meaning of claim 1 would be essential to the inventive concept if ‘there had been a sufficiently clear indication to the skilled person that strict compliance with the figure of 0.10M was intended.’ The Patents Court therefore found that if Regen’s patent had been valid, it would have been infringed.

*Regen Lab v Estar* indicates that following *Actavis v Eli Lilly*, strict numerical limitations will not necessarily demarcate a patent. This conclusion is problematic, since it allows a patentee to rely on numerical limits at the drafting stage as evidence of novelty, only to later claim infringement by a variant that falls outside the patent’s supposed limitation. The patentee is thereby able to have her cake and eat it: she takes the benefit of numerical claims (assist in establishing novelty) without conceding the burden (limited scope of monopoly). Meanwhile, the third party is left in an uncertain situation: what will amount to a ‘sufficiently clear indication’ that the patentee intended strict compliance with the numerical values included in the patent? Litigation is required to establish its meaning, and inspiration from other jurisdictions is lacking, since remarks from senior judicial figures suggest that the UK approach is unorthodox. Additionally, the UK’s ruling on infringement in *Regen Lab v Estar* conflicts with the German ruling on the same dispute. In the German equivalent of the case the Regional Düsseldorf District Court dismissed

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78 ibid [242].
79 ibid [252].
80 ibid.
81 The UCL Faculty of Law discussion (n 27).
Regen’s claim of infringement. 82 These conflicting outcomes reinforce the point that judicial harmonisation has inevitable limits unless subject to a common and supreme authority.

Unfortunately, Actavis v Eli Lilly does not seem to allow for a more balanced approach to numerical limitations: Lord Neuberger has conceded extra-judicially that his personal view of numerical claims may be inconsistent with the judgment. 83 Given the tension between Lord Neuberger’s extra judicial opinion and his ruling in Actavis v Eli Lilly, it seems that he overlooked the impact his judgment would have on numerical claims in patent law. This oversight is leading English law in a worrying direction that is based wholly on patentee-sided considerations.

B. The role of prosecution history

The risk of overly broad patent monopolies is increased by Actavis v Eli Lilly’s stance on prosecution history. Clearly wary of an American-style prosecution history estoppel, which is of general applicability, subject to the limitations set out in Warner Jenkinson Co v Hilton Davis Chemical Co 84 and Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co, 85 the UK Supreme Court only allows a prosecution history estoppel in two exceptional circumstances. This reinforces the suggestion outlined above that a patentee may accept a narrow monopoly during prosecution only to argue for a broader patent during infringement. Thus, all patentees who do not fall within one of Lord Neuberger’s exceptions will be able to reach back and claim something during infringement that they

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83 The UCL Faculty of Laws discussion (n 27).
have expressly denounced at the drafting stage. Again, such patentees get the best of both worlds: accepting a narrow monopoly during prosecution makes it more likely that a patent will be granted, but the patentee can then claim a much wider right during infringement.

If alleged infringers wish to rely on one of Lord Neuberger’s recognised exceptions, they may face an uphill battle in attempting to do so. The first exception in particular may require much litigation to flesh out, despite Lord Neuberger considering this category ‘self-explanatory’. 86 When exactly is a point ‘truly unclear’ on examination of the specification and claims, and when does the file ‘unambiguously resolve’ the issue? Since no examples are given in Actavis v Eli Lilly, the solutions to these questions are less obvious than Lord Neuberger suggests.

6. Effect on innovation

Overly broad patentee protection disincentivises innovation. This is a serious drawback given that patents are very often justified on the grounds that they promote innovation. 87 Merges and Nelson discuss the effects of overly broad protection, noting that ‘when a broad patent is granted or expanded via the doctrine of equivalents, its scope diminishes incentives for others to stay in the invention game, compared … with a patent whose claims are trimmed more closely to the inventor’s actual results.’ 88 Extending patent protection further makes it difficult for

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86 Actavis v Eli Lilly (n 1) [88].
87 For a more detailed discussion, see Dominique Guellec and Bruno van Pottelsberghe de la Potterie, ‘The Economics of the European Patent System: IP Policy for Innovation and Competition’ (OUP, 1st ed. 2007).
competitors to predict how the claims will be construed, resulting in legal uncertainty and thereby discouraging inventions which build on the teachings of a pre-existing patent. This is an especially relevant concern for the pharmaceutical sector. Since it costs an estimated £1.15 billion and twelve years to research and develop one new medicine, many innovations in this area depend on pre-existing drugs, i.e. incremental innovation. Such innovation is valuable for four reasons. First, response to a particular drug can vary significantly across patients, so having many therapeutic alternatives allows physicians to decide which treatment will best suit an individual patient. Additionally, the availability of different therapeutic options means that patients are more likely to comply with their treatment regimen. Third, an entirely new drug rarely constitutes the best version of that drug: as Lybecker points out, ‘subsequent development allows for improvements in a therapeutic class that would otherwise never occur.’ Finally, incremental innovation encourages competition, resulting in favourable prices for consumers. Unfortunately, the likelihood of incremental pharmaceutical innovations infringing patents may have increased following *Actavis v Eli Lilly*. Researchers must now decide whether they are willing to run the risk of infringement in developing treatments.

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91 ibid 26.
92 ibid 27.
93 ibid 28.
94 ibid.
that build on existing drugs. In a worst-case scenario, *Actavis v Eli Lilly* may deter incremental innovation.

This possibility is exacerbated by the fact that under Lord Neuberger’s approach, even equivalents requiring an inventive step may infringe. His position diverges from that in German law, which reaches the opposite conclusion. Lord Neuberger argued that adopting the German position was unnecessary since the existence of an inventive step may entitle the infringer to a new patent. 95 This raises the immediate question of which perspective a court would use to address the issue of inventive equivalents. One assumes that the judge would adopt the perspective of a person skilled in the art, but such a hypothetical addressee is famously unimaginative (i.e. lacks the capacity for creativity), as noted by Lord Reid in *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd* 96 and reaffirmed by Jacob LJ in *Rockwater v Technip*. 97 The person skilled in the art would thus not consider an inventive equivalent to fall within a patentee’s monopoly. It can therefore be doubted whether ‘inventive equivalents’ should even be categorised as ‘equivalents’ – the fact that they are inventive suggests a distinctive rather than equivalent feature. Given this conceptual confusion, it may be difficult to even recognise an inventive equivalent in practice. Lord Neuberger’s recognition of inventive equivalents undermines his claim that *Actavis v Eli Lilly* limits the UK’s doctrine of equivalents to ‘immaterial variations’. 98 The German position is to be preferred: it sets a clear limit to the doctrine of equivalents, meaning that

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95 *Actavis v Eli Lilly* (n 1) [64].
97 *Rockwater v Technip* (n 68) [7].
98 *Actavis v Eli Lilly* (n 1) [34].
competitors can more easily assess whether their products
infringe.

A second objection to the UK approach is Lord Neuberger’s view that an infringer would be able to obtain a new patent. The infringement trial necessarily takes place some time after the filing date or validly claimed priority date but the assessment as to the inventive step of the infringed patent is made by reference to the state of affairs at the priority date. This means that even if the infringer might have been entitled to a new patent at the priority date, between the priority date and the infringement trial other prior art may have become available which would render the variant non-inventive. The grant of a new patent might at this stage be unfeasible. Lord Neuberger’s stance on inventive equivalents introduces a confusing element into the doctrine that may hinder innovation by weakening the position of competitors.

The arguments concerning breadth of patentee protection and effect on innovation are particularly pertinent to cancer research, which depends on the wide-ranging expertise of clinicians, molecular biologists, computational biologists, statisticians, nanotechnology experts and chemical engineers. 99 This means that there are many potential infringers who may be hesitant of investing in projects that could, following Actavis v Eli Lilly, face legal challenges. The decision may therefore deter further discoveries in this area, which is unfortunate given the inherent social aspect of intellectual property relating to cancer research.

7. Conclusion

*Actavis v Eli Lilly* is an example of judicial attempts across EPC Member States to align their approaches in preparation for the UPC. However, the doctrine of equivalents allows for overbroad patentee protection. The UK’s conception of the doctrine is especially problematic in this respect, as becomes clear when one examines *Actavis v Eli Lilly*’s effect on numerical claims and prosecution history. Furthermore, overbroad patentee protection undermines innovation, which may have very detrimental consequences, particularly in the pharmaceutical sector – at worst, it may hinder incremental innovation.