AIPPI CHRISTMAS MEETING

8 NEW SQUARE
INTELLECTUAL PROPERTY

ACTAVIS BEDS DOWN

The re-formulated questions:

- i)Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?

- ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

- iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

What is the meaning of "literal meaning" or "normal interpretation"?

"As Henry Carr J put it in paragraph 202 of *Illumina*, normal interpretation means purposive construction."

Birss J

Liqwd & Olaplex v L'Oreal

Birss J – a few thoughts Liqwd & Olaplex v L'Oreal

- "construing a patent purposively to identify the normal interpretation…may not be precisely the same as every nuance of the process of the determination of claim scope which was mandated by *Kirin-Amgen* prior to *Actavis*"
- "I will say only that I can see room for arguing that for validity purposes some account ought to be taken of the wider scope".

Icescape v Ice-World

Lord Kitchin:

- "It is, in my view, clear that this approach is markedly different from that which the courts in this country have adopted since *Catnic*"

- "So I have no doubt that (despite Lord Neuberger's use of the term "literal" in considering issue (ii) (and to which I will come in a moment) issue (i) involves purposive interpretation".

Floyd LJ in Icescape

- "It should not be thought, however, that the claims do not continue to have an important function.[…] The claims remain the starting point for the subsequent analysis of variants. Although we may have edged closer to it, the new approach does not transgress the second of the outlawed approaches in the Protocol, which treats the claim merely as a somewhat vague guideline".

JUSHI GROUP
NUMERICAL RANGES

- "The approach to be adopted to the interpretation of claims containing a numerical range is no different from that to be adopted in relation to any other claim".
- "The scope of any such claim must be exactly the same whether one is considering infringement or validity".
- "There can be no justification for using rounding or any other kind of approximation to change the disclosure of the prior art or to modify the alleged infringement".

Floyd LJ

Quoting Kitchin LJ in *Convatec*

Use of prosecution history?

- "It should be emphasised that reference to the prosecution history is the exception, and not the rule". - Henry Carr J (L'Oreal v RN Ventures).

- "In my view this is a very good illustration of why it is generally so unprofitable to explore the prosecution history". – Lord Kitchin (Icecape).

UP v Huawei: FRAND

- Global licensing
- Meaning of non-discrimination limb of FRAND
- Correct approach to the CJEU judgment in *Huawei v ZTE*

UP v Huawei: Global Licensing

- In considering relief for patent infringement of a UK SEP, can the English Court settle the rates and terms of a global licence and grant an injunction until such time as the implementer enters into that licence?
- Yes.

FRAND – Global Licensing

- Relief for patent infringement and the ETSI undertaking are separate.
- For patent infringement the usual relief is an injunction. This is likely to follow with a SEP if the owner has offered a FRAND licence which has not been accepted.
- A global licence can be FRAND.

FRAND – Global Licensing

- Settling the rates and terms of a global licence is not an interference with foreign rights.
- A range of terms can be FRAND. If the SEP owner offers FRAND terms, the implementer must accept those terms even if different terms (e.g. lower rates) are also FRAND.

FRAND – Non-Discrimination

- The issue is whether a SEP owner can offer a higher rate to a similarly situated licensee without any objective justification?
- The answer is that the ND element of FRAND requires that all licensees are offered a benchmark rate representing the true value of the portfolio or a lower rate.

FRAND – *Huawei v ZTE*

- THE CJEU in Huawei v ZTE did not lay down mandatory criteria for how to approach FRAND negotiations.
- The CJEU provides a safe harbour to avoid infringement of Art. 102 TFEU.

FURTHER FRAND DISPUTES

- *Conversant v Huawei & ZTE* : Appeal judgment pending.
- *Apple v Qualcomm*: consideration of ETSI undertaking and service out.

Warner-Lambert v Generics

- Sufficiency and infringement of Swiss Form claims
- Arnold J construed claim 1 to cover all types of pain and claim 3 to cover all neuropathic pain. There was basis only for peripheral neuropathic pain. Claims 1 and 3 (together with other subsidiary claims) were invalid for insufficiency. The findings were (materially) upheld on appeal.

Plausibility
Lords Sumption, Reed & Briggs

- “The principle is that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true”.
- “The test is relatively undemanding. But it cannot be deprived of all meaning or reduced, as Floyd LJ's statement does, to little more than a test of good faith”.
- “The proposition that a product is efficacious for the treatment of a given condition…. is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion”.

Plausibility
Lords Sumption, Reed & Briggs

- “The effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by *a priori* reasoning”.
- “Sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. The disclosure may be supplemented or explained by the common general knowledge of the skilled person”.
- “Where the asserted therapeutic effect is plausible in the light of the disclosure in the patent, subsequent data may sometimes be admissible either to confirm that or else to refute a challenger's contention that it does not actually work it cannot be a substitute for sufficient disclosure in the specification”.

Plausibility
Lords Sumption, Reed & Briggs

Para. 47 of the judgment of Floyd LJ:

- "A test designed to prevent speculative claiming need go no further than requiring the patentee to show that the claim is not speculative: the specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction than that". *No longer the approach?*
- The application to the facts: "it is possible" is not enough.

Plausibility dissent
Lord Briggs & Lord Mance

- "Despite the use of phrases such as "reasonable prospect" and "might well produce", there is a real risk that the test as described by Lord Sumption would amount to, or be understood as, involving a requirement to establish a *prima facie* case on the material contained in the specification. In my opinion, the authorities analysed above do not put the standard so high". – Lord Mance
- "I do not interpret those principles as requiring the patentee to demonstrate within its patent a prima facie case of therapeutic efficacy" – Lord Briggs.

Warner Lambert - infringement

- Arnold J : even if valid, no infringement. The relevant test is the subjective intention of the manufacturer.
- Floyd LJ: the relevant test is the objective intention of the manufacturer. A manufacturer can be taken to intend the foreseeable consequences of his actions save that (i) downstream use must be intentional and not accidental and (ii) intention may be negatived if the manufacturer had taken all reasonable steps to prevent downstream infringing use.

Purpose Limited Patents infringement

<u>Lord Sumption & Lord Reed : outward presentation</u>

- “The badge of purpose is the physical characteristics of the product as it emerges from the relevant process, including its formulation and dosage, packaging and labelling and the patient information leaflet which in EU (and other) countries will identify the conditions for whose treatment the product is intended. I shall call this, for want of a better phrase, the "outward presentation" test”.

Purpose Limited Patents infringement

Lord Mance: outward presentation +

- "A process leading to a composition or product, which does not make clear that its permitted use is limited will infringe".
- "I prefer however to leave open whether there might be some circumstances in which a generic manufacturer could or should be expected to go further, by a notice positively excluding the patent-protected use".

Purpose Limited Patents infringement

Lord Mance:

- "Normally, a generic manufacturer, and it follows others such as doctors, pharmacists and end users, should be protected from infringement of a Swiss-form patent if the manufacturer ensures that the generic product resulting from its manufacturing process is produced, prepared and marketed with a clear limitation to patent-free uses".

Purpose Limited Patents infringement

Lord Briggs & Lord Hodge : a “so called” subjective intent test

- “The so-called subjective intent test favoured by Actavis would I think accommodate all forensic means whereby a purpose of the generic manufacturer to serve (and profit from) the market for neuropathic pain could be proved, including but not limited to the packaging on the product. Anything from which the court could properly find that the manufacturer had such a purpose could be relied upon, including targeted disclosure, during litigation, of documentary records of the manufacturer's decision-making processes”.
- “I call it a "so-called" subjective test because a person's intention is as much a matter of fact as the state of his digestion, and this is true of corporate persons as much as of individuals”.

C-423/17: Warner Lambert AG Kokott

Interpretation of Articles 10, 11 & 21(3) of Directive 2001/83:

- “The notification of a subsequent carve-out [*of the patented indications or dosage forms from the summary of product characteristics]* must therefore be regarded as an application to limit the previously granted marketing authorisation for a medicinal product. It is irrelevant in this connection whether by the carve-out the authorisation holder merely wishes to avoid infringements of patent rights or is intentionally seeking to limit the marketing authorisation”.

The Mince Pies

- SPCs – meaning of "product protected by a basic patent in force"
- *Sandoz v Janssen* – whether a claim in Markush form was sufficient. Reference to CJEU
- *Teva v Gilead* – Application of CJEU reference in Truvada litigation

The Mince Pies

<u>Abuse of process/late raised points</u>

- *Teva v Gilead:* attempt to file new evidence post CJEU. Refused by Arnold J.
- *Liqwd v L'Oreal:* attempt to run a new point on cross-examination and then to file new experiments post judgment. Both refused by Birss J.
- *Warner-Lambert.* Attempt to amend claims post-trial refused by Arnold J, upheld by SC.

The Mince Pies

<u>The points permitted</u>

- *Edwards v Boston:* point had been put in cross-examination sufficiently.
- *Regeneron v Kymab:* Kitchin LJ permitted sufficiency point not dealt with by the Judge despite it not being brought to Judge's attention prior to final order.
- *Illumina v Premaitha:* Henry Carr J permitted a new claim on a new patent not asserted in the past action.

The Mince Pies

- Arrow declarations – *GSK v Vectura*
- Relief – *Regeneron v Kymab*
- Confidentiality clubs – *TQ Delta v Zyxel*