

Infringement and Enforcement

29 January 2010

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Where to sue?

- Forum shopping
- Timescales
- Disclosure/evidence
- Costs
- Recovery of costs
- Likelihood of favourable decision





Issuing proceedings in the United Kingdom

- Patents Court
- Patents County Court
- Patent Office Opinions (non-binding)



What can infringe?

- products
- processes
- products obtained from processes

Infringing acts – products

- manufacture
- disposal
- offer to dispose
- use
- importation
- keeping

Hypothetical "Viagra" claim:

"5-[2-exthoxy-5-(4-methyl-1-piperazinylsulphonyl) phenyl]-1-methyl-3-npropyl-1,6-dihydro-7H-pyrazolo [4n,3-d] pyrimidin-7-one [sildenafil] or a pharmaceutically acceptable salt thereof."





Infringing acts – processes

- use of the process
- offering process for use in the UK, knowing or it being obvious that use of the process will infringe

Viagra patent – Claim 1:

"The use of a compound of formula (I) ... for the manufacture of a medicament for the ... treatment of erectile dysfunction in a male animal, including men."



Infringing acts – product obtained directly from patented process

- disposal
- offer to dispose
- use
- importation
- keeping



Secondary Infringement

Supplying/offering to supply means for putting invention into effect

- means must relate to an "essential element" of the invention
- knowledge requirement

Common design / joint tortfeasors



Do I infringe? Claim construction

Approach will vary between jurisdictions

European Patent Convention, article 69:

- monopoly defined by the claims
- description and drawings used to interpret claims
- purposive construction

Approach still varies considerably between EPC member states



Mayne Pharma v Pharmacia Italia (2005)

Claim 1:

"An injectable, <u>ready-to-use</u>, sterile, pyrogen-free, anthracycline glycoside solution which consists essentially of a physiologically acceptable salt of an anthracycline glycoside dissolved in a physiologically acceptable aqueous solvent therefor at an antracycline glycoside concentration of from 0.1 to 50 mg/ml, <u>which has not been reconstituted</u> <u>from a lyophilizate</u> and the pH of which has been adjusted to from 2.5 to 5.0 solely with a phsiologically acceptable acid, the said acid being selected from hydrocholoric, sulfuric, phosphoric, acetic, succinic, tartaric, ascorbic, citric, glutamic, methanesulphonic or ethanesulphonic acid."



Remedies

- injunction
- delivery up/destruction of patented products
- damages
- account of profits
- declaration of validity and infringement
- costs



Rights Conferred by Publication

- damages only
- cannot bring proceedings until grant
- act must infringe claims as published and granted
- reduced damages if unreasonable to expect patent claims to be granted



Potential defences to infringement

- Do not in fact infringe
- Patent invalid / not in force / defective title
- Experimental purposes relating to subject matter of invention
- Private, non-commercial use
- Trials conducted for the approval of generics
- Innocent infringement (re damages)



Avoiding infringement proceedings

- Keep an eye on your competitors
- Patent watches
- Take a licence
- Build a patent portfolio give your competitors something to fear
- Location of activities, especially clinical trials
- Design around



Pre-empting infringement proceedings

Attack often the best means of defence

- oppose/revoke the patent
- declarations of non-infringement
- forum shopping



Thank you

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