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Inventive step – what to develop?

Where a patent's novel feature provides no new effect the UK courts may still consider arguments for inventive step, as illustrated by the recent decision of the UK High Court regarding the patent for the anti-malarial Malarone®.

Malarone® contains a combination of the drugs atovaquone and proguanil and has been a successful anti-malarial in the UK for some years. Recently, the UK High Court found that a patent protecting Malarone® was obvious, in a decision which illustrates the UK Courts' willingness to consider arguments for inventive step that are not based on a new or improved effect.

The prior art

The combination of proguanil and atovaquone was known from a talk by Dr Hutchinson, one of the inventors. The talk disclosed not only the idea of treating malaria with a combination of atovaquone and proguanil, but also a small successful clinical trial.

The patent

The patent claimed a combination of proguanil and atovaquone in the ratio of 2:5. The ratio was the only new feature and had no technical significance. The patentee argued that nevertheless the skilled person would not develop the combination of these drugs having heard Dr Hutchinson's talk because:

- the talk was incomplete;
- it showed no reason to combine the drugs;
- the audience questioned its results;
- there were alternative avenues for research; and
- there were commercial reasons not to develop the combination.

The talk was incomplete

The patentee argued that the skilled person would be discouraged from pursuing the combination of atovaquone and proguanil because Dr Hutchinson's talk relied on a small number of patients and had no control group. However, under cross-examination, the patentee's expert agreed that the trial was a valid "proof of concept study" which the skilled person would consider developing further.

Would a combination be developed?

The patentee argued that it was irrational for the skilled person to combine atovaquone and proguanil if the effect of these two drugs was merely additive, but the court disagreed for two reasons. Firstly, if the effect was additive then there were still reasons to develop the combination (e.g. convenience). Secondly, the talk was found to suggest that the combination was synergistic and so the skilled person would decide to develop the combination.

Challenges to the talk

The patentee argued that the audience at Dr Hutchinson's talk challenged some of his conclusions and so developing the combination was not obvious. The court agreed that the reaction of the audience was important evidence, but decided that the members of the audience were simply behaving as "good scientists" by questioning the information presented.

Alternative avenues for research

The patentee argued that there were other avenues for research, so the skilled person would have pursued these instead of combinations of atovaquone and proguanil. However, the court was not convinced that there were any approaches with a greater prospect of success and so the skilled person would develop the combination disclosed by Dr Hutchinson.

Commercial factors

The patentee also cited commercial factors as evidence for the presence of an inventive step, including the high cost of research and an alleged perception that anti-malarial drugs were not profitable. The patentee suggested these factors would have discouraged the skilled person from developing a combination of atovaquone and proguanil, but the court held that these commercial factors were irrelevant when assessing inventive step.

The decision

The court decided that the patent was obvious because the skilled person would have considered Dr Hutchinson's talk and then developed the combination of atovaquone and proguanil.

In summary, the UK courts consider inventive step in detail even when the novel feature provides no new effects, which may contrast with some readers' experience at the European Patent Office. This case also underlines the potential risks posed by disclosures made by an inventor prior to filing a patent application.

Authors: Paul Howard & David Holland

Need advice?

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