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Conor Medsystems Inc

- v -

Angiotech

Pharmaceuticals Inc

RSC Law Group Seminar
9 November 2009

Relevance of the case

- Technical contribution as a requirement of inventive step (obviousness)
- “Obvious to try” approach to invalidity

What's it all about?



The problem:

- restenosis

The solution:

- a taxol-eluting stent

The Patent (EP 0706376 B2)

Claim 1:

A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an anti-angiogenic factor and a polymeric carrier the factor being anti-angiogenic by the CAM assay, and wherein said anti-angiogenic factor is taxol, or an analogue or derivative thereof.

Claim 11:

A stent according to any one of Claims 1 to 5 for treating narrowing of a body passageway.

Claim 12:

A stent according to Claim 11 for treating or preventing recurrent stenosis.

The Patent (EP 0706376 B2)

- CAM assay – demonstrated that taxol effective in preventing angiogenesis
- No data to demonstrate that a taxol-eluting stent would treat/prevent restenosis
- No data as to the dose required
- No evidence that such a stent would be safe

Inventive Step / Obviousness

Patents Act 1977 s.3

“An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms the state of the art...”

Inventive Step / Obviousness

Windsurfing / Pozzoli approach:

1. Identify the skilled addressee and the 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 the differences between the matter cited as forming part of the “state of the art” and the inventive concept or the claim as construed
4. Do those differences construe steps which would have been obvious or do they require a degree of invention?

Patents Court (first instance)

Claimant's case:

Enough to show that paclitaxel (taxol) worth experimentation

Patentee's case:

Not obvious to use taxol in a drug-eluting stent, as would have been considered to be potentially too toxic

Patents Court (first instance)

Pumfrey J:

“Is it sufficient for Conor to show that taxol is an obvious candidate for testing on a drug-eluting stent in addition to the material specifically identified in Wolff, or is it necessary to show that taxol is an obvious, or the obvious, material to use in a drug-eluting stent for administration to human beings? Put another way, is the patent vulnerable only if it can be shown that the skilled person would have an expectation of success sufficient to induce him to incorporate taxol in a drug-eluting stent, or is it sufficient that without any expectation of success he would test or screen taxol?”

Patents Court (first instance)

Pumfrey J:

- Assess the contribution to the art disclosed by the specification
- “... in this case obviousness will be established if on balance the evidence shows that the skilled man would consider taxol to be worth testing to see what its properties were.”

Court of Appeal

- Upheld first instance judgment
- “... the information in the patent actually adds nothing to the knowledge of the skilled man. So the patentee has done nothing *by his disclosure* to deserve a monopoly. True it is he mentioned taxol as an idea for a drug eluting stent, but the skilled man, upon reading Wolff would naturally think also of taxol along the other anti-replicates specifically mentioned.”
- On the CAM assay:

“But this is miles away from indicating that taxol is a particularly suitable anti-angiogenic for a drug eluting vascular stent or that the CAM assay is a test for a drug which will actually work to prevent restenosis in a drug eluting vascular stent.”

House of Lords

- Overturned Court of Appeal
- Inventive concept to be determined by the claim
- Lord Hoffman:

“In my opinion, however, the invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description. There is no requirement in the EPC or the statute that the specification must demonstrate by experiment that the invention will work or explain why it will work.”
- Teaching of the specification w.r.t. Claim12 was that a taxol-coated stent would prevent or treat restenosis

House of Lords

- Enough (for obviousness) that specification discloses enough to make the invention plausible
- Patents Court judge and Court of Appeal failed to answer the correct question, “namely whether it was obvious to use a taxol-coated stent to prevent restenosis
- None of the pleaded prior art identified taxol as particularly suitable
- Claim 12 of the Patent not obvious

House of Lords

“Obvious to try”

Approved *Kitchin J in Generics (UK) Ltd v Lundbeck A/S*



“The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.”

Comments



- Clarifies disclosure threshold for obviousness
- Plausible vs. speculation
- Does not affect support and sufficiency requirements
- Timing of patent applications

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Thank you

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