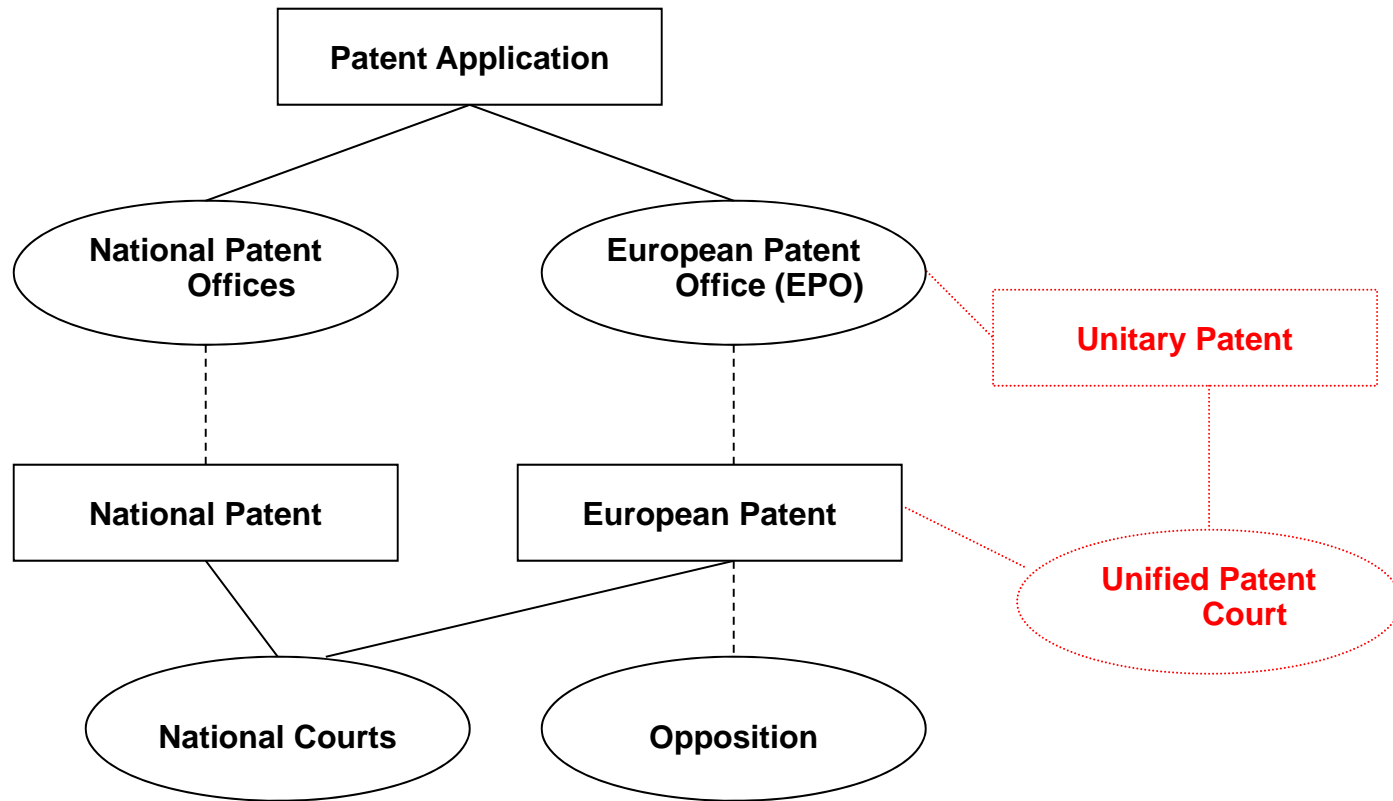


WIPO Life Sciences IP Disputes
Basel, 22 May 2015

European Patent Litigation: UK perspectives

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The European Patent System



The National Patent Courts

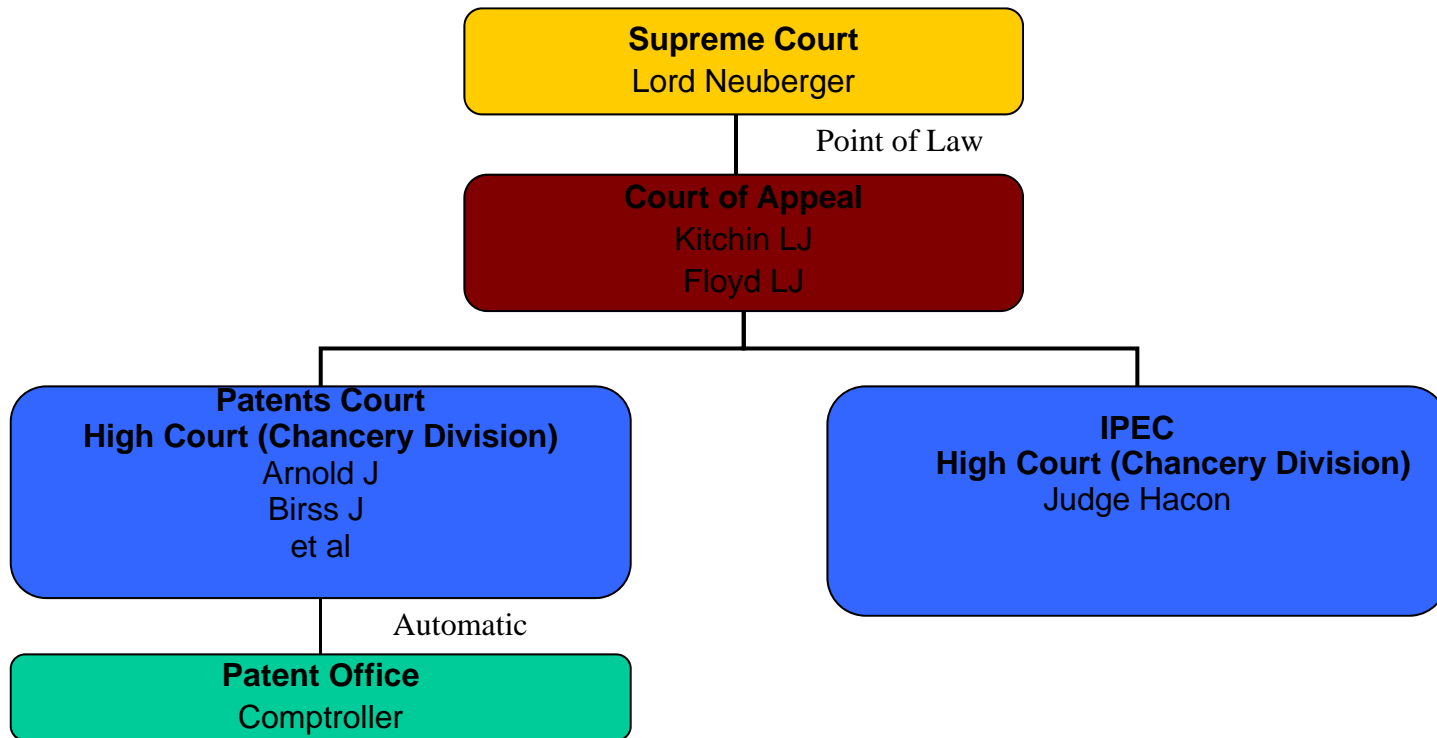
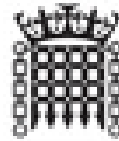
- **The law in EP countries is broadly the same** – European Patent Convention
 - Applied differently: can lead to different outcomes
- **The procedure in EU countries is partly harmonised** – The IP Enforcement Directive
 - Applied differently: different procedural tools, e.g. disclosure/cross-examination

UK – Key Features



- Two specialised patent courts:
 - **Patents Court (High Court)**
 - **Intellectual Property Enterprise Court (IPEC)**
- Handle all [life science] IP disputes
 - Patent validity / infringement (generally heard together – no bifurcation)
 - SPC validity / infringement – referrals to CJEU
 - Patent licence disputes
- Split proceedings (i) liability; (ii) damages
- Thorough judgments dealing with all issues
- Specialist, technically qualified judges

English Courts for Patent Matters



UK – Case Management



- Increasingly active case management (IPEC and now PC)
- Judge has broad discretion
 - Interim applications for injunctive relief
 - Determination of preliminary issues
 - Disputes over scheduling /case amendment / procedures
 - Amendment of patent claims in course of litigation
 - Availability of declaratory relief
 - CJEU referrals: SPC Regulation
Biotech Directive
- Parallel EPO actions:
 - EPO decisions not determinative
 - Cases will rarely be stayed - *GSK v Genentech*; *IPCom v HTC*
 - Court may ask TBA to speed up –
Eli Lilly v HGS; *Eli Lilly v Biogen*; *Regeneron v Kymab*

UK – Procedural Tools



- **Extensive procedural tools to prove / challenge case**
- **Proving infringement**
 - Pre-action disclosure
 - Infringement -
 - Patent licences – *The Big Red Bus Company Ltd v Ticketogo Ltd*
 - Third party disclosure — *Norwich Pharmacal v Customs & Excise*
 - Disclosure / PPD
 - Inspection of processes
 - Reversal of burden of proof with process claims
- **Other Procedural tools**
 - Cross-examination of witnesses / party experts
 - Observed experiments

UK - Confidentiality



- Court - filed documents open to inspection
- Hearings open to the public
- Disclosure documents / PPD often designated as “confidential” and for purposes of UK proceedings only
- Documents read by judge or referred to in open court become public
- Order to maintain confidentiality *pro tem* at trial
- Review of confidentiality at hearing post judgment

UK – Available Relief



- Declaratory relief available:
 - Declaration of non-infringement
 - Potentially pan-European? – *Actavis v Eli Lilly (on appeal)*
 - Revocation proceedings (without the need for standing)
 - Declaration as to availability of SPC – *Eli Lilly v HGS* but *ViiV v Teva*
- Injunctions, including Preliminary Injunctions (see below)
- Damages or Account of Profits
- Loser pays majority of opponent's actual legal costs
 - On an issue by issue basis
 - Assessed if not agreed – costs budgeting now relevant

UK – Preliminary Injunctions



- **Preliminary Injunctions** – *American Cyanamid*
 - Serious issue to be tried
 - Patentee to suffer irreparable loss?
 - Defendant to suffer irreparable loss?
 - Balance of convenience
- Preliminary injunctions are particularly important to protect price in regulated markets such as the biopharma and medical devices
- Has led to *clearing the way doctrine* in pharma v generic cases
 - *SKB v Apotex*

UK – Clearing the Way



- Particular relevance to generic cases – disruption of originator monopoly can have dramatic and irreversible effects on price due to the reimbursement system for medicinal products.
- Established UK case law doctrine that generic market entrants should ‘clear the way’ by seeking revocation or declaratory relief. If they do not, they are at risk of being restrained from launch pending full trial (*SKB v Apotex*, followed in many cases subsequently).
 - minimise the risk of injustice in the interim, pending resolution of the dispute at trial.
 - Injunction backed by a cross-undertaking in damages, which may be significant.
 - Potential for cross-undertaking to extend to the NHS (as the ultimate payer for the products) - little case law on this aspect.

UK – Patents Court Timing



- **Timing**
 - **First instance trial: 10 – 15 months**
 - **Streamlined procedures available**
 - *Mayne v Pharmacia* (pharmaceutical patent non-infringement action) came to trial within five months of the Claim Form being issued.
 - *Sandoz v Roche* (a pharmaceutical patent revocation action) came to trial six months after the CMC.
 - **Court of Appeal: 10 – 12 months**
 - **Injunction usually stayed pending appeal**

UK – Patents Court Costs



- **Court fees**
 - Flat fees for commencing court proceedings: approx £2,000
- **Legal fees**
 - usually hourly rates, but “contingency” type arrangements permissible
 - Lawyer’s costs in UK generally higher as common law system with disclosure, longer trials, xx etc
 - Average costs around £1m for a one patent, 4 – 5 day trial (but depends on technology, complexity etc)
 - Appeal costs approximately 30% of high court

UK – IPEC



- **Intellectual Property Enterprise Court (IPEC, previously PCC)**
 - Reformed in 2010 with His Honour Colin Birss QC – experienced technically qualified barrister
 - Replaced by Hacon J (technically qualified barrister)
 - Front loaded procedure similar to German procedure
 - Full written pleadings setting out arguments and evidence
 - Active case management
 - Party experts less prominent
 - Disclosure only available if necessary
 - short trial 1-2 days maximum
 - Limit on costs recovery – max £50,000
 - Lower value disputes – max £500,000

UK – IPEC (cont'd)



■ Intellectual Property Enterprise Court

- Intended for:
 - Lower value or low complexity disputes
 - Intended for smaller companies but some use by larger companies
 - Eg *Baxter v Fresenius Medical Care*
- Cost is much lower than High Court
 - £150,000 – 350,000 (possibly less, depending on nature of dispute)
- Popular for lower value / less complex patent cases and also trade mark disputes

Enforcement of UK judgments

Validity

- Revocation or amendment of patent claims recorded at UKIPO

Damages

- Directly enforceable against UK-based Defendants / assets
- Failure to comply with a court order may carry risk of imprisonment
- Enforcement of UK judgment abroad
 - Brussels Regulation or the Lugano Convention;
 - countries with which the UK has a reciprocal agreement in place;
 - Difficulty in countries for which none of the above apply - notably the USA, Japan and China. Commence local proceedings for enforcement under common law.

UK – Typical Factors for choosing / benefits



- **For patentee:**

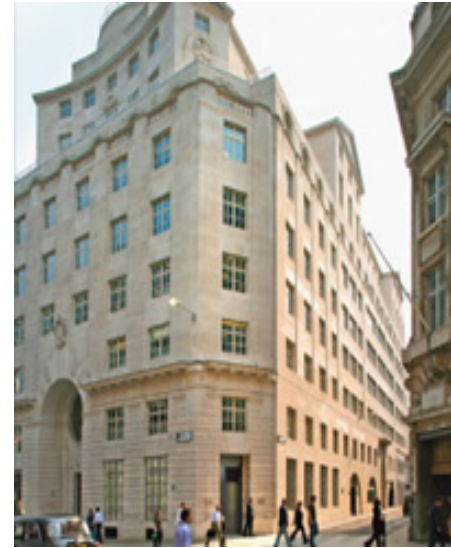
- Speed
- Preliminary relief
- Fully reasoned judgment (which can be exported)
- Evidence gathering (including for other proceedings)
- Protect specific UK market

- **For potential defendant:**

- Infringement and validity heard together
- Thorough analysis of validity even where prior art has been considered in the EPO, UK court takes independent view
- Revocation decision may be useful in eg bifurcated German

Thank you!

Any questions?



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