# CASE NOTE ON THE CASE OF NOVARTIS V. FOCUS

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## CITATION NUMBER

[2016] EWCA Civ 1295

## PARTIES

| Claimants/Appellants | Defendants/Respondents |
|---|---|
| (1) Novartis AG | (1) Focus Pharmaceuticals UK Ltd |
| (2) LTS Lohmann Therapie-Systeme AG | (2) Actavis Group PTC EHF |
| (3) Novartis Pharmaceuticals UK Ltd | (3) Actavis UK Ltd |
| *AND* | *AND* |
| (1) Novartis AG | TEVA UK Ltd |
| (2) LTS Lohmann Therapie-Systeme AG | |
| (3) Novartis Pharmaceuticals UK Ltd | |

## PATENT IN QUESTION

It is a European Patent (UK) numbered 2,292,219 which is entitled as ***"Transdermal therapeutic system for the administration of rivastigmine".*** It is used for preventing, treating or delaying the disease of Alzheimer from developing further.

## FORUM (ORIGINAL / APPELLATE)

Forum is Appellate. This case lied in the Court of Appeal which was an appeal from the High Court of Justice Chancery Division.

## FACTS

It is the case of the Appellants that the Defendants infringed their Patent (Patent in question). The defendants in their defense denied all allegations and instead pleaded for revocation of the Appellants' Patent based on the grounds of *added matter, obviousness and insufficiency*.

The judgment in the original case delivered by Mr. Justice Arnold held that the patent acquired by the Appellants had no *inventive step* and was also not valid for *added matter*. It is also noteworthy that the patent was opposed by 13 opponents in the original case. This judgment is an appeal against the abovementioned decision.

The disputed patent *"Transdermal therapeutic system for the administration of rivastigmine"* had a single claim regarding *rivastigmine* which is to be used for preventing, treating or delaying the development of Alzheimer's disease. *Rivastigmine* was to be administered in a transdermal therapeutic system i.e., a patch, which was required at a particular starting dose.

There was no mention of a starting dose of *Rivastigmine* in the original application filed by Appellant unlike its mention in the Patent. The only mention of its dose stated that this invention allowed a higher starting dose and therefore was effective in reducing number of titration[i] steps to reach the suitable therapeutic dose. The application filed only offered the structure and arrangement of the transdermal patch which according to the Appellants were the core of their invention. Nevertheless, the actual Patent revealed that the starting dose of

*Rivastigmine* as claimed by the Patent holders could only be provided by a patch which do not possess the structure and arrangement as mentioned in the application. Therefore in the original case, Justice Arnold held that the prior art as stated by the Appellants did not reveal a starting dose for the reason that it was obvious.

Hence, the present case is an appeal from the abovementioned decision.

## POINTS OF LAW

**Section 72(1)** of the Patents Act of UK, 1977 talks about Revocation of a Patent on the basis of four grounds:

1. *Non-patentability*- It talks about the criteria of novelty and inventive step.
2. *Non-entitlement*- It is related to the grant of patent to a person not entitled for it.
3. *Insufficiency*- It is regarding the patent specification which does not describe the invention sufficiently so as to enable it to be reproduced by the skilled person.
4. *Added matter*- It is related to the subject-matter of the patent when extends beyond the content of the originally filed application.
5. *Unallowable post-grant extension*- It means that the protection conferred by the patent has been extended by an amendment which should not have been allowed.

In the given case, the following three grounds are in dispute:

***1) Added matter***

The disputed patent had a single claim on *Rivastigmine* which was to be administered in a transdermal therapeutic system i.e., a patch, which was required at a particular starting dose. There was no mention of a starting dose of *Rivastigmine* in the original application filed by Appellant unlike its mention in the Patent. Therefore the court held that the subject-matter of the patent extended beyond the content of the originally filed application and hence invalidated the Patent on the ground of *Added Matter*.

***2) Obviousness***

The application filed by the Appellants offered the structure and arrangement of the transdermal patch which according to the Appellants were the core of their invention.

Whereas, the actual Patent revealed that the starting dose of *Rivastigmine* as claimed by the Patent holders could only be provided by a patch which do not possess the structure and composition as mentioned in the application. Therefore, the court held that that the prior art as stated by the Appellants did not reveal a starting dose for the reason that it was obvious.

3) ***Insufficiency***

The judge rejected the claim of the defendants regarding the patent being invalid on the ground of insuffiency.

## DECISION

In the present case, Justice Kitchin upheld the previous judgment delivered by Justice Arnold. The court held that the criteria of *obviousness* had some relation to the fact that whether or not the *skilled team* will monitor *the prior art* regarding the size of the patch and further try to match the starting dose to that of the lowest known therapeutic dose contained in existing *rivastigmine* capsules. Nevertheless, the Court came to the conclusion that previous judgment was correct to hold that it was obvious to provide the starting dose as mentioned in the Patent and therefore the original judgement on obviousness was therefore upheld.

## RELATED CASE LAWS

1. ***Teva v. Boehringer Ingelheim***[ii]

*(Decided by the High Court of England and Wales, London UK, 21 October 2015)*

The dispute was regarding the amendment sought by Boehringer to amend its claims of the Patent under section 75 of the Patents Act 1977. The Patent was regarding capsules which was supposed to be used in a dry powder inhaler for the purpose of delivering tiotropium bromide to patients with chronic obstructive pulmonary disease ("COPD") or asthma. Teva initiated a revocation action in June 2014 chiefly on the ground of lack of *inventive step*. This amendment sought was refused because it lacked inventive step.

2. ***Generics v Lundbeck***[iii]

The given case was regarding the validity of a patent on the ground of *'insufficiency'*. The patent was on a drug named *Escitalopram* which was used in curing depression. The court held that "*a product patent ought not to be revoked on the ground of insufficiency, even where the actual inventive step was in the method by which the product could be made".*

3. ***Synthon v Smithkline Beecham***[iv]

The important question in the given case involved the issue of the concept of *'enabling disclosure'* for determining the criteria of *Novelty*. The Respondent had a patent on a substance called *paroxetine* which was useful in the treatment of depression. The Appellant prayed for the revocation of this patent on the grounds of lack of novelty. This court held that *the patent had been anticipated.* The court further laid down the difference between 'enablement' and 'disclosure'.

## ENDNOTES

[i] A titration is a technique where a solution of known concentration is used to determine the concentration of an unknown solution.

[ii] [2015] EWHC 2963 (Pat)

[iii] [2009] UKHL 12; [2009] R.P.C. 13

[iv] [2005] UKHL 59; [2006] R.P.C. 10