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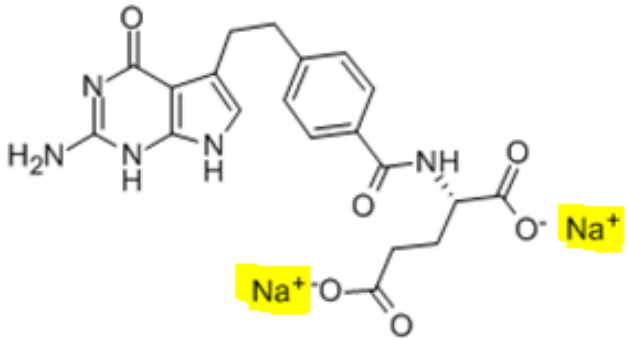
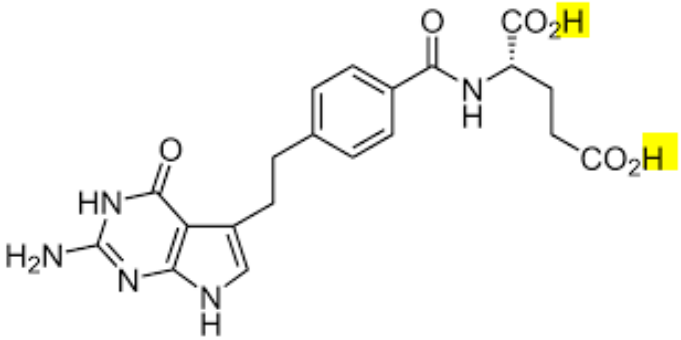
Doctrine of Equivalents





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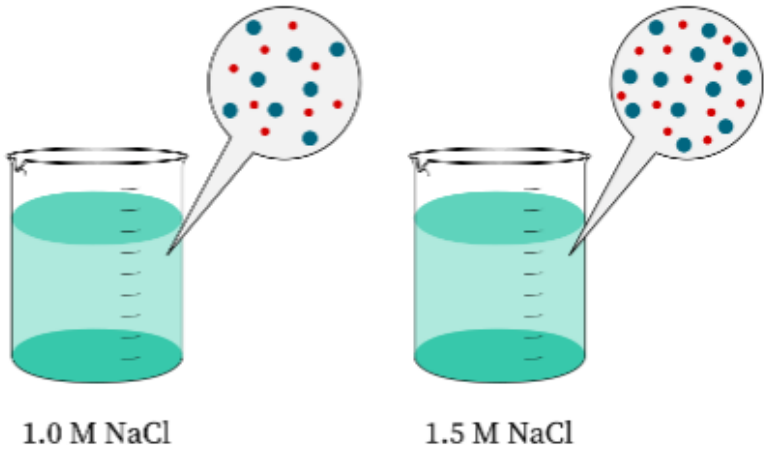
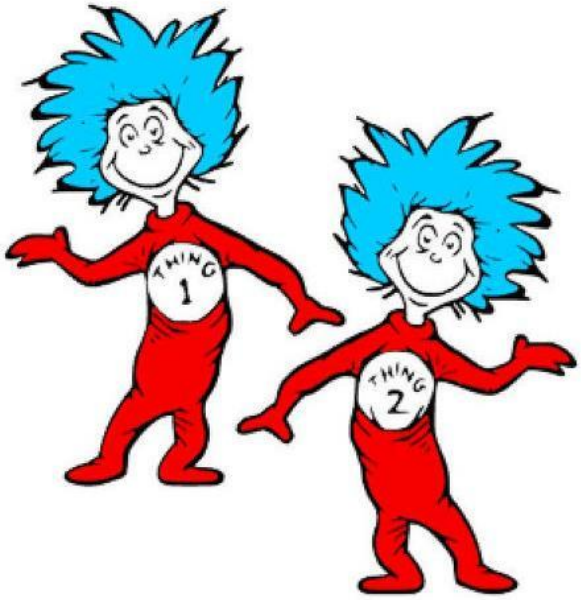
Overview

- What is the doctrine of equivalents?
- Where is it applied?
- What was the UK approach previously?
- Actavis v Eli Lilly
- Current approaches
- Comment



What is the doctrine of equivalents?

- A legal rule that allows a court to hold a party liable for patent infringement even though the infringing product or process does not fall within the **literal** scope of a patent claim, but nevertheless is **equivalent** to the claimed invention



What is the doctrine of equivalents? (2)

- Its purpose is to prevent an infringer from stealing the benefit of a patented invention by changing only minor or insubstantial details of the claimed invention while retaining the same functionality

Where is it applied?

- Operates in some form in several countries e.g. US, Germany and various other European countries and Japan

US

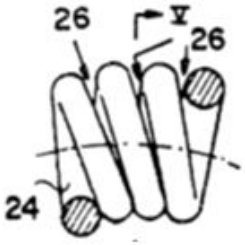
- Analysis is applied to individual claim limitations, not to the invention as a whole
- Legal test is whether the difference between the allegedly infringing feature and the claimed feature is "insubstantial"
- Limited by prosecution history estoppel
- Proposed equivalents must not cover the prior art

Where is it applied? (2)

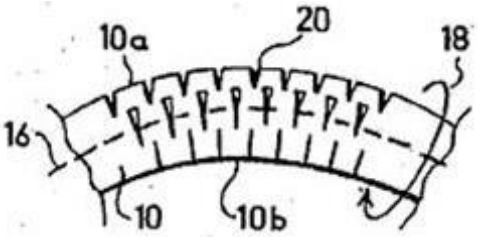
Germany

- Applies a 3-step test known as the Schneidmesser questions:
  - Does the variant solve the problem with means that have the same effect?
  - Would the skilled person have realised this at the priority date?
  - Are the considerations that the skilled person applies drawn from the technical teaching of the patent?
- Must also pass the Formstein test:
  - Does the variant lack novelty or inventiveness?
- No prosecution history estoppel

What was the UK approach previously?



Improver Questions (1990)



- **Q1**. Does the variant have a material effect upon the way the invention works?
- **Q2**. Would this have been obvious at the patent publication date to a skilled person?
- **Q3**. Would the skilled person nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention?

What was the UK approach previously? (2)

Kirin-Amgen v Hoechst [2004] UKHL 46

- The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance.

What was the UK approach previously? (3)

European Patent Convention – amended 2007

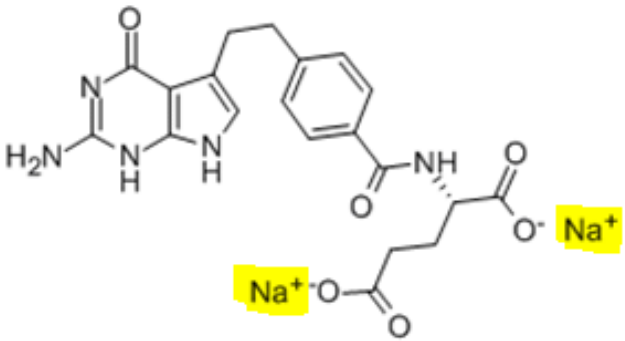
- Protocol on the Interpretation of Art 69(1) EPC (extent of protection):
  - Scope of protection not to be limited by the literal meaning of the claims
  - Due account shall be taken of any element which is **equivalent** to an element specified in the claims

Actavis v Eli Lilly [2017] UKSC 48

- **Patentee**: Eli Lilly found a way to reduce toxicity of anti-cancer drug pemetrexed by administering it in combination with vitamin B12

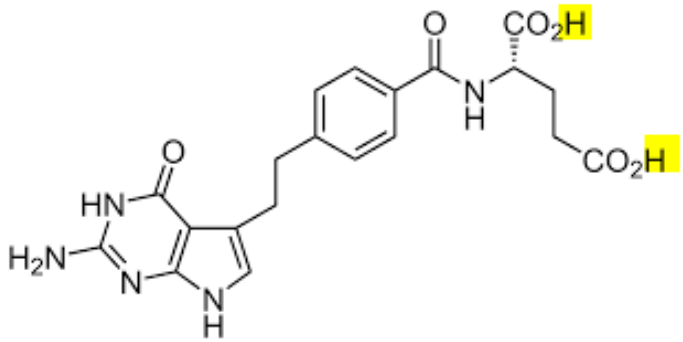
- **EP 1313508 B1**: concerns the use of the salt pemetrexed disodium in combination with vitamin B12

1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin.



Actavis v Eli Lilly (2)

- Actavis' generic products contained either the diacid, the dipotassium salt or the ditromethamine salt of pemetrexed as the active ingredient



- **Patents Court**: Claims not infringed in the UK, or in France, Italy or Spain

- **Court of Appeal**: Indirect infringement but no direct infringement

Actavis v Eli Lilly (3)

Supreme Court Judgment - Claim Construction & Scope of Protection

- Infringement best approached by addressing two issues through the eyes of the person skilled in the art:

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

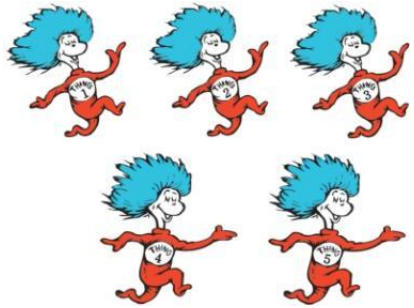
- **ii**. Does the variant nonetheless infringe because it varies from the invention in a way which is immaterial?

- If the answer to either question is "**yes**",
  - **there is infringement**

- Otherwise,
  - **there is not**

Actavis v Eli Lilly (4)

- On issue (i) clearly the Actavis products do not infringe



- For issue (ii) the Improver questions were reformulated:

- **Q1**. Does the variant achieve substantially the same result in substantially the same way as the invention?

- **Q2**. Would it be obvious to the skilled person, 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?

Actavis v Eli Lilly (5)

- **Q3**. Would such a reader 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?

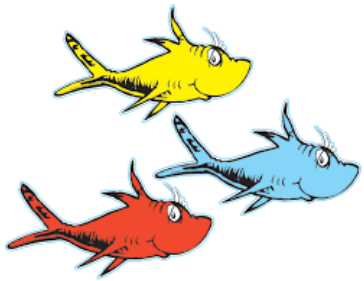
- To show non-literal infringement the answers must be
  - "**yes**", "**yes**" and "**no**"

Actavis v Eli Lilly (6)

Was There Non-Literal Infringement?

- **Q1**. ('Is it an equivalent?') - Actavis products achieve substantially the same result in substantially the same way
  - "**yes**"

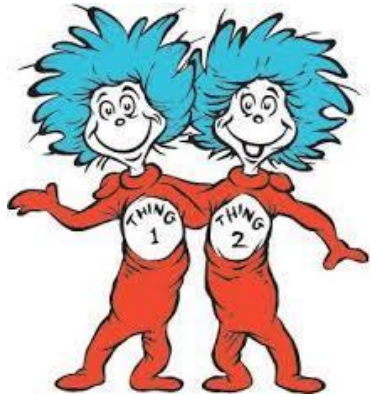
- **Q2**. ('Can the skilled person tell from the patent, with knowledge at the date of infringement, whether it's an equivalent?')
- – Under old approach there would have been no infringement since it would not have been obvious that substituting other salts would work, but knowing that they do work it is obvious that they do so in substantially the same way
  - "**yes**"



Actavis v Eli Lilly (7)

- **Q3**. ('Did the patent nonetheless exclude the equivalent?') – Less focused on the claim language and considering the whole specification at the infringement date
  - "**no**"

- Direct infringement (established under UK, French, Spanish & Italian law)



Actavis v Eli Lilly (8)

Prosecution history estoppel

- During prosecution, the claims were limited first to pemetrexed and then to pemetrexed disodium
- Court considered that the contents of the prosecution file did not justify departing from the conclusion of infringement. On this point it indicated:
- "reference to the file would only be appropriate where
- (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or
- (ii) it would be contrary to the public interest for the contents of the file to be ignored"

Current approaches

- Since Actavis v Eli Lilly there have been 14 cases where the DoE has been pleaded
- Of those 14, there were 10 cases in which infringement under the DoE was found
- However, in only 4 of those 10 cases was the relevant patent also held valid
- 5 cases where prosecution history was relied on, all but one were unsuccessful in defending an infringement claim

Current approaches (2)

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

- Estar process differed in two features from the claimed invention:
  - (i) the gel in the separation tube, and
  - (ii) the molarity of the sodium citrate solution was 0.136 M, not 0.10 M.

- **Multiple differences** – should be considered **together**
- **Numerical limitations** – **DoE applies**

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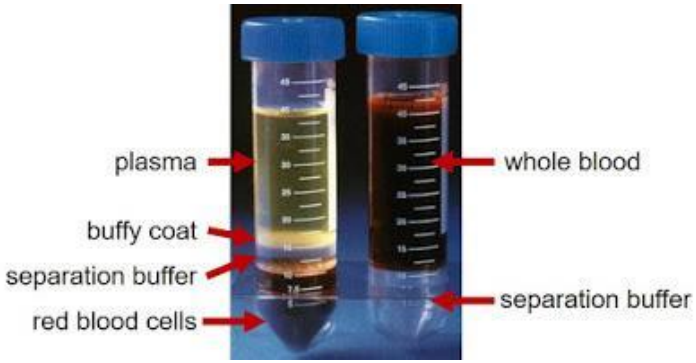

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Current approaches (3)

Regen Lab v Estar - Applying the Actavis Questions:

- **Q1**. Exploitation of the inventive concept is not affected by whether the thixotropic gel was polyester-based or not, nor by the molarity of the sodium citrate solution being 0.136 M instead of 0.10 M

- **Q2**. Expert view that it achieves substantially the same result in the same way corresponded to that of the skilled person at the priority date

- **Q3**. Not a sufficiently clear indication in the specification or from common general knowledge that strict compliance with the figure of 0.10 M was intended

  - **Would have been infringed according to DoE**

Current approaches (4)

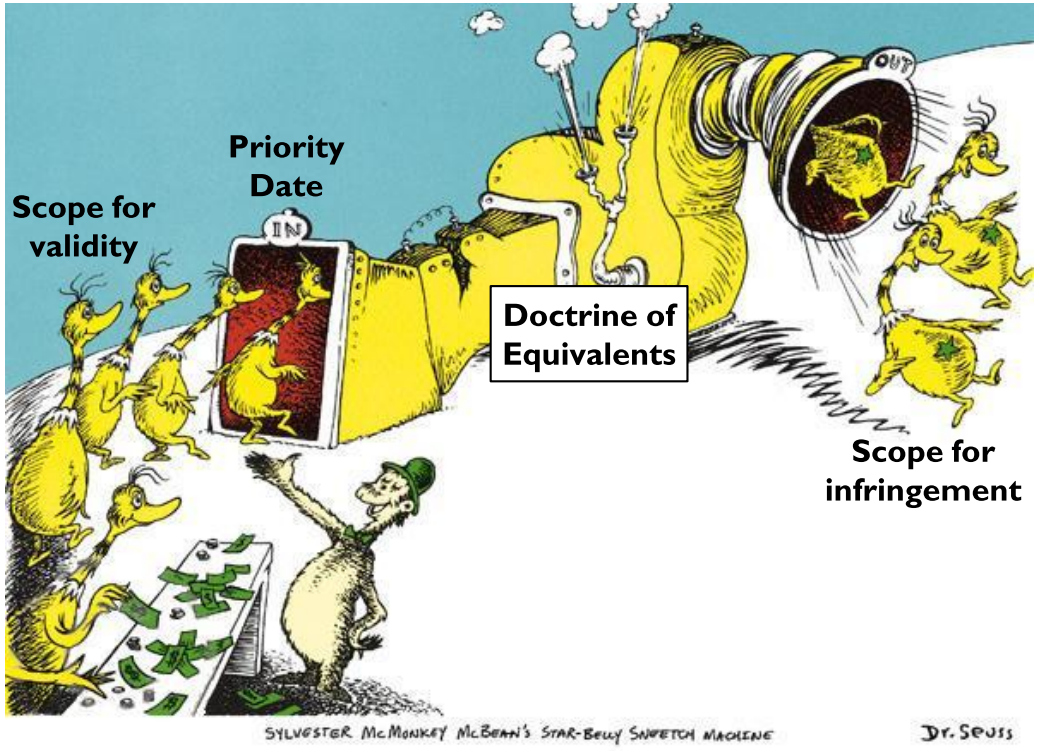
Regen Lab v Estar – comment:

- Focus on the inventive concept
- Numerical limitations treated no differently
- Can still infringe even if multiple claim features are missing, provided utilising inventive concept
- Recourse to prosecution history had no effect on claim scope, even though specific concentration of sodium citrate argued as a novel feature over prior art

Current approaches (5)

Formstein Defence?

- Actavis v Eli Lilly did not address validity – is there a role for equivalents?
- Can a patent be valid over prior art (or an obvious modification thereof) which would fall within the scope of the claims under the Actavis questions? (Gillette Defence)



Current approaches (6)

Technetix v Teleste [2019] EWHC 126 (IPEC)

- Patent found to be invalid in view of prior art
- On infringement, Teleste's defence argued that "*if its product fell within the scope of claim 1, it was entitled to a defence to infringement if the product lacked novelty or inventive step over the prior art*"
- Teleste would have been entitled to a Formstein defence, if such a defence existed in English law, since the product would infringe under the DoE, but not the normal interpretation of the claim, and that based on the expert evidence the product would not be inventive over the common general knowledge.

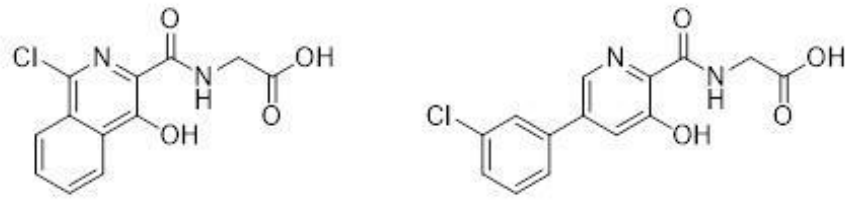
technetix

TELESTE

Current approaches (7)

FibroGen v Akebia [2020] EWHC 866 (Pat)

- Judge found 5 of 6 patents invalid for insufficiency
- Then considered if Vadadustat infringed Claim 17A (Compound C) of EP 2289531



Compound C Vadadustat

- **Inventive concept** is a matter of **interpretation** and whether the **variant achieves the same result in the same way** is partly a question of fact and therefore the **burden of proof** for this test lies with the **patentee**

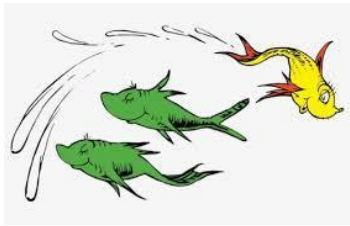
FibroGen

Akebia® THERAPEUTICS

Current approaches (8)

FibroGen v Akebia [2020] EWHC 866 (Pat)

- Inventive concept not **any** compound that treats renal anaemia by inhibiting HIF-PH as argued by the claimant but the **use of the specific compound C** for treating renal anaemia by inhibiting HIF-PH
- Substantially the same result in substantially the same way?
  - Necessary to consider the structure of the respective molecules and their mechanisms of action
- Vadadustat had a "*quite different*" structure to Compound C and not proven that the molecule achieved substantially the same result in substantially the same way (Q1)
- Clear that the patentee intended that strict compliance with the normal meaning of "Compound C" was an essential requirement of the claim (Q3)
  - **No infringement according to DoE**



Current approaches (9)

FibroGen v Akebia – comment:

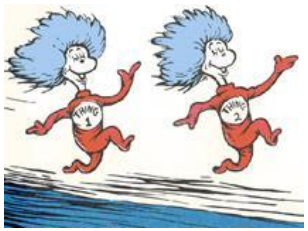
- Appears that Lord Arnold has tried to temper the effects of the DoE in this judgment
- Patentee must prove the alleged infringement provides substantially the same result as the invention and in the same way
- Claim limitations, at least those based on validity, can impact later equivalence arguments
- Not in the public interest to ignore prosecution history that contradicts equivalence arguments

Overall Comment

- Currently the application of the DoE in the UK is somewhat unpredictable but this should settle down over the next few years
- Will numerical limitations ultimately be given more heed as they are in Germany?
- Searching – consider potential equivalents for UK FTO
- Drafting:
  - May include a more general framing of the nature of the invention for subsequent use in assessing the i. concept
  - Remains important to avoid unnecessary suggestions that particular features are essential
  - May expressly exclude undesired variants to avoid a broader claim scope with possible validity problems in any subsequent infringement action

Comment (2)

- Do 'work-arounds' still exist? Any variant which achieves substantially the same result in substantially the same way, could infringe, regardless of the wording of the claim
- Why should you be able to capture a variant that was not known to be an equivalent at the priority date? Is this fair to the public?
- Does the DoE reward bad drafting?



Thank you!

Questions?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