



EUROPEAN PATENT LITIGATORS ASSOCIATION (EPLIT)

ACTAVIS V LILLY

MILAN, 14 MAY 2018

EUROPEAN PATENT LITIGATORS ASSOCIATION

Actavis UK Limited and others (Appellants) v Eli Lilly and Company
(Respondent)

Eli Lilly and Company (Appellant) v Actavis UK Limited and others
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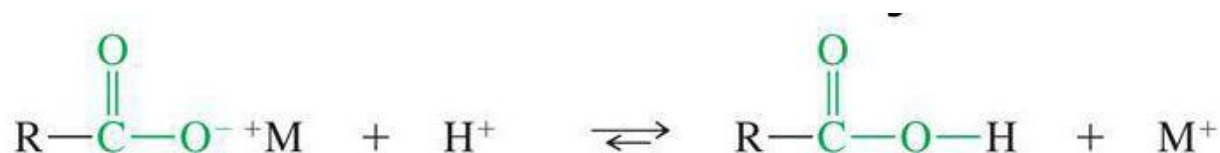
Eli Lilly and Company (Appellant) v Actavis UK Limited and others
(Respondents)

[2017] UKSC 48



Technical Synopsis

- Eli Lilly's patent claimed the use of pemetrexed disodium in combination therapy with vitamin B12 for inhibiting tumor growth (Swiss-type claim and a product claim)
- The application as filed claimed antifolates in general. The claim had to be restricted in view of prior art. There was only support for pemetrexed disodium, and not pemetrexed generally
- Pharmaceuticals are often used in the form of salts (such as sodium or potassium salts) for reasons of ease of dissolution, formulation, stability and the like
- The nature of the salt may affect stability, toxicity, solubility, dissolution rate and bioavailability, but does normally not affect its pharmaceutical activity



Synopsis

- Eli Lilly – patentee claiming pemetrexed disodium
- Actavis – maker of pemetrexed -free acid, -ditromethamine, -dipotassium
- Patents Court found that Actavis products did not directly or indirectly infringe in GB, FR, IT and ES
- Court of Appeal allowed Lilly’s appeal – but only for indirect infringement
- Lilly appealed to Supreme Court against decision of no direct infringement
- Actavis cross-appealed to Supreme Court against the decision of indirect infringement
- Lilly appeal allowed – direct, and if not indirect, infringement
- Actavis appeal dismissed



Issues

- Reviewed earlier UK case law on infringement
 - Catnic (purposive construction - Diplock)
 - Improver (Protocol questions - Hoffmann)
 - Kirin Amgen v TKT (purposive construction is the “bedrock” and Improver only guidelines - Hoffmann)
- Reformulated assessment of scope of protection because the old questions conflated claim interpretation with infringement:
 - *Does the variant infringe any of the claims as a matter of normal interpretation?*
 - *If not, does the variant nonetheless infringe because it varies from the invention in a way or ways which is, or are, immaterial?*
- Created limited file history estoppel



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New test for equivalents

- 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**?



Subsequent cases

Mylan v Yeda [2017] EWHC 2629 (Pat) Arnold J

- “Normal interpretation” is purposive construction – confirmed in subsequent cases

Fischer & Paykel v ResMed [2017] EWHC 2748 (Ch) Meade QC

- Followed Mylan in the absence of any higher guidance
- Confirmed that Actavis requires regard for the “invention” and not just the claims
- No view expressed on anticipation by equivalents...

L’Oreal v RN Ventures [2018] EWHC 173 (Pat) Carr J

- “Normal interpretation” is purposive construction – referred to previous cases
- Choice of one version from all disclosed embodiments limits the claim scope - but avoided specifically relying on supporting German case law
- Limited implications of file wrapper estoppel
- No view expressed on anticipation by equivalents...





Now over to the panel...



The Netherlands

Dijkstra v Saier – Supreme Court – 22 December 2006

- The patentee may only rely on the examination file if the skilled person, after studying the description and drawings, has reasonable doubt as to the meaning of the claims
- Third parties may always rely on the examination file

Medinol v Abbott – Supreme Court – 4 April 2014

- Literal interpretation of the claims is to be avoided
- Confirms that therefore the inventive concept is a point of view to be taken into account
- Inventive concept determined from the perspective of the skilled person on priority date
- Determination of infringement (equivalents) on date of infringement



The Netherlands

Eli Lilly v Teva – Court of Appeal The Hague – 8 May 2018

- The skilled person would recognize that nature of the cation is not relevant
- Examination file confirms that Lilly wanted broader protection – claim amendments in view of Art. 123(2) EPC do not create estoppel if not occasioned by technical reasons
- Function-way-result

Resolution Chemicals v Shionogi & AstraZeneca – Advocate General – 24 November 2017

- Claim 1: Rosuvastatin or a non-toxic pharmaceutically acceptable salt thereof
- Description [0007]: The term “a non-toxic pharmaceutically acceptable salt thereof” refers to a salt in which the cation is an alkali metal ion, an alkaline earth metal ion, or an ammonium ion. Examples are Sodium and calcium are preferred.
- Does rosuvastatin zinc infringe?
 - District Court The Hague – 15 July 2015: no
 - Court of Appeals The Hague – 16 February 2016: yes
- Supreme Court decision expected end of May 2018



Italy

Italian Supreme Court decisions on DoE (2004, 2011, 2012, 2015, 2016)

Test for establishing infringement by equivalents:

- does the allegedly equivalent feature allow to obtain the same final result as the claimed one?
- does the allegedly equivalent feature
 - show an inventive character compared with the patented one?
 - form part of the state of the art of the patented one? (Turin appeal court, 2012)

File history estoppel in Italian case law (e.g. Milan court 2015)

- Interpretation of scope of protection must be compatible with patentee's behaviour during examination/limitation
- Not possible to interpret "into" the claim subject-matter (a) excluded by the patentee of his own volition (b) the exclusion of which is essential for claim's validity



Italy

Pemetrexed (Milan court 2017)

- File history shows that claims were intentionally limited by Lilly (to obtain valid patent)
 - Formal reasons for limitation are irrelevant/outweighed by intentions (objective conduct) of patentee
 - Interpretation extending to other pemetrexed salts would amount to abuse by patentee + prejudice third parties' legal certain right
- scope of protection **cannot** extend to other pemetrexed salts, not even by equivalents

What about UK supreme court decision?

- Different defendants; no contractual relationship between GB and IT defendants
- Immediate applicability of GB decision to IT territory: controversial (!)
- GB product different from IT product
- Evidence on record + technical debate in IT proceedings go beyond evidence/arguments in GB proceedings



Germany

Long History of applying the Doctrine of Equivalence

Schneidmesser Questions (FCJ, March 2, 2002 – *Schneidmesser I, II (Cutting Blade I, II)*)

- Does the modified embodiment solve the problem underlying the invention by means which have objectively the same technical effect?
- Was the skilled person enabled by his expertise on the priority date to find the modified means as having the same effect?
- Are the considerations that the skilled person 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)?
- Is the modified embodiment anticipated or made obvious by the state of the art? (Formstein defense)?

No Prosecution History Estoppel in principle (FCJ *Kunststoffrohrteil* 2002)

- „For determining the scope of protection of a patent events in the grant procedure which preceded the grant of a patent are in principle irrelevant“.

Dedication to the Public (FCJ *Okklusionsvorrichtung* 2011)

- If the description discloses several possibilities of how a certain technical effect can be achieved, but only one of these possibilities has been included in the patent claim, the use of one of the other possibilities does not usually constitute an infringement of the patent by equivalent means.



FRANCE

Test for the infringement by equivalent means in France:

A means that does not identically reproduce the patent claims constitutes an infringement by equivalents when the following conditions are fulfilled :

- **Preliminary condition:** the function of the means covered by the patent has to be novel. When the function is not novel, the court will not apply the doctrine of equivalents
- **1st condition:** the means performs the **same function** as the patented means :
 - same “first technical effect”, i.e., the effect directly and immediately produced by the the means for achieving the result (different from the result)
- **2d condition:** the means achieves the **same results** as the patented means:
 - the nature of the results has to be identical,
 - BUT, the quality and degree of the results may not be the same



FRANCE

Test for the infringement by equivalents is an **objective test**:

- **Obviousness** of the modified means for the person skilled in the art is **NOT a criteria** under French law for the analysis of the infringement;
- The **intention** of the patentee is **NOT taken into consideration**
- **However, French courts refer to prosecution history**



Equivalence is appreciated in an objective manner



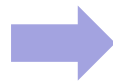
FRANCE

What a French court would have decided in the Actavis v. Eli Lilly case?

- Preliminary condition : **the function of the means must be novel**

1st interpretation: Pemetrexed disodium was known for its function of inhibition of tumor growth. Therefore, its function was NOT NOVEL at the filing date of EP 1 313 508.

Even if the function of pemetrexed diacid is the same as the function of pemetrexed disodium, i.e., inhibition of tumor growth – this function was not novel – Therefore, a French court would consider the Actavis product (based on pemetrexed diacid) as not infringing.



NO INFRINGEMENT



FRANCE

What a French court would have decided in the Actavis v. Eli Lilly case?

- Preliminary condition : **the function of the means must be novel**
2d interpretation: the patent is a combination of known means: pemetrexed disodium salt with vitamin B12
The known means cooperate together with a **global function which is novel**

The UK Supreme Court followed that interpretation, referring to a decision of the French Court of Cassation of September 15, 2009:

“the Court of Appeal, which defined the **new function covered by the combination of means** of the patent, and found, (...) that the device complained of, although different in form, **fulfilled the same** with a view to achieving a **result of the same nature**, (...) the existence of acts of infringement”

- The global function of pemetrexed disodium with vit B12 is new
- The function of pemetrexed diacid is the same as pemetrexed disodium
- Achieve a result of the same nature

➔ INFRINGEMENT



FRANCE

What a French court would have decided in the Actavis v. Eli Lilly case?

- **Reference to prosecution history?**

Initial claim: antifolate in combination with a methylmalonic acid lowering agent

Objection for lack of support

Modified claim: pemetrexed disodium salt ..in combination with vit. B12 or a pharmaceutical derivative thereof

French court would have concluded that the patentee may not extend the scope of its claims to pemetrexed diacid as it voluntarily limited the scope of its claim to overcome an objection

 NO INFRINGEMENT





Questions

