

Litigating Pharma Patents in UK

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Litigating Pharma Patents in UK

- No. of recorded Judgments in High Court in 2016 to date is 14

- Cost of typical pharma case trial: £1 to £3 million

- Time to Trial
 - Interlocutory application -3/4 months
 - Main action following interlocutory application – 6 months
 - Main action without interlocutory proceedings – 12/15 months

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Stays pending oppositions at the EPO – Rare in pharma cases

■ Actavis v Pharmacia 2014

- Validity proceedings before High Court whilst opposition proceedings were pending against the UK designation at the EPO.

The patentee (Pharmacia) sought a stay and offered:

- (i) to expedite the opposition
- (ii) not seek an injunction until the opposition was concluded, and
- (iii) only to seek minimum damages (1% of net sales) between launch and conclusion of the opposition.

The stay was refused. The significant factor seems to have been delay creating uncertainty for the parties.

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Availability of Interlocutory Injunctions

- General rule is American Cyanamid v Ethicon 1975
 - If there is a “serious question to be tried” the decision to grant an injunction should depend on the balance of economic inconvenience.
 - The Court should not try the merits of the case on the basis of contested affidavit evidence Note: The House of Lords was told the appeal would last 12 days.
 - The Cyanamid rule in most patent cases – means no interlocutory injunction.

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The Cyanamid rule in pharma cases

- Usually an injunction will be granted but patentee must prove that there is even a serious case to be answered.

Warner-Lambert v Actavis 2015

- The Judge held that the argument that the defendant's product directly infringed a Swiss-type process claim was not seriously arguable.
- Also patentee must prove irrevocable loss.

Cephalon v Orchid Europe 2011

- This was a case where the Court held that the patentee would be able to increase the price of the patented product following generic competition.

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- The Cyanamid rule leads to the “clearing the way principle” in generic/originator cases.
- Note that the price for an interlocutory injunction is a cross-undertaking in damages to defendant and increasingly to third parties such as the UK NHS and other bodies.

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Final Relief

- Discretionary permanent injunction

- Damages

- Ancillary Relief
 - delivery up or destruction

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Key Procedures in English pharma trials

- Party expert witnesses who will provide very detailed written reports
- Oral cross-examination of experts and other witnesses at trial
- Appeals may be brought – on legal principles alone. Very rarely will there be additional evidence on appeal.