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European patent prosecution & litigation:
UK patent litigation

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Speakers, slides & questions

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Email us after the webinar with any follow up questions.

Agenda

Overview	
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	Prosyscor v Netsweeper (normal duties)
Inventor compensation	Shanks v Unilever
Patent validity	Novartis v Dr Reddy's (added matter)
	Actavis v ICOS (reasonable prospect of success)
	Pfizer v La Roche (Arrow declarations)

Agenda

Patent infringement	Regen Lab v Estar (multiple differences; numerical ranges)
	Technetix v Teleste (Formstein defence)
FRAND	

Overview

- 14 patent infringement/validity judgments
- 6 Court of Appeal judgments
- 2 Supreme Court judgments
- Of 14 patents where validity and infringement in issue, 4 patents valid and infringed

Overview

Patents (2010-2019)	117
Valid	43 (36.75%)
Invalid	74 (63.25%)
Infringed	60 (51.28%)
Non-infringed	44 (37.61%)
Valid and infringed	32 (29.06%)

Patent entitlement: BDI Holding v Argent

- Key point:
  - The use of “inventive concept” when assessing entitlement
- What is the context?
  - 2004: Argent commissioned BDI to design and oversee the construction of a biodiesel plant.
  - 2014: Argent filed two European patent applications for a biodiesel composition
  - 2017: BDI filed a claim at IPEC for a declaration that it was entitled to the patents.

Patent entitlement: BDI Holding v Argent

- What is the applicable law?
  - s. 7(2),1977 Act: A patent for an invention to be granted to the inventor [subject to certain exceptions]
  - s. 7(3),1977 Act: “Inventor” means the actual deviser of the invention.
  - *University of Southampton's Applications:* “Deciding upon inventorship will … involve assessing the evidence adduced by the parties as to the **nature of the inventive concept** and who contributed to it."

Patent entitlement: BDI Holding v Argent

- What is the inventive concept?
  - HHJ Hacon:
    - The core, the essence and the heart of the invention and
    - The new technical insight conveyed by the invention

Patent entitlement: BDI Holding v Argent

- What did the court decide?
  - Argent: Inventive concept was the biodiesel composition in the claims
  - BDI: Biodiesel composition was obvious and the only inventive concept was the method of production from the specification
  - HHJ Hacon: Insufficient evidence to establish biodiesel composition claims were obvious. Argent was entitled to the patent.

Patent entitlement: BDI Holding v Argent

- Why is this important?
  - To identify the inventive concept, one **may** need to identify the prior art.
  - Consider running a validity assessment on the patent in support of arguments for entitlement.

Patent entitlement: Prosy. v Netsweeper

- Key point:
  - The meaning of “normal duties” of an employee
- What is the context?
  - January 2009: Mr Kite employed by Netsweeper
  - March 2009: Mr Kite develops the inventive concept (in part) in his own time, on his own equipment and as his own project
  - March 2009: Mr Kite posts summary of the inventive concept (in part) on Netsweeper’s internal website
  - March 2009: Mr Erb further develops the inventive concept

Patent entitlement: Prosy. v Netsweeper

- What is the context (cont.)?
  - August 2009: Mr Kite posts a revised summary on Netsweeper's internal website
  - Netsweeper does not develop inventive concept
  - 2010: Mr Kite leaves Netsweeper's employment to establish Prosyscor (assigning his IP rights to Prosyscor)
  - 2013: Netsweeper files a patent application
  - 2017: Prosyscor filed a claim at IPEC for a declaration that it was entitled to the patent.

Patent entitlement: Prosy. v Netsweeper

- What is the applicable law:
  - S. 39, 1977 Act: "… an invention made by an employee shall … belong to his employer … if … it was made in the course of the **normal duties** of the employee …"
- What are normal duties?
  - "(4) The starting point in defining normal duties is the contract of employment; having considered the terms of the contract one must ask: what was the employee employed to do? …

Patent entitlement: Prosy. v Netsweeper

- What are normal duties (cont.)?
  - (5) However, the contract of employment is not the sole arbiter of normal duties. The overall question is whether the employee was employed to try to innovate and if so, what general sort of areas his innovation duties covered at the relevant time, i.e. the date on which the invention was made …
  - (8) An invention is made 'in the course of' an employee's normal duties under s.39(1)(a) generally in contradistinction to being made in a frolic of his own."

Patent entitlement: Prosy. v Netsweeper

- What did the court decide?
  - Mr Kite developed the inventive concept (in part) as an employee of Netsweeper.
  - Netsweeper was entitled to the patent.
- Why is this important?
  - If role is research and development / product development, it will be difficult to argue that any development is not within the course of employment.

Inventor compensation: Shanks v Unilever

- Key point:
  - Entitlement to compensation for employee inventions
- What is the context?
  - 1982: Professor Shanks, employed by Central Resources Ltd (CRL) a subsidiary of the Unilever Group (Unilever), invents Electrochemical Capillary Fill Device (ECFD)
  - CRL assigned the rights to the Shanks patents to Unilever PLC for £100
  - 1984-1985: patents filed for ECFD technology (Shanks patents)
  - Unilever licensed the patents and later sells the patents, with the licences.
  - Estimated that £24.55m in revenues was attributable to the Shanks patents.
    Estimated costs of obtaining and maintaining the patents of £250,000.
    Net benefit for Unilever: £24.3m, rounded at **£24m**

Inventor compensation: Shanks v Unilever

- What is the context? (cont.)
  - 2006: Pr. Shanks applied for compensation under (old) s.40 PA 1977:

"40(1). Where it appears […] that the patent is (having regard among other things to the **size and nature of the employer's undertaking**) **of outstanding benefit to the employer** […] the court or the comptroller may award him such compensation […]" *(emphasis added)*

  - Before the case reached the Supreme Court:
    - Compensation **refused**: the benefit of these patents was found to be **not outstanding**
    - Fair share otherwise estimated at 3% or 5% of the net benefit
    - Questions raised on whether compensation should take time value and/or tax into account or not

Inventor compensation: Shanks v Unilever

- What did the Court say?
  - Employer is CRL
  - Benefit derived or expected to be derived by CRL
    - "the court must consider the position of the actual employer and the benefit which the assignee has in fact gained or is expected to gain"
  - Outstanding: size and nature of the employer's **undertaking**?
    - Is this CRL? Unilever or part of it?

"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**." (para 51)

Inventor compensation: Shanks v Unilever

- Outstanding: **size and nature** of the employer's undertaking? No one-size fits all assessment…
  - Aspects that can be relevant to assessing the size and nature of the undertaking (non-exhaustive):
    1. Comparison with benefit that would normally have been expected to arise from the duties for which the employee was paid
    2. Level of risk to the business
    3. Relative rate of return
    4. Opportunity to develop a new line of business or to engage in unforeseen licensing opportunities (yes)
    5. Size of the undertaking: what might be a normal benefit obtained by a large undertaking (e.g. using its size and power in negotiations) can possibly be outstanding for a smaller undertaking
- "all of these matters point strongly to the conclusion that the Shanks patents were an **outstanding benefit** to CRL having regard to the size and nature of its undertaking" (para 71 – emphasis added)

Inventor compensation: Shanks v Unilever

- **Tax** – Compensation is pre-tax: “In my judgement the first step is to quantify the benefit and the next is to decide how much compensation would secure for the employee a fair share of it. The employee must account for any tax due on that share and the employer must account for any tax due on the balance.” (para 58)
- **Time Value** – to be added to the compensation amount: “Professor Shanks seeks an award which reflects the fact that, on the assumption he prevails on the other limbs of his appeal, he has for many years been kept out of a fair share of the benefit Unilever has derived from the Shanks patents.” (para 65)
- **Fair Share**: 5% of £24m + time value since 1999 taken into account

- Decision: **£2m compensation ordered**

Inventor compensation: Shanks v Unilever

- Why is it important?
  - First Supreme Court decision on employee compensation
    - Inventors and Employees have now much clearer guidance on the application of Sections 40-41 of PA 1977 and on when a case may be considered of outstanding benefit or not.
    - “Too big to pay” is not a convincing approach, the benefit must be put in context
  - Only second time employee compensation has been awarded by the Court (see Kelly and Chiu v Ge Healthcare Ltd [2009] EWHC 181

Patent validity: Novartis v Dr. Reddy's

- Key point:
  - EPO and UK may take different approaches to added matter and selection patents
- What is the context?
  - 2015: Novartis granted patent for everolimus in combination with exemestane for use in the treatment of hormone receptor positive tumour, wherein the tumour is a breast tumour
  - 2018: EPO Opposition Division finds patent invalid for added matter
  - 2019: SPC for everolimus expires

Patent validity: Novartis v Dr. Reddy's

- What is the context (cont.)?
  - 2019: Dr Reddy's planned a launch of a generic everolimus
  - Novartis applied for a preliminary injunction. Dr Reddy's counterclaimed for invalidity
  - Application recited the use of a wide class of rapamycin and derivatives for a large number of uses, of which the claimed combination of compounds was one selection
  - Opposition Division concluded that the selection of items from two lists was added matter.

Patent validity: Novartis v Dr. Reddy's

- What did the court decide?
  - Patents Court held that there was no ground for finding the patent invalid for added matter.
  - "I do not accept that … a teaching which consists of a combination of … two individualised lists … necessarily means that that combination is now to be treated as an un-individualised generic disclosure."
  - Specification taught that everolimus was the paradigm rapamycin derivative to choose from the research and development compounds. There was, therefore, a disclosure of it with exemestane to treat breast cancer.
  - Interim injunction granted.

Patent validity: Novartis v Dr. Reddy's

- Why is this important?
  - English court may be applying a less rigid test to added matter for selection patents than the EPO.

Patent validity: Actavis v ICOS

- Key point:
  - Review of the law of obvious to try
- What is the context?
  - 1997: Daugan teaches the use of tadalafil for treatment of male erectile dysfunction with doses in the range of 0.5-800mg per day and an example of 50mg.
  - 2003: ICOS is granted patent related to the use of tadalafil in dosage form for the treatment of male erectile dysfunction for doses 1-5mg up to a maximum of 5mg per day
  - 2014/2015: Actavis, Teva and Mylan challenged the validity of the patent.

Patent validity: Actavis v ICOS

- What were the relevant facts?
  - The skilled addressee, if given the Daugan patent, would take tadalafil forward into a routine pre-clinical and clinical trial programme as an oral treatment for erectile dysfunction.
  - Phase IIb would involve establishing the optimum dose for biological activity with minimal side-effects. If a first study used a dosing range of 25, 50 and 100mg it would unexpectedly show no difference in efficacy between the three doses, demonstrating an apparent therapeutic plateau.
  - It was very likely that the skilled addressee would subsequently try a lower dosing regime, although there would not be a reasonable expectation of success for 5mg/day.

Patent validity: Actavis v ICOS

- Did this render the patent obvious?
  - Patents Court: No.
  - Court of Appeal: Yes.
- What was the issue?
  - Must it be obvious before the skilled addressee embarks on its investigation, and in light of the prior art, that a 5mg/day dose of tadalafil would be safe and effective?

Patent validity: Actavis v ICOS

- What did the court decide?

1. Whether at the priority date something was “obvious to try”;
2. The routine nature of the research and any established practice of following such research through to a particular point;
3. The burden and cost of the research programme;
4. The necessity for and the nature of the value judgments which the skilled team would have;
5. the existence of alternative or multiple paths of research;
6. the motive of the skilled person;
7. whether the results of research are unexpected;
8. hindsight;
9. whether a feature of a claimed invention is an added benefit; and
10. the nature of the invention.

Patent validity: Actavis v ICOS

- What did the court decide (cont.)?
  - Patent obvious
- Why is this important?
  - Need to consider these factors when assessing obviousness
  - Difficult to see how a dosage regime arrived at through routine pre-clinical and clinical tests could be considered inventive

Patent validity: Pfizer v Roche

- Key point:
  - The limitations of Arrow declarations.
- What is the context?
  - Pfizer wished to launch a biosimilar monoclonal antibody drug called bevacizumab
  - Roche had a “thicket” of patents and patent applications which created uncertainty
  - Pfizer sought an Arrow declaration that its proposed use was obvious.

Patent validity: Pfizer v Roche

- What is the context (cont.)?
  - Roche de-designated the UK from all relevant patent families
  - Roche argued that an Arrow declaration should not be made (and declined to argue the technical case)
- What is the law?
  - When considering whether to grant an Arrow declaration, the court will consider: a) justice to the claimant; b) justice to the defendant; c) whether the declaration will serve a useful purpose; and d) whether or not there are any other special reasons

Patent validity: Pfizer v Roche

- What was the issue?
  - Did the court have jurisdiction to grant an Arrow declaration where there was no applicable UK patent/patent application? If so, in what circumstances should it grant this declaration?
- What did the court decide?
  - The court had jurisdiction but would only exercise its discretion if there was a “useful purpose”

Patent validity: Pfizer v Roche

- Was there a useful purpose?
  - Prima facie case that biosimilar was obvious at the relevant date
  - Roche's patent prosecution practice was to shield its portfolio from scrutiny by the Patents Court.
  - An Arrow declaration would be of "real commercial value" to Pfizer as it would reduce the uncertainty it faced in other jurisdictions.
  - An Arrow declaration may assist settlement.
  - **However:** This was not enough

Patent validity: Pfizer v Roche

- Was there a useful purpose?
  - “There is uncertainty relating to the UK market but that derives from the fact that the goods are to be supplied from a separate jurisdiction (Belgium) in which the uncertainty remains. Now what Pfizer really wants is a UK judgment so as to use it in Belgium … The true purpose of an *Arrow* declaration in this case would be for it to be used in foreign courts. I am not persuaded that that is enough.”

Patent infringement: Regen Lab v Estar

- Key point:
  - Application of the doctrine of equivalents to: a) multiple differences and b) numerical limitations (*obiter*)
- What is the context?
  - 2016: Regen Lab granted patent for a method for the preparation of platelet rich blood plasma. Claim required a polyester based thixotropic gel and a buffered sodium citrate solution at 0.10M.
  - 2017: Regen Lab sued Estar for patent infringement for the supply of kits used to prepare plasma in the UK. Estar counterclaimed for revocation of the patent.

Patent infringement: Regen Lab v Estar

- What is the context (cont.)?
  - Estar's product was not polyester based and used sodium citrate solution at 0.136M.
- Should the doctrine of equivalents test be applied to each difference separately or together?
  - "The question is whether the accused product or process is a variant falling within the scope of the claim taking all equivalents into account. Of course, it will often be convenient to consider equivalents one by one, but there must be a single overall answer in relation to each accused product or process."

Patent infringement: Regen Lab v Estar

- How does the doctrine of equivalents apply to numerical limitations?
  - Does the variant achieve substantially the same result in substantially the same way as the invention? Yes
  - Would it be obvious to the skilled addressee, at the priority date, knowing the above, that it does so in substantially the same way as the invention? Yes
  - Would such a reader of the patent have concluded that the patentee nonetheless intended strict compliance with the literal meaning of the relevant claim(s)? No

Patent infringement: Regen Lab v Estar

- How does the doctrine of equivalents apply to numerical limitations (cont.)?
  - “The third question would only be answered yes if there had been a sufficiently clear indication to the skilled person that strict compliance with the figure of 0.10M was intended. In the present case anyway, I think that could only have come from the patent specification or something in the skilled person's common general knowledge. There was no such indication.”

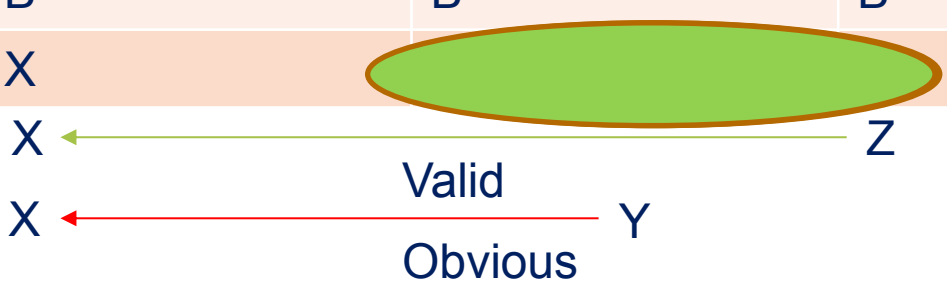
Patent infringement: Regen Lab v Estar

- Why is this important?
  - Doctrine of equivalents is being applied broadly.

Patent infringement: Technetix v Teleste

- Key point: Formstein defence may be available (*obiter*)
- What is the issue?

Prior art	Product	Patent
A	A	A
B	B	B
X		



Patent infringement: Technetix v Teleste

- What did the court decide?
  - Formstein defence may exist
  - Introduces a fourth limb to the test in Actavis v Lilly: “Does the variant, having regard to the state of the art, lack novelty or is the variant obvious to a skilled addressee?”
  - “One way of reconciling [this] … would be to say that if an accused product … is an equivalent and for that reason is nominally within the scope of the claim, but the equivalent would have lacked novelty or inventive step over the prior art at the priority date, then it is deemed to fall outside the scope of the claim, thus providing a defence to infringement.”

Patent infringement: Technetix v Teleste

- Why is this important?
  - Balances validity and the doctrine of equivalents.
- Also see: Emson v Hozelock

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