

Merck's anti-baldness drug patent held valid thanks to Swiss form claims

Actavis UK Ltd v Merck & Co Inc [2008] EWCA Civ 444¹

On 21 May 2008, the Court of Appeal of England and Wales overturned the lower Patents Court decision and instead followed the decision of the European Patent Office ("EPO"), on the basis that the EPO had recently arrived at a settled practice for second medical use patents (i.e. "Swiss form claims").

In this case, the dispute centred on whether a new dosage scheme for treatment of the same disorder as previously treated would be judged as being novel or whether the novelty had to subsist in the new therapeutic application itself. The provisions of the European Patent Convention Art 54 (enacted as s.2(6) of the UK's Patents Act 1977) state that:

"In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art"

Specifically, Merck owned patents for the drug finasteride, both for the treatment of benign prostatic hyperplasia (prostate enlargement) and a later patent for the treatment of androgenic alopecia (a condition which included both male and female pattern baldness). Crucially, each patent taught different dosage schemes.

Merck defended its later patent by citing *Eisai G5/83* [1985] OJ EPO 64, a decision in which an Enlarged Board of the EPO had ruled that:

"It is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case where the process of manufacture as such does not differ from known processes using the same active ingredient."

¹ Extracts of this Judgment have been reproduced above from <http://www.bailii.org/ew/cases/EWCA/Civ/2008/444.html>

On this basis, the Court of Appeal ignored its own arguably conflicting prior case law to hold that, in this case, the new dosage regime was enough to confer novelty in a Swiss form claim. The Court of Appeal was influenced by the fact that in Germany and New Zealand (as well as the EPO), Swiss form claims, whose novelty depends on a new treatment by a different dosage regime (or method of administration), are treated as novel.

However, such a decision does not mean that just specifying a new dosage regime in a Swiss form claim will give rise to a valid patent. On the contrary, the Court of Appeal made the following observation in this regard:

"nearly always such dosage regimes will be obvious – it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present (where...treatment for the condition with the substance had ceased to be worth investigating with any dosage regime) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim".

The previous statements are for information purposes only, and do not constitute legal advice. Questions regarding the matters discussed above, and any requests to be subscribed to the free electronic distribution of this publication, may be directed to Marija J. Danilunas at +44 207 459 5017 / mdanilunas@dl.com or Piers Strickland at +44 20 7459 5267/ pstrickland@dl.com or to any other Dewey & LeBoeuf lawyer with whom you regularly consult.

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