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Second Medical Use Patent Enforcement

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The reality of generic "skinny labels" …..

1	INN/generic prescribing - 83%
2	indication is not on the prescription
3	pharmacist will cross dispense
4	generic medicine will be used for the patented indication

… and everyone knows it!

The test for infringement: the "mens rea"?

Direct infringement

A

- invention = EPC 2000 claim , product, ie medicine
- S.60(1)(a) Patents Act 1977
- who infringes? – Supplier of medicine, ie generic company
- mens rea: (via claim interpretation) knowing the medicine will be used for the patented indication

B

- invention = Swiss form claim, process (making, packaging, labelling, obtaining skinny MA for product) of preparation of medicine for patented indication
- S.60(1)(c) Patents Act 1977; "*where the invention is a process…he disposes of…any product obtained directly by means of that process*"
- who infringes? – Supplier of medicine (being a product of the process), ie generic company
- mens rea: (via claim interpretation) knowing the medicine will be used for the patented indication

Contributory infringement

- invention = Swiss form claim, process ending with dispensing of the medicine for patented indication
- who infringes? – Supplier of the "means relating to an essential element of the invention" (the medicine), ie generic company
- mens rea: in the statutory provision, knowing the medicine will be used for the patented indication

The generic company should …

Clear a path for itself before the Courts and then launch:

- patent invalid; and/or
- declaration of non-infringement; OR

Obtain changes to:

- clinical commissioning software system; and
- prescribing software;

to only permit prescribing by generic/INN name for the specific active ingredient for non-patented indications

Launch at risk but modest "design around" with:

- a removable label/sticker that specifies eg: "NOT TO BE DISPENSED FOR EPILEPSY"
- obligation on pharmacist to make reasonable check on the indication
- contractual restrictions with pharmacist customers: eg: "your total supply from generic sources of [active ingredient] shall not exceed 21% of your total supplies of that product"

Be upfront with the innovator in good time to clarify reimbursement categorisations

- Innovator branded product Category C price to remain and pharmacist to be reimbursed for any branded prescription at that price.

THEN: open market competition on price between innovator and generics for non-patented indications.

Questions?

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