



AIPPI CHRISTMAS MEETING

8 NEW SQUARE
INTELLECTUAL PROPERTY

A Robust start

Novartis v Dr Reddy's

- EPO OD held patent invalid for added matter
- Patentee sued for interim injunction.
- D said no arguable case and applied for summary judgment that patent was invalid
- Birss J held no arguable case that the patent was invalid and suggested giving summary judgment *against D*.
- In the end, interim injunction granted.

APPLICATION OF ACTAVIS REGENLAB V ESTAR

Claim for process to make platelet rich plasma required 2 features:

- Polyester based thixotropic gel
- Buffered sodium citrate solution at 0.1M.

Ds product was not polyester based and used sodium citrate solution at 0.136M

Held: infringed.

Note: CGK territorial.

Plausibility – Eli Lilly v Genentech

- Arnold J explaining Lord Sumption in *Warner Lambert*.
- Warner Lambert concerned second medical use Swiss Form claim.
- *Warner Lambert* did not refer to HGS on industrial applicability but principle the same.
- Arnold J bound by *Warner Lambert*, the requirement of plausibility depends on context but required no modification for application to claim to a new member (newly found in humans) of a known family.

SPC Squatting

Eli Lilly v Genentech

Question whether under Art. 2, 3(b) and/or (d), an SPC can be based on an MA held by a third party who has not given consent.

Arnold J held that the law was not clear and referred the question to the CJEU.

Because Arnold J had revoked the basic patent (albeit under appeal) the CJEU held the reference to be inadmissible.

TRANSLATIONS

Illumina v TDL

- Counsel agreed that what matters is how the original Japanese is understood.
- Arnold J:
“I am doubtful that this is correct, since the skilled person is located in the UK. It seems to me that it follows that the skilled person is deemed to read the prior art in English translation”

ARROW DECLARATIONS

Pfizer v Hoffmann La-Roche (1)

- Pfizer wished to launch biosimilar antibody (bevacizumab) for treatment of various cancers onto UK market.
- Roche had patents covering the proposed use.
- Pfizer claimed that its proposed use was obvious at the earliest relevant date and requested a Declaration that its proposed use was obvious.
- Roche de-designated the UK from all relevant families

PFIZER V ROCHE (2)

- Question following *AbbVie* was whether the absence of UK patent protection was sufficient to prevent a declaration.
- Roche applied for a preliminary issue and failed
- Pfizer's case was that product would be imported via Belgium and a declaration would assist in preventing interim relief there and elsewhere where there were patents.

Pfizer v Hoffman La Roche (3)

- Pfizer also argued that uncertainty meant it could not decide whether to launch on a skinny label or full label – affecting the UK.
- Roche declined to answer the technical case; fighting only on whether declaration should be made.
- Judge held there was uncertainty in the UK market but the purpose of a declaration was to be used in foreign courts. This is not sufficient.

TAKEDA V HOFFMANN-LA ROCHE

ENABLEMENT (1)

- What exactly needs to be enabled by the prior art? Must it be the very thing disclosed or is it sufficient if a skilled person would produce something different from the prior art which still fell within the claims?
- The issue was that the skilled person could not make the same antibody as was labelled Anti-D1 in the prior art. There was insufficient information to do so.

Takeda v Roche (2)

- Birss J held prior art enabling to make a version of Anti-D1 without undue burden.
- *“it would be a great deal of work and it would not be identical to the antibody which the authors of Bihoreau but from all the evidence in this case...the skilled team seeking to make their own version of Anti-D1 would succeed”*
- Obviousness or novelty? Held: Anticipation.

Actavis v ICOS

Obvious to Test (1)

- Court of Appeal held that based on the Judge's own factual findings he should have held claim 7 was obvious.
- Claim 7 was directed to the treatment of sexual dysfunction by administration of a dose no more than 5mg tadalafil per day.
- The invention is finding that that dose is effective with minimal side effects.

Actavis v ICOS (2)

- Lord Hodge reviewed the approach to obvious to try.
- Central issue was whether it must be obvious before the skilled team embarked on its investigation, and in light of the prior art, that a 5mg/day dose of tadalafil would be safe and effective?
- The Court of Appeal had held that based on the Judge's findings it was obvious anyway to embark on the routine research and the result would then be revealed.

Actavis v ICOS (3)

- Lord Hodge agreed.
- *“uninventive steps which the skilled person would take after the priority date to implement the Daugan patent are not excluded from consideration in assessing obviousness of the alleged invention at the priority date”.*
- To the oft cited passage of Kitchin J in *Generics v H Lundbeck* on the factors for obviousness, Lord Hodge added *“the routineness of the research”.*

Actavis v ICOS (4)

Lord Hodge:

“I do not construe the judgments of the Court of Appeal as supporting any general proposition that the product of well-established or routine enquiries cannot be inventive. If that had been what the experienced judges had said, I would have respectfully disagreed. But it is not. As Jacob LJ in Actavis v Merck (above) para 29, there is no policy reason why a novel and inventive dosage regime should not be rewarded a patent. A fortiori, efficacious drugs discovered by research involving standard pre-clinical and clinical tests should be rewarded with a patent if they meet the statutory tests”.

INVENTOR COMPENSATION

SHANKS v UNILEVER

S. 40:

“Where it appears....that the employee has made an invention belonging to the employer for which a patent has been granted and the patent is (having regard among other things to the size and nature of the employer’s undertaking) of outstanding benefit to the employer and by reason of those facts the employee should be awarded compensation...the Court may award him such compensation...determined under s.41.”

Section amended by the Patents Act 2004 to make compensation payable when the invention (and not just the patent) has been of outstanding benefit. Amendment only applies to patents applied for after 1 January 2005.

SHANKS v UNILEVER

INVENTOR COMPENSATION (2)

- The employer is the inventor's actual employer.
- The benefit is the benefit in the hands of the employer after deduction of any costs to the employer of securing that benefit.
- Outstanding is an ordinary English word meaning exceptional or such as to stand out. It refers to the benefit in money or money's worth to the employer.
- Undertaking means simply a unit or entity which carries on a business activity.
- The employer (CRL) was part of a larger group of companies and the work was exploited by the larger group as a whole.

Shanks v Unilever (3)

- The Court looks at the commercial reality of the situation from the perspective of the inventor's employer.
- Where the company operates a research facility for the benefit of the whole group, the focus is the extent of the benefit to the group and how that compares with the benefits derived from the group from other patents for inventions arising from research carried out by that company

Shanks v Unilever (4)

- “Too big to pay”?
- *In my judgement there is no single answer to this question. Many different aspects of the size and nature of the employer's business may be relevant to the enquiry. For example, the benefit may be more than would normally have been expected to arise from the duties for which the employee was paid; it may have been arrived at without any risk to the business; it may represent an extraordinarily high rate of return; or it may have been the opportunity to develop a new line of business or to engage in unforeseen licensing opportunities. In the circumstances of this case and for the reasons I have given, a highly material consideration must be the extent of the benefit of the Shanks patents to the Unilever group and how that compares with the benefits the group derived from other patents resulting from the work carried out at CRL.*
- *Similarly, as Patten LJ explained at para 28, a straightforward comparison of profitability may be sufficient, in the case of a smaller company, to show an outstanding benefit without recourse to wider considerations of the scope of an employee's duties or the expectations the employer may have had about the anticipated level of return.*
- *On the other hand, I think a tribunal should be very cautious before accepting a submission that a patent has not been of outstanding benefit to an employer simply because it has had no significant impact on its overall profitability or the value of all of its sales*

Shanks v Unilever (5)

- Benefit was outstanding
- Should be assessed net of tax and accounting for the time value of money
- Arnold J wrong to lower the fair share to 3% and Hearing Officer amount of 5% restored.
- Overall award of £2 million.

FRAND

- Jurisdiction for the UK Court to determine global licences even if royalties derived from the UK are less than 1% confirmed (*Conversant v Huawei*).
- Injunction will be granted following infringement trial if D found to infringe and does not agree to take a FRAND licence (*TQ Delta*)
- Possible for a Defendant irrevocably to abandon reliance on the FRAND undertaking. Injunction and damages will follow (*TQ Delta CA*)

FRAND (2)

- May not be able to claim the right to be granted a FRAND licence for the UK only. That is different from saying that a D no longer relies on the grant of any licence to resist injunctive relief (*TQ Delta CA*)
- Interim relief refused prior to a finding of infringement where D would not undertake to enter in a future a licence and the Patent would expire prior to trial (*IPCom v Xiaomi*)

FRAND (3)

- But warnings still given by the Courts of the dangers of refusing at an early stage to agree to take a FRAND licence settled by the Court (IPCom v Vodafone):

It is clearly one potential outcome of this case that the '666 patent will be upheld and there will be no FRAND undertaking in place before expiry. Woe betide Vodafone at that stage to suggest it needs more time to think through the implications of what has happened. With luck it will also be after the Supreme Court has given judgment and after a lot of work will already have been done on the FRAND matter (Birss J)

FRAND (4)

- Starting to see anti-suit injunctions and anti-suit of anti-suit injunctions as the forum frenzy intensifies (see *IPCom v Lenovo*)
- Seen a “reverse FRAND” case where an implementer wishes to obtain a UK determination of a global licence from a US pool administrator and Philips (*Vestel*)
- Awaiting judgment on whether proper damages where the D submits to an injunction are to be assessed as a global royalty (*Philips v ASUS*)

LATE ADVANCED POINTS

L'Oreal v Liqwid

- Court accepted that construction points often occur to parties late and in any event are questions of law.
- Court considered the approach to the application of new evidence and experiments.
- Davis LJ made clear that although of course the Court wishes to reach the right result, it could not be said that the proposed evidence would inevitably mean that L'Oreal would succeed. Further applications cannot be decided solely on whether the evidence might lead to a different outcome. A more wide ranging assessment based on the overriding objective was needed.

Stay pending the EPO

Coloplast v Salts

- Issue arose over whether *American Cyanamid* approach of potential irreparable harm was applicable and how to deal with potential amendments.
- Suggestion of undertaking needed to repay damages and costs
- Held: *American Cyanamid* has no role to play in the *Glaxo* guidelines. Amendment is a function of the system. Costs undertaking not required.

Ambiguity?

Anan Kasei v Neo

- Better termed “uncertainty” (Floyd and Lewison LLJ).
- See summary of the approach to uncertainty and “Biogen” type insufficiency.

Can the skilled addressee change?

Conversant v Apple

- Answer yes
- The application covered a wide range of computing devices
- The patentee amended the patent to limit it to smart phones
- Birss J held there is nothing wrong in principle for the effect of a claim amendment to mean that the skilled person relevant to the amended claim may be different from the one applicable to the application.

Costs

Conversant v Huawei

- Huawei succeeded on added matter and the Conversant patent was held to be invalid.
- Huawei had relied on 20 separate issues on invalidity or non-infringement.
- Court ordered *Huawei* to pay *70% of Conversant's costs*
- Interim payment to the losing party of 60% of 70% of its costs.