opinion of Mr Justice Arnold was that a coffee capsule would be an essential element of the invention. Further, the capsule was important from a technical point of view in that it was required to have a particular configuration to mate with and operate effectively within the coffee machine.

A third issue under consideration was whether coffee capsules would constitute 'staple commercial products'. The view of Mr Justice Arnold was that they would not: such a product must be supplied for a variety of uses before it could be considered to be a staple commercial one. The coffee capsules in question here were designed specifically for use in certain machines and did not exist before the machines existed; when they did first exist, they were only suitable for use in those machines.

Finally, the court considered whether the coffee capsules supplied by Dualit were suitable for putting the machine invention into effect, taking into account whether the introduction of a capsule supplied by Dualit would constitute 'making' the invention. Mr Justice Arnold was of the view that the capsules were subsidiary to the machine on the basis that, among other reasons, they cost a lot less and had a much shorter product life. It was also noted that the capsules and the machines had independent commercial existences. In view of the fact that the capsules were consumable products, he held that consumers of the machines would assume that they were entitled to obtain the capsules from any source. Further, the capsule did not incorporate the inventive concept of the patent, which was directed to the way in which the machine operates. Combining these factors, the invention was not 'made' simply by inserting a compatible capsule into a machine.

In conclusion, therefore, it was held that the supply of consumable coffee capsules did not infringe the patent directed to the portionized coffee machine.

Practical significance

This decision provides a positive outlook for suppliers of consumable products. Following a similar track to the recent Supreme Court decision in *Schütz v Werit*, in which replacing a consumable part of a compound product was considered to constitute mere repair, and not manufacture, of the product, this judgment confirms that the courts do not approve of patent proprietors seeking to limit the supply of consumable products intended to be used in or with a related patented product, where such separate protection for such consumables is not warranted.

Darren Smyth and Paula Flutter
EIP
Email: dsmyth@eip.com; pflutter@eip.com

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Any evidence of plausibility admissible—but not enough

Generics [UK] Ltd (t/a Mylan) v Yeda Research And Development Co Ltd and Teva Pharmaceutical Industries Ltd [2013] EWCA Civ 925, Court of Appeal, England and Wales, 29 July 2013

The court, while upholding the decision of Mr Justice Arnold, clarifies that post-dated evidence is admissible in determining whether the alleged technical advance of a patent is plausible.

Legal context

The landmark European Patent Office (EPO) Board of Appeal case AgrEvo (*AgrEvo* T 939/92 [1996] EPOR 171) establishes that the extent of the monopoly conferred by a patent must be justified by the technical contribution to the art, and that accordingly the technical result or effect of the claimed invention must be shared by everything falling within the scope of the claim. The later Johns Hopkins case (*Johns Hopkins University School of Medicine/ Growth Differentiation Factor* T 1329/04 [2006] EPOR 8) clarified that the specification must disclose enough to make the relevant effect 'plausible' and that post-published evidence 'may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve'.

The question arising in the present case was this: if the specification makes the technical effect 'plausible', to what extent is later evidence is admissible to contradict the effect made plausible in the specification?

Facts

The Yeda patent, licensed to Teva, EP (UK) No 0 762 888, claimed 'copolymer-1' having a certain molecular weight distribution. The description clarified that 'copolymer-1 is a mixture of polypeptides composed of alanine, glutamic acid, lysine and tyrosine in a molar ratio of approximately 6:2:5:1'.

Mylan sought revocation of the patent and a declaration of non-infringement in relation to a product with a tyrosine content nearly 30 per cent higher than the indicated ratio. At first instance, Arnold J found the patent valid and infringed.

Copolymer-1 is a treatment for multiple sclerosis (MS), and the claimed molecular weight material was alleged in the patent to be less toxic. The data in the patent supporting this reduced toxicity were held at both instances to show this to be plausible, but Mylan argued that later clinical trials did not substantiate the effect. The main question under validity was how this later evidence was to be considered. It is important that, as the Court of Appeal pointed out, the later trials showed 'no evidence of a difference. That is, as Mylan accepts, not the same thing as positive evidence that the two materials have equivalent tendency to cause side effects. No evidence of a difference is not the same thing as evidence of no difference.' So Mylan

had perhaps cast doubt on the technical effect, but not demonstrated its absence.

In relation to infringement, the main question was whether the tyrosine content was sufficient to remove Mylan's product from the scope of the claim.

Analysis

At first instance, Arnold J stated that '[p]ost-dated evidence may not be relied upon . . . to contradict a technical effect which is made plausible by the specification in order to found an allegation of obviousness', which may have appeared to establish a new precept of law that would perhaps have seemed surprising to some practitioners. However, this is clarified by the following statement:

> [I]f the specification does make it plausible that the invention solves the technical problem, I do not consider that it is open to an applicant for revocation to rely upon post-dated evidence as casting doubt on this so as to place an evidential burden on the patentee to demonstrate affirmatively that the invention does solve the technical problem.

It is important to view the earlier statement in this light, and to keep in mind that Mylan did not have affirmative evidence that the claimed invention did not work, and was only attempting to shift the burden of proof back to Yeda. It was possibly not meant in the broad sense in which the acontextual words could be interpreted. It was clear in the first instance decision that, if there had been clear evidence that the invention did not work (there being no reduced toxicity), the patent would have been invalid for insufficiency in any case (in respect of which it was not disputed that evidence of any date was admissible).

At any rate, the Court of Appeal has clarified in a welcome manner that later evidence is admissible to contradict a technical effect made plausible in the patent specification, and thus that the claims do not involve an inventive step. Floyd LJ clearly stated:

> I respectfully disagree with the judge when he concluded that it was not open to Mylan to challenge an effect made plausible by the specification. For my part, I cannot see any principled objection to the admission of evidence as to the true nature of the advance made by the invention in connection with an objection of lack of inventive step.

It is clear, however, from the Court of Appeal judgment that the evidence, even if later, must be in respect of the technical effect that is in the patent and which is relied on by the patentee to support an inventive step. This accords with Arnold J's statement that:

> post-dated evidence may be relied on to confirm that the disclosure in the patent either does *or does not* make it plausible that the invention solves the technical problem.

Even though the Court of Appeal considered the evidence of the later clinical trials, on the facts, the evidence was held insufficient to discharge Mylan's burden of proof to demonstrate lack of inventive step, and so the validity of the patent was upheld.

In relation to infringement, the first instance decision is clearly influenced by the argument that for the amino acid with the lowest abundance, adding one residue of that amino acid will change the relative composition by a greater amount, and therefore a greater variability is to be permitted in respect of the tyrosine content. This argument did not find favour with the Court of Appeal, which appreciated that copolymer-1 is a mixture of random copolymers of differing chain lengths, so that the tyrosine content is infinitely variable in a manner no different from any of the other three amino acids.

Here however Yeda prevailed on the burden of proof. The Court of Appeal declined to uphold a positive finding of non-infringement, but upheld Arnold J's refusal of a declaration of non-infringement on the basis that 'Mylan did not adduce sufficient evidence to justify a finding that they did not infringe'. In particular, Floyd LJ stated that there was

> no evidence to show that a 29.6% variation in the molar fraction of one amino acid is greater than that which could occur from amino acid analysis and copolymer-synthesis. That was the relevant question on infringement, and the evidence did not provide the answer to it.

Practical significance

This decision has confirmed that the situation with regard to admissibility of post-published evidence is in fact what most practitioners previously assumed: even if a patent renders plausible a technical effect upon which an inventive step can be recognized, if later evidence demonstrates that this technical effect does not in fact exist, this evidence is admissible for an inventive step attack on the patent and the patent can be found invalid on that basis.

Darren Smyth
EIP
Email: dsmyth@eip.com

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Insufficiency finally upheld as ground for invalidity of antibody claim

Eli Lilly & Company v Janssen Alzheimer Immunotherapy [2013] EWHC 1737 (Pat), Patents Court, England and Wales, 25 June 2013

Mr Justice Arnold determines that a patent directed towards antibodies to ß-amyloid peptide, for the treatment of Alzheimer's disease, is invalid for insufficiency.