

# WORLD INTELLECTUAL PROPERTY REPORT >>>

News and analysis on IP law, regulation and policy from around the world. For the latest updates, visit [www.bna.com](http://www.bna.com)

International Information for International Business

VOLUME 31, NUMBER 7 >>> JULY 2017

Reproduced with permission from World Intellectual Property Report, 31 WIPR 45, 7/1/17. Copyright © 2017 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

## Patents/Litigation

# How to Use Experimental Evidence in English Patent Litigation



By Tom Carver, partner, JA Kemp, London; email: [TCarver@jakemp.com](mailto:TCarver@jakemp.com)

Experimental evidence can play a valuable role in patent litigation. It is not uncommon in patent validity proceedings for an expert will say to they would, when presented with a piece of prior art, have conducted a particular experiment in order to progress the research. Without then conducting the actual experiment that they said they would have done, it is impossible to know what the result of that experiment would have been. Knowing the result of that experiment is sometimes critical to a case, such as when the defen-

dant argues the patent is invalid due to lack of novelty or inventive step or indeed sufficiency.

Experimental evidence is also frequently needed to ascertain the fact of whether or not an allegedly infringing product falls within the claims of a patent. For example, are the particle sizes of the allegedly infringing product within the range specified in the patent? Is there any of the infringing product in the mixture being marketed? Unless the opposing party is prepared to admit the fact in question, the party asserting the fact will need to prove it by experiment.

Experimental evidence is permitted in a number of jurisdictions in Europe, including in oppositions at the European Patent Office (EPO). However, the most rigorous testing of experimental evidence, and therefore the most reliable evidence, is in the High Court of England and Wales.

Any party may submit a report of an experiment at the EPO or in a civil law trial, but the content of that report cannot be challenged in cross-examination and there is little opportunity to explore the details of the

experiment or how the experimental protocol was decided upon. There is therefore scope for what Lord Justice Jacob, a former Court of Appeal judge, called “litigation chemistry,” by which he meant that experimental protocols can be finessed in order to obtain the “correct” result. The procedure at the High Court of England and Wales ensures that experimental evidence can be thoroughly tested by the opposing side.

## Procedure

A party wishing to rely on an experiment to prove a fact in High Court proceedings must first serve on the other side a Notice of Experiments. This is a formal document, usually served after disclosure or discovery and before expert evidence is exchanged, which sets out the facts which the party seeks to establish and gives full particulars of the experiments proposed to establish them (CPR 63 PD 7.1). The party receiving the Notice must respond stating whether or not each fact is admitted and may request the opportunity to inspect a repetition of some or all of the experiments detailed in the Notice.

The party seeking to rely on the experiment must then apply to court for permission, which will generally be granted unless the court deems the experiment’s expense disproportionate to the probative value, and the party will then repeat the experiment in the presence of the opposition. The witnessed repeat will then be the results that will be relied on at the trial, not the results included in the original Notice. The party seeking to rely on the experiments will include in the trial documents a copy of the Notice, a copy of a report of the repeat, and an expert witness will give evidence as to what the experiments prove. The expert can be cross-examined on any aspect of the design, the repeat, and the significance of the experiments.

The opposing party may wish to conduct its own experiments, either to prove facts it wishes to prove in reply, or to try to disprove facts seemingly proven by the first round of experiments.

## How to Minimize Risk

A “live” performance in any industry inevitably entails risk, and live scientific experiments are no exception. Experiments can fail and if it fails during the witnessed repeat then the party seeking to rely on those experiments will all of a sudden have a missing link in the chain of evidence on which they rely. They will not be permitted to rely on the data in the Notice of Experiments unless the judge agrees and even then very little weight will be given to it. So, how best to prepare and design experiments so as to minimize the risk of them failing?

First, the golden rule is to keep experiments simple. The more complicated the experiment, the more likely it is to go wrong. Ascertain the narrowest facts to be proven by experiment and design the simplest experiment sufficient to prove those facts. Anything more is a hostage to fortune.

For example, I was once involved in a case which hinged on the question of whether or not a skilled team would

have identified a new member of a virus family. In order to identify the new member at the priority date, the skilled person would have had to obtain tissue infected by the virus, extract template DNA from that tissue, design some PCR (polymerase chain reaction) primers and then perform PCR on the extracted DNA using those primers.

At first it seemed that we would have to repeat that entire experiment in order to prove our point. However, on reflection we realized that certain steps, such as obtaining infected tissue and extracting the DNA, would have been routine at the time and there was no need for us to repeat them and to risk them going wrong. The only critical fact we needed to prove was that the primers our expert says he would have used would have worked. We therefore simplified the experiment down to the single, easily performed step of testing the primers in a PCR experiment on some pre-prepared DNA.

The opposition objected, saying that our experiment did not prove that the skilled person could have conducted all the steps of the experiment at the priority date, because we used reagents unavailable at the priority date, namely the purified DNA of the then unknown virus. At trial the judge agreed with us that those were routine steps and that any competent laboratory would have been able to execute them. Our simple experiment worked and proved to be valuable evidence that the primers the skilled person would have selected would have been effective.

Second, the expert witness who will testify at the trial about the experiment and what it proves must be fully involved in designing the protocol. The expert must be able to explain and justify all decisions relating to the design and execution of the experiment. If the expert is asked a question and answers unconvincingly, the evidential value of the experiment will be lessened.

Third, try not adjust the protocol over a series of “work up” experiments until you obtain the “correct” result. Documents relating to work up experiments must be disclosed to the other side, and if it is apparent from those work up experiments that various conditions or other aspects of the protocol had to be finessed in order to make the experiment give the desired result, then that may well reduce the evidential value of the experiment.

Fourth, practice the experiment. Laboratory technicians are not robots and can get nervous when conducting an experiment in the presence of eminent professors, half a dozen lawyers and other assorted hangers on (including, usually, a video recorder). Practice makes perfect and so if it is not too expensive then it is well worth performing a dry run or two (note these are not work up experiments, but dry runs).

## Dealing With Other Side’s Experiments

Experimental protocols tend to be designed carefully, and sometimes the carefully designed protocol conceals a gift to the other side. Success or failure of an experiment can depend on seemingly small factors so it is important, when witnessing a repeat, to take a note of every detail no matter how seemingly insignificant. Once

back in the office the team can pore over the details to try to identify aspects of the protocol on which the opposition's expert should be cross-examined.

As mentioned above, it is open to either side to conduct Experiments in Reply. This could be a repeat of the other side's protocol under different conditions in order to show a different result.

In a case I worked on our client had based an anticipation attack on a patent on the existence of an experimental protocol in a scientific journal dated before the priority date. Our client the claimed the protocol produced, when followed, compound X, the subject of the patent. When our expert conducted an experiment following that protocol it resulted in compound X. However, when the other side "followed" the protocol no compound X was produced. At first glance both sides appeared to be conducting an identical experiment but producing different results. On closer inspection, our expert realized that the other side was using a different filter paper for a particular step of the experiment. Crucially, the prior art protocol specified a particular brand and pore size filter paper, which our expert had used, but the other side did not. The different filter paper appeared to prevent the production of compound X. It was a small and seemingly insignificant detail on which the fate of the patent turned.

## Other Jurisdictions

Assuming your experimental evidence survives the witnessed repeat and cross-examination of your expert at trial unscathed then it can be extremely useful and reliable evidence when deployed in other jurisdictions. It is very difficult for a foreign judge or an EPO Examiner to gainsay evidence that has been through the mill of the intensive English proceedings and survived all attacks.

Conversely, an experimental report submitted at the EPO, unwitnessed and not subjected to cross examination, can be discredited fairly easily if later put into High Court proceedings. Experimental evidence prepared for U.S. proceedings has often been finessed to the point of becoming "litigation chemistry" and it can therefore be difficult to use it in English High Court proceedings. It is generally best to start afresh.

## Summary

Seeking to rely on experimental evidence is high risk but can be high reward. There is no answer to a well-designed and focused experiment used to prove a particular point. When designing the experiment, the aim should always be to remove any unnecessary frills: the simpler the better. When analyzing the opponent's experiments, look closely at each choice of technique and reagent and question why it was used.