

# Being equitable about equivalents

By John Hornby

## 1. UNINTENDED CONSEQUENCES?

Has Lord Neuberger in *Actavis*<sup>1</sup> introduced “an amorphous general inventive idea”<sup>2</sup> test to determine UK patent infringement by equivalents? Are “inessential integers”, once found extremely rarely<sup>3</sup>, now to be embraced as part of normal UK practice? Have UK patent claims become “a puzzle game”<sup>4</sup>?

Lord Neuberger, clearly did not believe that he had changed UK law considerably with his decision in *Actavis* or that the decision would have a substantial impact. At a UCL conference<sup>5</sup> following *Actavis*, he referred to *Kirin-Amgen*<sup>6</sup> (the previous leading authority on infringement in which purposive construction was confirmed as the correct approach) as having been “slightly wrongly” decided. He also remarked upon “the relative infrequency with which equivalents are applied in other jurisdictions where they have been accepted.” However, having adopted an equivalency test, the point is coming up frequently in UK cases and those cases appear to be suggesting that the answers to some of the above questions are “yes”. Generalised ideas, inessential integers and puzzles have all become part of the landscape.

## 2. THE ACTAVIS QUESTIONS AND WHY THE FIRST IS KEY

There are three equivalency test questions but it is the first that, in the cases decided post-*Actavis*, has been key. Why?

The questions are:

*“i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?”*

*ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?”*

*iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?”*

Before turning to the individual questions, a marker is appropriate regarding the meaning of “variant”. Lord Neuberger used the *Improver*<sup>8</sup> questions (directed at determining purposive construction) as his starting point

for setting out the UK equivalency test. In those questions, Hoffmann, J. (as he then was) defined the word “variant” as follows:

*“a feature embodied in an alleged infringement which fell outside the primary, literal or a contextual meaning of a descriptive word or phrase in the claim (‘a variant’).”*

However, in *Actavis*, Lord Neuberger’s “variant” must be referring to more – at least to all the features of, or corresponding to, those of the inventive concept. The relevance of other features is addressed below when dealing with Question i). In what follows, “variant feature” is used to describe a variant as the term was used in *Improver*.

Question ii) assumes that: the variant achieves substantially the same result in substantially the same way as the inventive concept revealed by the patent; and the person skilled in the art would know that it achieves that result. The question asks if it would have been clear to the person skilled in the art at the priority date that the alleged infringement achieves that (i.e., substantially the same result) in substantially the same way as the inventive concept revealed by the patent.

How might a negative answer be achieved to Question ii)? In *Actavis* (at paragraph 64), Lord Neuberger, considered whether a variant that was itself inventive would lead to such an answer, reflecting what he found was sometimes the case in Germany. However, whilst not deciding the point, he said that he was not sure that requiring the variant to be non-inventive was “appropriate”<sup>9</sup>.

Of Question ii), Arnold, J. observed recently:

*“There are likely to be few cases in which this question will be answered in the negative.”*<sup>10</sup>

Notwithstanding that each case turns on its own facts, the skilled person’s lack of understanding of how the variant works on the assumptions to be made, whilst logically possible, would seem to be improbable. The Judge went on to hold “*In the present case the answer must be yes.*” And, so it must be (in the author’s view) in the vast majority of cases.

Question iii) again derives from the *Improver* questions. However, rather than asking whether strict compliance with claim language was intended by the patentee (perhaps more accurately the patent applicant)<sup>11</sup>, the question asks whether the patentee intended that such strict compliance was an essential part of the inventive concept. The difficulty with the question is that, for it to be answered in the affirmative, one has to be prepared to revisit the question of what the inventive concept is. If not, the answer to the question has to be “no” and the question is redundant.

Looked at one way, question iii) is asked as a check that the Court has correctly identified “the inventive concept

revealed by the patent”, as required by question i). In the post-*Actavis* cases, Question iii) has received little attention and the author suggests that this is because the Courts have not been prepared to go back and consider what the patentee was putting forward as the relevant invention.<sup>12</sup> And that brings us to how the UK Courts have, post-*Actavis*, gone about identifying inventive concepts under Question i), including the weight attached to what the patentee states about the matter in the patent.

## 3. QUESTION I) AND DETERMINATION OF THE INVENTIVE CONCEPT IN ACTAVIS

That the *Actavis* questions will need some “interpolation” has already been stated by the Court of Appeal. So, the reference to “literal meaning” in question i) has been said to mean “normal meaning”<sup>13</sup>. The same point may later be made about question iii), should the Courts ever look closely at that question.

Also, there is then the question as to whether “normal meaning” is exactly the same as the old purposive construction explained in *Kirin-Amgen*. That the word “normal” implies a purposive approach has been said by the Courts on several occasions<sup>14</sup> but it has also been doubted that it is the same purposive construction as under the old law.<sup>15</sup>

There are, however, some more significant questions.

- (1) How is an inventive concept to be identified?
- (2) Of what significance are integers of the claim that are not part of the inventive concept?

Regarding (2), if certain integers are excluded altogether from an inventive concept, then features (if any) of the alleged infringement corresponding to those integers are highly unlikely to be of any relevance. Once excluded, they won’t impact significantly (or more likely, at all) on the result of using the relevant inventive concept or the way in which that result is achieved. Those features, and their effects, can then easily be disregarded, as will become clearer later when specific post-*Actavis* cases are considered.

This highlights the paramount importance of question (1). An unduly broad inventive concept will lead to a correspondingly broad “effective claim” for the purposes of the doctrine of equivalents, without further curtailment by the language of the actual claim.<sup>16</sup> In sum, those integers not within the inventive concept, and corresponding features (if any) of the alleged infringement, can readily be ignored altogether – i.e., rendering the claimed integers truly inessential.

Turning to question (1) above (how to identify an inventive concept), Lord Neuberger does not set out detailed guidance as to what he meant by “inventive concept” (or his alternative phrase, “inventive core”). He did refer to authorities from other European Patent Convention (EPC) states in formulating the UK equivalency test but he recognised that there was no uniformity of approach in those states (paragraph 32). He didn’t cite any definition of “inventive concept” from Dutch law, where that phrase is used (paragraph 51), or of “inventive core” from Italian law, where that phrase is used (paragraph 48).

<sup>1</sup> *Actavis v Eli Lilly* [2017] UKSC 48.

<sup>2</sup> The Swedish Doctrine of Equivalence (2011) by Professor Bengt Domeij, Uppsala University, top of page 3, available in English at <http://uu.diva-portal.org/smash/get/diva2:391087/FULLTEXT01.pdf>.

<sup>3</sup> Patents for Inventions, Blanco White, 5th Edition, paragraph 2-111.

<sup>4</sup> *Napp v Dr Reddy’s* [2016] EWCA Civ 1053 at paragraph 71 per Floyd L.J. “A patent specification is not intended to be a puzzle game in which the skilled person must come up with his own theory as to what degree of precision was intended by the patentee.”

<sup>5</sup> University College London conference, 1 Nov 2017, “Equivalents: K = Na. Is the Genie out of the Bottle?”. Available on line - see at about 1hr, 6mins: [www.youtube.com/watch?v=y84hUeArgMs&feature=youtu.be](http://www.youtube.com/watch?v=y84hUeArgMs&feature=youtu.be)

<sup>6</sup> *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9.

<sup>7</sup> Paragraph 66 of *Actavis*.

<sup>8</sup> *Improver v Remington* [1990] FSR 181 at 189.

<sup>9</sup> Note that, as a practical matter, it may be difficult for the alleged infringer to maintain that its variant is inventive, whilst the patentee’s alleged invention was not. In other words, the alleged infringer may be forced to elect early on whether to say that both its variant and the claimed invention are obvious or both are inventive.

<sup>10</sup> *Eli Lilly v Genentech* [2019] EWHC 387 [Pat] at paragraph 598, discussed further below.

<sup>11</sup> However, patentee is used in this article since that is the word used in the Judgments cited and quoted.

<sup>12</sup> See, for example, paragraph 70 of *Icescape v Ice-World* [2018] EWCA Civ 2219 discussed below.

<sup>13</sup> Paragraph 66 of *Icescape* [ibid].

<sup>14</sup> *Mylan v Yeda* [2017] EWHC 2629 at paragraph 138, *Ilumina v Premaitha* [2017] EWHC 2930 at paragraph 201, *Icescape* at paragraph 60.

<sup>15</sup> *Eli Lilly v Genentech* [2019] EWHC 387 [Pat] at paragraph 294: “As HHJ Hacon sitting as a High Court Judge pointed out in *Regen Lab SA v Estar Medical Ltd* [2019] EWHC 63 [Pat] at [202]-[207], it is no longer necessary to take equivalents into account in such an interpretation, because it is now possible for a patentee to contend that a patent has been infringed by virtue of the doctrine of equivalents even if it is not infringed when the claims are given a normal interpretation.” See too HHJ Hacon in *Coloplast v McGregor Healthcare* [2018] EWHC 2797 at paragraph 71.

<sup>16</sup> Subject to questions ii) and iii), whose significance is limited, as discussed earlier.

In *Actavis* itself, claim 1 of the patent<sup>17</sup> was in Swiss form and called for a combination of pemetrexed disodium and vitamin B12 (or a derivative). Equivalency concerned the substitution of a sodium ion with other counter-ions (potassium being one). Lord Neuberger held:

*“... the inventive concept of the patent is the manufacture of a medicament which enables the pemetrexed anion to be administered with Vitamin B12 ...” (Paragraph 61.)*

Although Lord Neuberger did not explain how he reached that conclusion, finding the sodium ion not to be part of the inventive concept was entirely consistent with the patent’s teachings (e.g., at paragraph 16). It is clear that the pemetrexed anion, formed on disassociation of the sodium salt in solution, was key but that the identity of the specific counter-ion (sodium) was not. Lord Neuberger also referred to common general knowledge (CGK), such as the trial Judge’s findings about potassium salts (paragraph 26(ii)):

*“... generally soluble, but there were exceptions. There were concerns about the potential toxicity of such salts, which was particularly significant if large quantities of the drug were involved.”*

However, it is not clear if, or how, findings of the trial Judge about CGK influenced the identification of what constituted the inventive concept, as opposed to Lord Neuberger’s general understanding of the specification. Certainly, there is no indication that he used it for the purposes of ignoring altogether the reference to sodium. And one could point to the ions of potassium, tromethamine or (in the case of the free acid infringement) hydrogen as being corresponding features to the sodium ion. Nonetheless, it does leave open the question of whether other counter-ions could have been substitutes. However, as a practical matter, only those counter-ions that didn’t significantly affect the action of the pemetrexed ion would be likely to ever come before a Court.

#### 4. GUIDANCE ELSEWHERE

The phrase “inventive concept” is used, both in the Patents Act, 1977 and in case law, to assist in the determination of other issues concerning UK patents. Lord Neuberger, having presided in the Patents Court on many occasions, would have been sufficiently familiar with UK patent law to know that.

#### 4.1 Unity of invention

Sections 14(5)(d), (6), 17(6) and 26(b), which concern unity of invention, are the only sections in the Patents Act, 1977 that refer to the phrase “inventive concept”. S.14(5) provides:

*“The claim or claims shall ... (d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept.” (Also see Art. 82 EPC.)*

Rule 16 of The Patents Rules, 2007 (see too EPC, Rule 44) provides some guidance as to how this should be done, and this is reflected in the UK Manual of Patent Practice (14.158):<sup>18</sup>

*“One criterion which would be suitable for some sets of claims would be to determine whether the common subject-matter of the claims is novel and involves an inventive step.”*

So, here “inventive concept” is to be determined by reference to patentability in the light of the state of the art. However, and as discussed below, that does not appear to how the phrase is (or ought to be) used in other areas of UK patent law. Unity has its own statutory definition and, in the author’s view, should be ignored for the purposes of considering how the phrase “inventive concept” should be construed when applying the doctrine of equivalents.

#### 4.2 Inventive step

Lord-Justice Jacob re-formulated the *Windsurfing*<sup>19</sup> approach, often used<sup>20</sup> in the UK to assess obviousness, in *Pozzoli SPA v BDMO SA [2007] EWCA Civ 588* at paragraph 23:

- “(1)(a) Identify the notional ‘person skilled in the art’;*
- (b) Identify the relevant common general knowledge of that person;*
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;*
- (3) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed;*



*(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?”*

Given that identifying the inventive concept is done at a stage prior to determining inventive step, it would seem tolerably clear that the terms do not mean the same thing, at least in this context. However, one can find judicial pronouncements suggesting otherwise, notably in *Generics (UK) v Lundbeck [2009] UKHL 12*, a case concerning insufficiency mentioned further below and in which Lord Neuberger was one of the members of the Appellate Committee.<sup>21</sup>

In *Pozzoli*, Jacob, L.J. gave some guidance as to how to identify the inventive concept, which included (underlined added):

- “... it is only through the eyes of the skilled man that one properly understand what such a man would understand the patentee to have meant and thereby set about identifying the concept.” (Paragraph 15.)*
- “So what one is seeking to do is to strip out unnecessary verbiage, to do what Mummery L.J. described as make a précis.” (Paragraph 18.)*
- “... if a disagreement about the inventive concept of a claim starts getting too involved, the sensible way to proceed is to forget it and simply to work on the features of the claim.” (Paragraph 19.)*
- “Identification of the concept is not the place where one takes into account the prior art. You are not at this point asking what was new. Of course the claim may identify that which was old (often by a pre-characterising clause) and what the patentee thinks is new (if there is characterising clause) but that does not matter at this point.” (Paragraph 21.)*

*“In the end, to my mind, what the skilled man’s take-home message from the claim in the context of the patent is, is really no more than “overlap the discs, hold them in the known way via their centres yet space them via a step-like arrangement so they can be got out.” (Paragraph 49, underlining added.)*

So, although one can find statements that indicate differently, here the focus appears to be on what the patentee has put forward as his invention,<sup>22</sup> rather than identifying differences between the claims and the state of the art. Note too that the exercise might only entail removing verbiage from a claim and that one might just revert to the claim as a whole.

#### 4.3 Entitlement

In entitlement disputes, the Courts seek to identify contribution(s) to the “inventive concept” by the relevant parties. Here, perhaps more than elsewhere, the cases are not consistent as to what the phrase means and what follows only comprises some highlights. Importantly, these disputes may be decided before grant and before there are any claims. In the latter case, there is little option but to look at what the patentee says in the patent’s description for guidance as to the identity of the inventive concept.

The House of Lords case of *Yeda v Rhone-Poulenc [2007] UKHL 43* provides guidance on the meaning of the phrase “inventive concept” as it is used in the context of entitlement. Lord Hoffmann held at paragraph 20:

*“It is not enough that someone contributed to the claims, because they may include non-patentable integers derived from prior art.”*

<sup>17</sup> European Patent (UK) No 1,313,508.<sup>18</sup> See too W 0006/97 (Foamed pressure sensitive tapes) of 18.9.1997, paragraph 6.4.

<sup>19</sup> *Windsurfing International v Tabur Marine [1985] RPC 59.*

<sup>20</sup> For the most recent guidance as to how UK Courts should assess inventive step, see the Supreme Court Judgment in *Actavis v ICOS [2019] UKSC 15* at paragraph 60 onwards.

<sup>21</sup> Lord Neuberger equates the terms inventive concept and inventive step at paragraph 101 and Lord Walker says that inventive concept is that “which entitles the inventor’s achievement to be called inventive” (underlined added) at paragraph 30. Contrast too Lord Walker’s description of the inventive concept at paragraph 28 with the trial Judge at paragraph 75(i), [2007] EWHC 1040 (Pat).

<sup>22</sup> See also Laddie, J.’s statement in *Brugger v Medic-Aid [1996] RPC 635* at 656 (decided before *Pozzoli*): “The important issue as far as this case is concerned is to identify correctly the inventive concept which the patentee must be taken to have put forward as underpinning his monopoly.”





It is hard to reconcile the statements of Jacob, L.J. in *IDA* with what he said in *Markem*. (Note here that, of course, the state of the art referred to in *Markem* includes the CGK referred to in *IDA*.) Further, at paragraph 43 of *IDA*, Jacob, L.J. appears to go further and equate the way in which “inventive concept” is used in entitlement to that used to determine unity. In the author’s view, the latter cannot be right and the approach endorsed in *Markem* is to be preferred to that in *IDA*. As Pumfrey, J. held in *Collag v Merck* [2003] F.S.R. 16 (paragraph 79):

*“... I should point out where there are a number of different contributions to the inventive concept described in a patent application, I do not think that it is correct to look only at the contributions that are inventive.”*

It follows that the inventive concept could, for example, include aspects of the relevant CGK.

#### 4.4 Repair

Earlier in this article, reference is made to Lord Neuberger’s familiarity with the phrase “inventive concept” in other areas of UK patent law. In *Schutz (UK) Ltd v Werit (UK) Ltd* [2013] UKSC 16, he gave the lead Judgment of the Supreme Court in a case concerning alleged infringement by repairing a patented article. At paragraph 67, he held:

*“... that it must be legitimate, in the context of addressing the question whether a person “makes” the patented article by replacing a worn out part, to consider whether that part includes the inventive concept, or has a function which is closely connected with that concept.”*

Then, at paragraph 69, he went onto explain:

*“In almost all patents, the claimed inventive concept is clearly identified or identifiable from the patent, and, if it is unclear or disputed, it will often be an issue in the proceedings anyway.”*

The above statement appears to be entirely consistent with the approach of Jacob, L.J. in *Pozzoli*, referred to earlier in the context of inventive step. It is also consistent with the same Judge’s statement in *Markem*, regarding entitlement. But, is it the approach that the Courts have adopted post-*Actavis* in the context of equivalents? In the author’s view it makes sense to use the term in the same way for validity, ownership and infringement.

## 5. POST-ACTAVIS DECISIONS

### 5.1 Icescape v Ice-World International [2018] EWCA Civ 2219

The decision in *Icescape* was made by a strong Court of Appeal. The Court’s approach to identifying an inventive concept for equivalency bears little resemblance to that in *Markem* or *Pozzoli*. However, the Court in *Icescape* does not explain the basis, by reference to authorities or otherwise, for adopting its approach.

The patent<sup>25</sup> in *Icescape* concerned an arrangement of

pipes for providing coolant to an ice rink, designed to have foldable components and be easily transported, whilst retaining fluid tight connections in use. The patent explained (at paragraph 4) that the aims of the invention were to allow rapid installation, reliable operation, differing skating area coverage and substantial/complete coolant recovery.

Claim 1 had a pre-characterising portion and, as broken down by the trial Judge, five characterising features. The infringing arrangement did not have characterising features D and E, which the Court found (at paragraph 70) on a normal construction required cooling elements to be connected in series. As a result of its different configuration, the assembly incorporated elements connected in parallel. Also, it meant that (paragraph 53):

*“... the whole assembly is more complicated as a result of the extra piping and will take longer to install and break down, contrary to the purpose of the patent.”* (Underlining added.)

Indeed, whilst a parallel configuration leads to a more even distribution of cooling, the disadvantage referred to above is also an inevitable consequence.

The trial Judge found that all of the features of claim 1 were part of the CGK with the exception of characterising feature C, which concerned a folding joint.<sup>26</sup> Against that background, the Court of Appeal found that feature to be the inventive concept.<sup>27</sup> Having stripped out the CGK, the effects of the variant feature (of integers D and E) were dismissed, and infringement found, because that variant feature (in Lord Kitchin’s words) “has nothing to do with the inventive core of the patent”. (However, the patent was found invalid for lack of novelty due to the failure of a crucial priority argument.)

And in paragraph 74, Lord Kitchin dealt with the third *Actavis* question, seemingly in a way that could only lead to a negative answer because the identification of the inventive concept was not substantively re-addressed:

*“There is no reason why the skilled reader would have thought that strict compliance with integers D and E was an essential requirement of the invention. The inventive core of the patent has nothing to do with the coupling of the elements together or whether the fluid flows through them in series or in parallel.”*

In sum, to identify the inventive concept, the Court: stripped out from the claim what had been found to be CGK (c.f., acknowledged as known in the patent); ignored that the relevant features were characterising features of the claim; and ignored that the features corresponding (at one level of generality) to those of the claim not within the inventive concept were more complicated and took longer to install and breakdown (i.e., more laborious and expensive), “contrary to the purpose of the patent”.<sup>28</sup>

As suggested earlier, it makes sense to have the same meaning attributed to inventive concept for obviousness and equivalents. However, the *Icescape* approach to identifying an inventive concept (for equivalents) is in conflict with the *Pozzoli* inventive step test (paragraph 23, quoted above).

First, if CGK is to be stripped out from a claim, why not other state of the art? If that were done, the *Pozzoli* test would be rendered inoperable. Second, how is *Pozzoli* to be applied when the invention comprises combining features that are individually CGK?<sup>29</sup> Third, and related to “second”, how should the Court approach *Pozzoli* when the obviousness attack is based on CGK alone?<sup>30</sup>

There is clearly an increased danger, if the *Icescape* approach is adopted, of salami slicing claims into bits of CGK and bypassing, not just what the inventor claims to be his invention, but also the inventor’s inventive step (if any). Note here that, in the *Pozzoli* test, the skilled person uses his CGK to understand the patent, not in an exercise of stripping it out of a claim to identify its inventive concept. (See the quoted passages from *Pozzoli* earlier.)

Further, what of Article (2) of the Protocol to EPC, Article 69? It provides:

*“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.”*

This clearly envisages identifying corresponding (equivalent) features in the alleged infringement to each of the integers of the relevant claim. It doesn’t contemplate ignoring claim integers altogether, although admittedly the distinction may depend on the level of generality to which one descends.

However, not only is the statement difficult to understand, but also strictly speaking it was probably made obiter (since the Court’s decision did not appear to call for determination of the precise point). Further, in *Welland Medical Limited v Philip Arthur Hadley* [2011] EWHC 1994 (Pat), Floyd, J. referred to paragraph 20 of *Yeda* and held (at paragraph 21):

*“I do not think that in this passage Lord Hoffmann was saying that one determines entitlement to subject matter in a patent application by reference to any detailed analysis of validity in relation to the prior art.”*

Prior to that decision, in *Markem Corporation v Zipher Limited* [2005] R.P.C. 31, Jacob, L.J. (giving the Judgment of the Court of Appeal), at paragraph 103 endorsed the following statement made in an earlier first instance decision:<sup>23</sup>

*“... it is the inventive concept or concepts as put forward in the patent with which one is concerned, not their inventiveness in relation of the state of the art.”*

The Deputy Judge in that earlier case repeated the same point elsewhere in his Judgment.<sup>24</sup>

However, one year after *Markem*, in *IDA Ltd v The University of Southampton* [2006] EWCA Civ 145, Jacob, L.J., giving the Judgment of the Court of Appeal, held:

- *“All that Professor Howse added to Mr Metcalfe’s idea is the common general knowledge of those in the art. There was nothing inventive about it and I do not see how Professor Howse could fairly be described as an inventor. The “heart” was Mr Metcalfe’s idea and his alone.”* (Paragraph 33.)
- *“Normally the addition of matter which is common general knowledge is the sort of thing often forming the subject of subsidiary claims of no significance as regards inventorship. Persons skilled in the art naturally add common general knowledge to their key ideas. The fact that here such an addition goes to the generality of the main concept and claim should not, and in my view does not make any difference.”* (Paragraph 37.)

<sup>23</sup> Stanelco’s Application [2004] EWHC 2263 at paragraph 15.

<sup>24</sup> “The Court is not concerned with issues of validity or inventiveness: merely with the concept as described.” (Paragraph 12.) “This enquiry does not involve any assessment of whether the invention represents a contribution to the art, or an inventive contribution (in the obviousness sense) to what the other inventor has come up with. ... What is relevant is what is put forward in the patent as inventive...” (Paragraph 18.)

<sup>25</sup> EP (UK) 1,462,755.

<sup>26</sup> Recorded in paragraph 16 of the Court of

Appeal judgment.

<sup>27</sup> Lord Kitchin at paragraph 72 and Floyd, L.J. at paragraph 98.

<sup>28</sup> Nor was any substantial attempt made to identify equivalent features in the allegedly infringing device to those of the claim (but, as mentioned elsewhere in this article, such an exercise may depend on the level of generality with which one approaches it).

<sup>29</sup> See *Accord Healthcare v Medac* [2016] EWHC 24 (Pat) at paragraph 122: “Many inventions involve a combination of known features.

However a combination of features, all of which individually were common general

knowledge, can give rise to a valid patent claim if that combination is new and non-obvious.”

<sup>30</sup> In *Ratiopharm v Napp* [2008] EWHC 3070 (Pat), Floyd, J. identified an inventive concept (paragraph 160) for the purposes of considering the *Pozzoli* test in an attack based on CGK alone. He then went onto consider the difference between that concept and the CGK (paragraphs 206 et seq), pursuant to the third *Pozzoli* step.

## 5.2 Regen Lab v Estar Medical [2019] EWHC 63 (Pat)

Regen's patent<sup>31</sup> claimed a method for the preparation of a blood plasma which was enriched in platelets and other blood factors, known as platelet rich plasma, or PRP. Claim 1 comprised steps of centrifuging blood, separating plasma from the erythrocytes and resuspending the enriched plasma. Specifically, it included the step of:

*"a) Centrifuging whole blood in a separator tube selected from:*

*- a glass separator tube containing a polyester-based thixotropic gel and a buffered sodium citrate solution at 0.10M..." (underlining added).*

HHJ Hacon explained (paragraph 226):

*"The Defendants' case on non-infringement was:*

*(1) the thixotropic gel of their product was not polyester-based; and*

*(2) the buffered sodium citrate solution was at 0.136M, not 0.1M as required in claim 1." (Note that, in fact, the claim called for 0.10M.)*

Regen's principal case on infringement was based on equivalents and HHJ Hacon emphasised his view of the need to identify clearly the inventive concept for that purpose at paragraph 234:

*"Sometimes during argument in the present case the inventive concept was identified by restating practically the entirety of the claim. This did not focus matters. It is both helpful and necessary to simplify the inventive concept as much as can accurately be done."*

The author questions what basis there is for this judicial statement about the necessity to simplify the inventive concept. Further, in the author's view, this desire to simplify claims has developed into a determination to find reasons to root out integers of claims, which has led to overly broad inventive concepts being found with no foundation in the patent itself. Further, as pointed out earlier, once integers have been rooted out, their effects, and those of any corresponding features of the alleged infringement, can easily be ignored.

At paragraph 222, the Judge explained what he considered, in general terms, to be an inventive concept:

*"I take the inventive concept or core of the invention to be the new technical insight conveyed by the invention – the clever bit – as would be perceived by the skilled person. This will be assessed by reference to the specification and the evidence."*

However, that explanation raises the questions: "clever in the light of what?"; and "evidence of what?" Again, this test does not appear to be in line with either *Pozzoli* or *Markem*, since it appears to be looking for something which is inventive over the state of the art.

The Judge went on to set out what he considered to be the inventive concept of claim 1 at paragraph 235:

*"... 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."*

So, the features the subject of the non-infringement case were held not to be part of the inventive concept and, as a result, infringement was found by equivalents. The concentration of the buffer solution (the solution being required to maintain a constant level of acidity, which affects coagulation) could apparently have been anything, despite the precision with which it was specified in the claim. And any thixotropic gel could be used, notwithstanding that the claim specified a polyester-based gel.

In the end, one does not know how HHJ Hacon arrived at his conclusion as to what the inventive concept – or "clever bit" – was. To borrow the Judge's own words (at paragraph 223) about the third *Actavis* question, "it is not legitimate just to disregard an integer of a claim without further reasoning." Yet (aside from referring to identification of the "clever bit"), that appears to be just what the Judge did when identifying the inventive concept and indeed answering the third question.

## 5.3 Technetix v Teleste [2019] EWHC 126 (IPEC)

The patent<sup>32</sup> concerned "tap units" that are used to reduce the strength of signals (provided to sophisticated junction boxes) and divide them for individual subscribers of cable TV or internet services. The Judge focused on cable TV in the Judgment. At trial, claim 1, which concerned a modular system that allowed a "directional coupler" to be replaced (so avoiding on site repair), was divided up into seven integers. On a normal construction, the alleged infringement did not have integers (2) and (4) (paragraph 107). So, the Judge went on to consider infringement by equivalents.

At paragraph 116, in finding that the inventive concept was integer (7), the Judge (HHJ Hacon) held:

*"It was common ground that claim 1, if valid at all, depended on integer (7) for its validity. Integer (7) set out the new technical insight, if there was one."*

The Judge had already found that claim 1 lacked novelty over the cited prior art (paragraphs 63 and 78). In the alternative (on assumptions favourable to Technetix, the patentee), it was held to lack inventive step over the same prior art (paragraphs 64/70 and 79/83). So, one is forced to conclude that the Judge was equating inventive concept with inventive step (if any). That is consistent with what the same Judge had said in *Regen* where he referred to "the clever bit".

It would appear to follow that at least this Judge (HHJ Hacon) does not believe that inventive concept is used in the same way for the *Pozzoli* test and for Question i) of *Actavis*. In *VPG Systems v Air Weigh [2015] EWHC 1862 (IPEC)*, the same Judge, when addressing inventive step, held at paragraph 33:

*"The inventive concept is not the same thing as the inventive step."*

And, as can be seen from the quote at the beginning of section 4.2 above, this has to be correct for the *Pozzoli* test to work.

In this respect, it is unfortunate that in *Technetix*, although the Judge referred to *Pozzoli* in his Judgment (paragraph 54), he did not go on and set out the analysis. Had he done so, this difference in approach would have come to light. As it is, one is left with an equivalency test that, for unexplained reasons, appears to depend on the relevant claim's inventiveness.

Before leaving this case, mention too should be made of the Judge's views on integers not within the inventive concept (paragraphs 110-1).

*"I do not accept ... that a patentee must always go through each integer of his claim and the corresponding features of the accused product or process, and wherever an integer of the claim is missing from the accused product or process (or arguably missing), identify its equivalent. ..."*

*All integers of a claim missing from the variant will be relevant to, for instance, whether the inventive concept has been exploited by the variant in substantially the same way to achieve substantially the same result. No integer can be ignored. ..."*

In the author's view, the above statements are hard to reconcile. On the one hand, the Judge states, in effect, that there can be inessential integers but then, on the other hand, he states that no integer can be ignored. If integers are carved out of the claim as not being part of the inventive concept, how is it that they (or corresponding features of the alleged infringement, if any) can impact on that inventive concept?

## 5.4 Marflow Engineering v Cassellie [2019] EWHC 410 (IPEC)

The patent<sup>33</sup> was for a method of installing a fluid using appliance, such as a shower, on a wall. The pipework passed through a "mounting member", or plate, on the outside face of the wall. Claim 1 was split up into eight integers at trial. There were two infringement arguments, which respectively concerned integers (a)/(h) and (e)/(g).

Integer (a) called for "a part of a fluid pipe extend[ing] outwardly of the wall" and (h) for "joining the outwardly extending pipe part to an inlet fitting of the appliance". Relevant here is paragraph 17 of the Judgment, where the Judge recited one of the disadvantages given in the patent of a prior art arrangement:

*"After the pipe parts and integral fittings have been joined, and the mounting plate is secured relative to the wall, the joint is inaccessible."*

In other words, in those arrangements, there was a pipe joint behind the wall after installation.

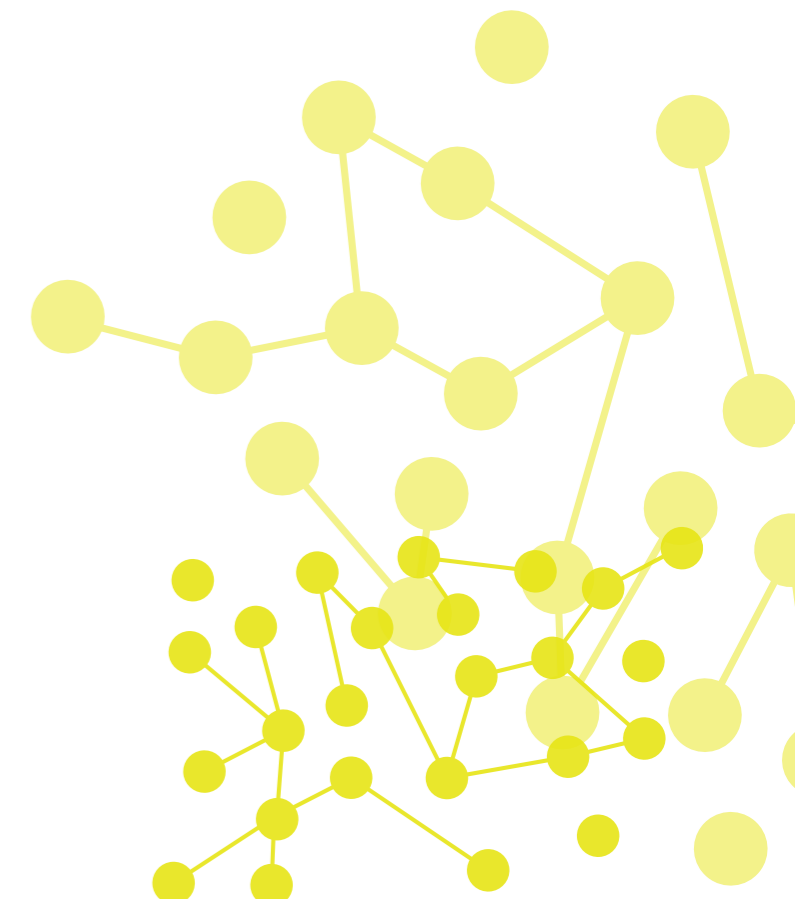
Integers (e) and (g) concerned the way in which the plate on the outside of the wall (referred to in the italicised

quote in the paragraph above), through which the pipes passed, is locked to those pipes. Those integers called for "tightening a locking element", which is on "a locking member", itself in or on the plate. Importantly here, the plate "provid[es] in or thereon, a locking member".

The Judge explained (paragraphs 25-6; 30) the points at issue on infringement:

• *"First, the water pipes in the wall are not connected directly to the inlets of the shower or other appliance. They terminate inside the wall and are connected to what I will call an 'intermediary pipe'. The intermediary pipe passes from the pipe in the wall, through the mounting member or plate, to the shower inlet to which it is attached." (25.)*

• *"Secondly, the intermediary pipe has a screw thread on its periphery. It is fixed to the plate using one nut each side of the plate. The nuts are rotated on the screw thread of the intermediary pipe until they abut opposing sides of the plate, locking the intermediary pipe into a fixed position relative to the plate." (26.) And so, "[t]he issue is whether [the locking member] must be attached to the mounting member or whether it can be attached elsewhere." (30.)*



<sup>31</sup> European Patent [UK] 2,073,862.

<sup>32</sup> UK Patent No. 2,382,473.

<sup>33</sup> UK Patent No. 2,368,888.





On a normal construction, the Judge found (paragraph 29) that, in the alleged infringement, “its intermediary pipe becomes a section of the fluid pipe within the meaning of claim 1”. In relation to the locking feature, he found (paragraph 38):

*“the locking member must be attached to the plate or form an integral part of the plate.”*

Having found that, on a normal construction, the alleged infringement did not have the latter feature (paragraph 58), the Judge went on to consider equivalents.

In considering equivalents (in relation to the locking feature), although the Judge referred (at paragraph 55) to his judgment in *Regen*, he now adopted a different approach to identification of the inventive concept. There is no reference in *Marflow* to “the clever bit”. Instead, the Judge looked to the specification for guidance and concluded that the particular locking means was not part of it. At paragraph 61, the inventive concept was held to be:

*“The idea of using a plate (mounting member) to install a fluid-using appliance by securing the plate to the wall, receiving the fluid pipes extending out of the wall through apertures in the plate and then using a locking means to lock the pipes in the plate.”*

Importantly, note the absence of the words “in or thereon”, which were present in the claim. In that regard, the Court noted (paragraph 62) that the specification contemplated different locking means to that exemplified in the specification (though not necessarily different from that claimed). That approach (of looking to the specification) is at least more in keeping with that adopted in *Markem* and *Pozzoli*. The Court also found that the infringing variant achieved the same advantages as the inventive concept (paragraphs 63-69).

However, by treating integers (a)/(h) in the manner that he did, the Judge glossed over an important point. The different locking means used in the alleged infringement required threaded pipework. As a practical matter, that mandated the infringement having an “intermediary pipe” and a joint behind the wall to connect with the fluid pipe. And that was one of the disadvantages that the patent sought to avoid. Because of the locking means used, the

infringement had, and had to have, a joint behind the wall (whether or not there were unrelated joints elsewhere in the pipework, the possibility of which influenced the Judge’s approach to integers (a)/(h) – see paragraph 29).

The inherent feature of integers (a) and (h) described earlier (no inaccessible joint behind the wall) should not, in the author’s view, have been disassociated from integers (e) and (g). In rebuttal, it might be said that the feature was well known and acknowledged as such in the patent (Judgment, paragraph 18). However, this case would be a perfect example as to why salami slicing a claim, and removing those slices which are CGK to identify an inventive concept, simply cannot be right. This patent was all about a combination of features.

Further, it is unfortunate that again, although the Judge referred to *Pozzoli* when addressing the inventive step attack on the patent (paragraph 41), he did not set out the analysis and identify an inventive concept for that purpose. Had he done so, and relied on the *Pozzoli* guidance set out earlier, a different result on infringement may well have followed.

### 5.5 Eli Lilly v Genentech [2019] EWHC 387 (Pat)

Of this case, Arnold, J. stated in his Judgment (paragraph 3):

*“this is one of the most complex patent cases I have ever tried.”*

However, there is no need for a summary of the relevant claim and facts of the case because the Judge did not need to find infringement by application of the doctrine of equivalents. Consequently, he only briefly considered the *Actavis* questions in case he was wrong on a normal construction.

In dealing with Question i), the Judge asked himself “does the variant achieve substantially the same result in substantially the same way as the invention?” In this case, the variant feature was an antibody that was, not only specific to a particular molecule referred to in the claim (IL-17A/F), but also to another allied molecule (IL-17A/A). He concluded that the answer to the question was yes, but the Judge did not, as part of that exercise, seek to identify an inventive concept. (See paragraph 598(i).) The Judge seems to have viewed the inventive concept as simply being what was in the claim.

With regard to third *Actavis* question (at paragraph 598(iii)), the Judge appeared to be willing to go back to the specification (including the description) to check what the patentee was saying – i.e., whether specificity to an additional molecule was ruled out. He held “that there is nothing in the Patent to indicate that the antibodies should bind to IL-17A/F only when used for therapeutic purposes.” Contrast that with the approach in *Icescape* referred to earlier.

## 6. CURTAILMENT

In other jurisdictions where there is a doctrine of equivalents, constraints have been put on its application through one or both of: prosecution history (file wrapper) estoppel; and a defence of practising the prior art.

What of the UK? Given the approach in some of the cases discussed above to determine the inventive concept, there is clearly a need for some curtailment. However, in the UK, the prosecution history, and practising the prior art, defences have themselves been curtailed.

### 6.1 Prosecution history

Lord Hoffman’s view about reviewing the prosecution history, expressed in *Kirin-Amgen* (paragraph 35), was that “life is too short for the limited assistance which it can provide.” In *Actavis*, Lord Neuberger appeared to have toned that attitude down, saying at paragraph 87 that:

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

In paragraph 88, he went on to identify two non-exhaustive circumstances where it might be appropriate to refer to the prosecution history:

*“(i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored.”*

On the facts in *Actavis*, the prosecution history was held not to assist the alleged infringer. Lord Neuberger stated (paragraph 89):

*“It seems to me clear that the reason why the examiner considered that the claims in the patent should be limited to pemetrexed disodium was because the teaching in the specification did not expressly extend to any other anti-folates. ... even if the examiner was right or at least justified in taking the stance that he did, I do not consider that that consideration can have any bearing on the question whether any pemetrexed salts other than pemetrexed disodium should be within the scope of the patent pursuant to the doctrine of equivalents.”*

Lord Neuberger does not explain why it wasn’t, on the facts, in the public interest to limit the application of the doctrine of equivalents in *Actavis*. Perhaps it reflected a general concern that the examination process does not involve all the enquiries that are made at a full-blown patent trial. Or perhaps it was the nature of the Examiner’s objection. Would a lack of patentability over cited prior art be treated differently?

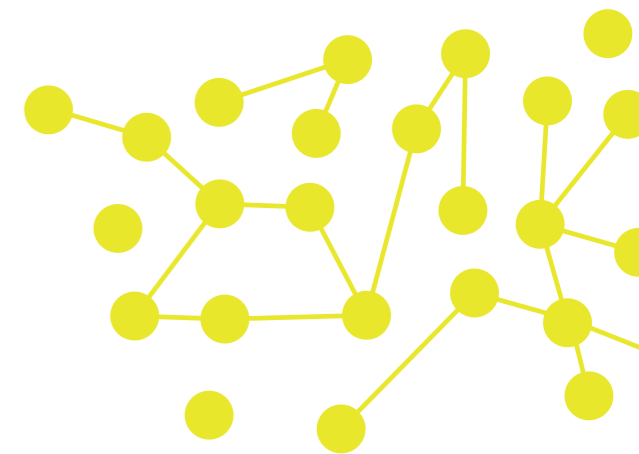
Prosecution history estoppel came up in *Icescape*, where the relevant amendment had been made in response to a lack of novelty objection. At paragraph 79, Lord Kitchin dismissed reliance on prosecution history estoppel for three reasons.

First, he found it impossible to determine whether the objection raised by the Examiner that led to the relevant amendment was a sound one. Second, he found it impossible to determine whether the relevant amendment was necessary to meet the Examiner’s objection. Third:

*“More importantly, it is impossible to discern in the correspondence any suggestion that Ice-World was surrendering an ability to argue that features D and E were inessential or that Ice-World was accepting that the scope of the claims did not extend to a system in which the feed and discharge manifolds were connected in parallel rather than in series.” (A series connection followed from the arrangement of features D and E – see earlier.)*

The upshot of this decision, particularly the quoted passage above, is that the “life is too short” view appears still to be prevalent, though the door has not been shut altogether on prosecution history estoppel.

Note too here the reference to “inessential” features in the quoted passage above. This is consistent with the Court of Appeal’s approach of not seriously trying to find features equivalent/corresponding to integers of the claim, but rather simply ignoring those integers that are not part of the inventive concept. That approach is reflected in other cases referred to above (for example, ignoring the sodium citrate concentration in *Regen*).



Lord Neuberger may have thought that *Actavis* was not a substantial departure from the old law, but disregarding integers is such a departure. Admittedly made before *Kirin-Amgen* (and indeed *Improver*, both of which owe their origins to the older case of *Catnic*<sup>34</sup>) the following quote would have held good prior to *Actavis*: “where it is a question of totally disregarding an explicit feature of a claim, such cases have been extremely rare.”<sup>35</sup>

Returning to prosecution history, the point came up again in *Regen*. In distinguishing *Smith*, cited by the EPO Examiner, *Regen*’s patent attorneys wrote (letter dated 31 May 2013; Judgment, paragraph 254):

“Hence for each tube, a specific combination of a particular tube’s material, particular thixotropic gel and particular anticoagulant is claimed. In addition, depending on the tube used, the anticoagulant is to be present in a specific state (solution or anhydrous) and at a specific concentration.

...

In summary, the primary feature of the processes which distinguishes them from those disclosed in [*Smith*] is the use of specific tubes.”

The anticoagulant referred to is sodium citrate (Judgment, paragraph 58). Claim 1 called for a concentration (molarity) of 0.10M. It also called for a polyester thixotropic gel.

The Judge dismissed the prosecution history argument at paragraph 255:

“I think that the letter of 31 May 2013 satisfies neither requirement specified by Lord Neuberger. There is no issue of construction or scope which is truly unclear if one confines oneself to the specification and claims of the patent, for the reasons discussed above. Nor would it be contrary to the public interest for the letter to be ignored. *Regen* argued before the EPO that the scope of the claim they were advancing did not overlap the disclosure of *Smith*. It does not. That is consistent with *Regen*’s argument on scope before me.”

So, although *Regen* relied on its claimed specific combination of features to distinguish *Smith*, that was not sufficient to tie it down to the specific integers of sodium citrate concentration and type of thixotropic gel within that combination when asserting infringement. The basis for that conclusion is said to be that the claim does not overlap with *Smith* since the latter does not disclose the claimed combination. However, when identifying the inventive

concept, the Judge effectively ignored several of the features of the claimed combination. Whether in accordance with *Actavis* or not, the difference in treatment of the claimed combination when identifying an inventive concept and applying prosecution history estoppel is striking.

## 6.2 Practising the prior art (*Gillette/Formstein/ensnarement*)

With regard to a defence of practising the prior art, well before *Actavis* the UK Courts had, from time to time, acknowledged the so-called *Gillette* Defence. That traces its origins to Lord Moulton’s speech in *Gillette Safety Razor v Anglo-American Trading* (1913) 30 RPC 465, at page 480:

“But he is entitled to feel secure if he knows that which he is doing differs from that which has been done of old only in non-patentable variations such as the substitution of mechanical equivalents or changes of material, shape or size. The defence that ‘the alleged infringement was not novel at the date of the Plaintiff’s letters patent,’ is a good defence in law ...”

Commentators have questioned if it is really a separate defence.<sup>36</sup> The point is that it is only a defence in that there can be no infringement of an invalid patent – i.e., it is not a free-standing defence. Perhaps for that reason, one commentator referred to it as a short cut.<sup>37</sup> In *Gillette* itself, the defence was not applied, the patent being held valid but not infringed. And, in *Fujifilm v Abbvie Biotechnology* [2017] EWCA Civ 1 at paragraph 56, the Court of Appeal recently preferred to see infringement and validity as being decided separately and referred to the “defence” both as a short cut and a cross-check.

There is now another way that the Court could approach this defence. As described earlier, in an inventive step attack in the UK, the Courts will often apply the *Pozzoli* test and that test requires the identification of an inventive concept. On the assumption that the inventive concept is to be ascertained in the same manner for the *Pozzoli* inventive step test and the *Actavis* equivalency test, then there could be a defence as follows. If the patentee has to cast his inventive concept so broadly to catch the alleged infringement by equivalents that the patent fails the fourth stage of the *Pozzoli* inventive step test, then there would be no infringement. And that defence would not require a finding of invalidity. (That would depend upon what the inventive concept was actually found to be.) Indeed, viewing inventive concept as a potential vehicle for such a defence provides a compelling reason for the *Actavis* inventive concept to be the same as that in *Pozzoli*.

One question to resolve for such a defence based on inventive concept would be on whom the burden of proof would fall to show respectively that the *Pozzoli* test was passed or failed. That matter is a point of distinction between the German *Formstein*<sup>38</sup> and US ensnarement defences discussed next.

The Judge in *Technetix* considered the above type of defences at paragraphs 85-101 and 126-133. He specifically referred to *Formstein* and ensnarement and considered that the UK Supreme Court or the Court of Appeal might, at some time in the future, introduce a *Formstein* defence (at paragraph 99). At paragraph 133, he found that “if a *Formstein* defence exists in English law, *Teleste* is entitled to the defence.”

Note that, as the author understands it, the *Formstein* defence, which provides a defence of practising the prior art, or what was obvious over it, is only available in the German infringement Courts as a defence to infringement by equivalents. Were it otherwise, the infringement Court would be adjudicating on validity over which it does not have jurisdiction. This point also reflects the distinction drawn between claim scope (validity) and extent of protection (infringement).

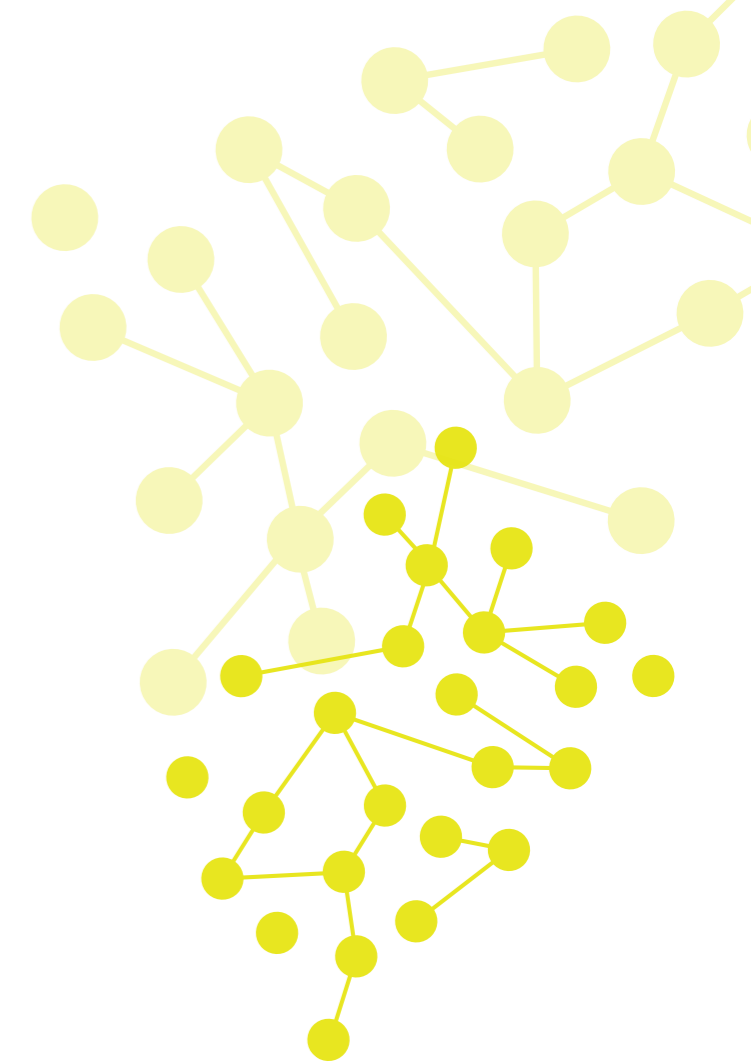
In relation to burden of proof, it is clear that, under German law, the alleged infringer must make out the defence. See *Formstein* itself at page 606<sup>39</sup> and the FCJ (or BGH) decision of 17. 2.1999 - X ZR 22/97 (at paragraph 1.4(f)).

By contrast, the US ensnarement defence puts the burden on the patentee (see *Jang*, referred to below, at page 15). If ensnarement is raised, the patentee will often produce hypothetical claims that it asserts would cover the alleged infringement but are not disclosed by the prior art or obvious over it. Such hypothetical claims are not allowed to introduce new limitations (to avoid the prior art). It is then for the patentee to show that the claims are patentable over the relevant prior art

The difficulty for a patentee in dealing with the hypothetical claim ensnarement rules is illustrated by *Jang v. Boston Scientific Corp. & Scimed Life Systems Inc., No. 16-1275 (Fed. Cir. Sept. 29, 2017)*. The patentee was ultimately unable to produce the requisite claims and his frustration was evident in the unsuccessful documentation petitioning the US Supreme Court in which the patentee described the rules as “Byzantine”.<sup>40</sup>

Apart from the burden of proof difference with *Formstein*, the hypothetical claim approach (where new claims are expressed to take account of equivalents) also gives the alleged infringer a broader defence. The defence is available if a different equivalent from the alleged infringement is not new and/or inventive over the relevant prior art. The more broadly the hypothetical claims are cast, the greater the risk of encompassing the prior art. However, *Jang* confirmed (at footnote 4) that another approach would be to ask if the alleged infringement would itself have been obvious over the prior art.<sup>41</sup> Nonetheless, the hypothetical claim approach appears to be the preferred method for the ensnarement defence analysis. See *Wilson Sporting Goods Co. v. David Geoffrey & Associates* 904 F.2d 677 (Fed. Cir. 1990) at 684.

There is a logical attraction to the US hypothetical



claim approach in that it gives the broader defence described above. If the scope of such a claim, as a consequence of covering the infringement, must also cover other equivalents that are not patentable over the prior art, why shouldn’t there be a defence? Further, as it is the patentee who is asserting infringement and that the patent should be afforded broader protection, why shouldn’t the onus be on the patentee to show that such a hypothetical claim would have been patentable with respect to the prior art? However, the only judicial indication to date is that the UK Courts might consider a *Formstein*-type defence. And the dos and don’ts of hypothetical claim drafting might prove to be cumbersome and time-consuming when compared with the *Formstein* approach.

Before leaving this topic, insufficiency merits a mention. It is possible that, using the hypothetical claim approach (or the inventive concept approach), an argument might be developed that a defence should be available because the hypothetical claim (or broadly cast inventive concept) was not enabled across its breadth. The point is not developed further in this article, not least because this “*Biogen*” insufficiency” could easily be the subject of a paper on its own. (That would include *Lundbeck*, discussed above.)

<sup>34</sup> *Catnic v Hill & Smith*, House of Lords, [1982] RPC 183.

<sup>35</sup> *Patents for Inventions, Blanco White*, 5th edn. at 2-111.

<sup>36</sup> E.g., Terrell, 18th edn, 14-266.

<sup>37</sup> *Patents for Inventions, Blanco White*, 5th

edn. has it under a heading of “short cuts” at 4-208.<sup>38</sup> Decision of the FCJ [April 29, 1986

- X ZR 28/85 – *Formstein*; “*Formstein*-neinwand”), reported in English at [1991]

RPC 597. “short cuts” at 4-208.

<sup>39</sup> *Ibid.*

<sup>40</sup> www.supremecourt.

<sup>41</sup> See *Conroy v. Reebok Intern., Ltd.*, 14 F.3d 1570, 1576-77 [Fed. Cir. 1994].

<sup>42</sup> *Biogen v Medeva* [1997] RPC 1.



## 7. IMPACT ON INTERIM INJUNCTIONS, “CLEARING THE WAY” AND ARROW’ DECLARATIONS

In the UK, generic pharmaceutical companies are well advised “to clear the way” – i.e., seek a declaration of non-infringement and/or revoke the relevant patent prior to launch. Failure to do so may substantially increase the risk of an interim injunction. See paragraphs 38-40 of *SKB v Apotex* [2003] EWCA Civ 137 – at paragraph 40:

*“The Judge was, in my view entitled to take into account when deciding to maintain the status quo that Apotex walked into the situation that they find themselves in with their eyes open to the risk that they were taking.”*

However, clearing the way may not be as straightforward as starting one set of proceedings. The EPC allows for the filing of divisional applications provided that an application, including a divisional application, is pending. “Cascading divisionals” can be filed several years after the original application, but still retain the original priority date. As a consequence, competitors may be unable to determine the extent of patent protection that may exist in the future over a specific product or process that it wishes to launch/use. This has proven to be a significant issue in the pharmaceutical sector.

In order to allow potential competitors to obtain commercial certainty (in the above circumstances), the UK Courts are prepared to grant a declaration that a particular product or process was not new or was obvious at the relevant priority date. *Fuji* (referred to earlier)<sup>43</sup> confirmed the availability in English law of these “Arrow declarations”.<sup>44</sup> Interestingly, the author understands that they may well not be available in Germany, it not being clear which Court in a bifurcated system would/could grant such a declaration.

With the advent of a UK doctrine of equivalents, one can see how Arrow declarations may become of increasing importance with regard to clearing the way for generic pharmaceutical companies. The potential problem of cascading divisionals has now been compounded by the uncertainty that accompanies a doctrine of equivalents,

particularly one relying on the identification of an inventive concept in the manner described in some of the cases above.

## 8. CONCLUDING REMARKS AND THE FUTURE

These are relatively early days for the UK Courts with respect to applying the *Actavis* equivalents test. However, in the author’s view, in some of the cases described above, the Courts have:

- *been too willing – indeed eager – to ignore claim integers altogether (inessential integers);*
- *paid too little attention to what the patentee says in the specification is the invention (c.f., *Pozzoli and Markem*); and*
- *unjustifiably assessed inventive concepts by reference to some or all of the relevant state of the art (again, c.f., *Pozzoli and Markem*) and thereby, for example, ignored features, seemingly CGK when viewed in isolation, which contributed to the inventive concept.*

Lord Neuberger clearly did not intend or think that *Actavis* would have the profound effect that it has by substantially relegating the status of patent claims. Moreover, the balance required by Article 1 of the Protocol to EPC, Article 69 has clearly been shifted in the UK in the direction of legal uncertainty. Parties and their advisors are being left to distil some generalised (though perhaps not amorphous) idea of what the extent of a patent’s protection might be.

On the other hand, in the more recent *Marflow* and *Eli Lilly* cases, the exercise of identifying broad inventive concepts by reference to the state of the art was not conducted. And, the judicial acknowledgement that a *Formstein* defence might exist in the UK has to be viewed as a welcome indication that the doctrine of equivalents will be constrained in some manner so as to achieve equitable results.

## 9. POSTSCRIPT

After the author finished writing the article above, HHJ Hacon gave Judgment in an entitlement case, *BDI v Argent* [2019] EWHC 765 (IPEC). If it wasn’t clear enough already, it should be in the light of that case that the issue of how to identify an inventive concept needs to be considered urgently by the Court of Appeal or Supreme Court. It is nonetheless appropriate to point out, at this juncture, that it is the arguments put before the Judge by the parties’ representatives that shape a Judgment. In this postscript, the author has confined himself to making two points.

First, in *BDI*, the different contexts in which the phrase “inventive concept” arises was discussed. The Judge held (in relation to entitlement, equivalents and inventive step; paragraph 21) that “*If the meaning given to ‘inventive concept’ differs at all as between Yeda, Actavis and Pozzoli, it is not by much.*” In the author’s view, this misses the point. As discussed above, the phrase *should* have the identical meaning for these three purposes but it is clear that the Courts in *Icescape*, *Regen*<sup>45</sup> and *Technetix* have not applied the same test for equivalents as set out in *Pozzoli*. The Judge did, however (and correctly, in the author’s view), consider the use of the phrase in unity as a special case.<sup>46</sup>

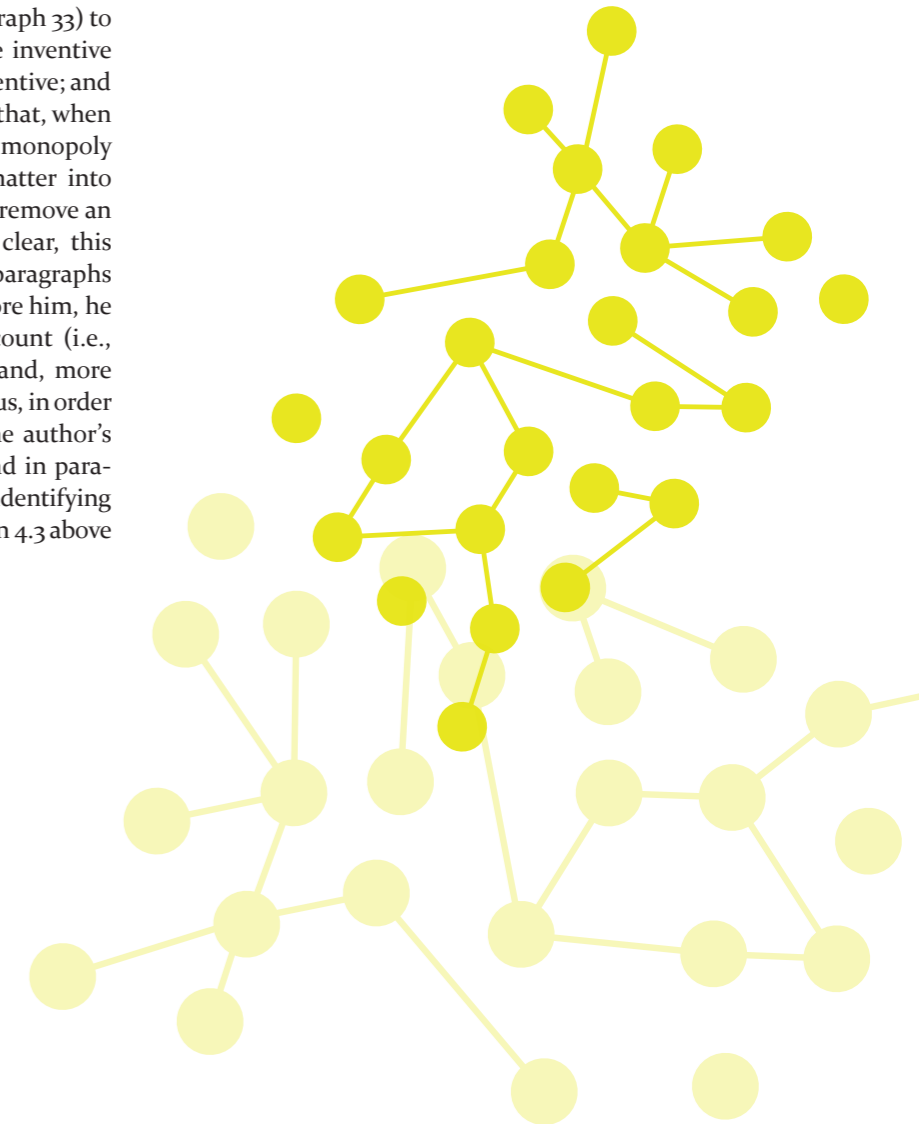
Second, the Judge in *BDI* also referred (paragraph 33) to *Markem* because: each party asserted that the inventive concept contended for by the other was not inventive; and in *Markem*, Jacob, L.J. had held (paragraph 88) that, when there is a self-evidently and unarguably invalid monopoly being claimed, the Court should take that matter into account when exercising its wide discretion to remove an invalid monopoly. Although it is not wholly clear, this may have led the Judge in *BDI* to conclude (paragraphs 38-9) that, had there been expert evidence before him, he would have: taken the relevant CGK into account (i.e., presumably, stripping it out, as in *Icescape*); and, more generally, considered what may have been obvious, in order to identify the inventive concept. This, in the author’s view, is clearly not what Jacob, L.J. had in mind in paragraph 88 of *Markem* as the correct approach for identifying an inventive concept (see too the quote in Section 4.3 above from paragraph 103).



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acted in a large number of IP disputes, which have often involved concurrent overseas litigation, and many of which has been in the life sciences sector. Additionally, John has acted in a substantial number of transactions where IP has been at the centre and drafted many commercial agreements involving IP.



<sup>43</sup> *Fujifilm Kyowa Kirin Biologics Co, Ltd v AbbVie Biotechnology Ltd & Another* [2017] EWCA Civ 1.

<sup>44</sup> Named after *Arrow v Merck* [2007] FSR 39.

<sup>45</sup> The Judge in *BDI* even referred (paragraph 27) to his Judgment in *Regen*, seemingly as illustrative of his finding at paragraph 21 about usage of the phrase in the three contexts of entitlement, inventive step and equivalents.

<sup>46</sup> The Judge held (in relation to unity; paragraph 28) that “Those who drafted art.82 and rule 44 EPC had in mind a ‘general inventive concept’ which is not similar to the inventive concept contemplated by the House of Lords in *Yeda*.” For reasons already explained, the author concurs that unity has its own definition but would not have chosen to compare it with the explanation of “inventive concept” given by Lord Hoffmann in *Yeda*.

<sup>47</sup> That inference is reinforced by paragraph 40, where the Judge held that “... where both sides’ witnesses stated that some technical matter would be known to the skilled person, I have treated it as an agreed fact.”