



Patents Court Allows Gilead Sciences Appeal

On 31st July 2008 Mr Justice Kitchin gave judgement in Gilead Sciences, Inc.'s appeal against the UKIPO Comptroller's decision refusing its application for an SPC application, SPC/GB05/041. Helen Jones (Partner, Gill Jennings & Every LLP), instructing Charlotte May, 8 New Square, acted for the appellant.

The SPC application was based on EP0915894 (the "Patent") and was for a "composition containing both tenofovir disoproxil optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate thereof, together with emtricitabine". Both tenofovir and emtricitabine are anti-retrovirals, used to combat HIV infection. This combination of anti-retrovirals is sold under the trade name Truvada™ and accounted for \$1.59 billion of Gilead's sales in 2007.

Tenofovir was specifically disclosed and claimed in the Patent. The only claim specifically mentioning a combination was claim 27, which was directed to a pharmaceutical composition comprising the novel compound "together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients". Emtricitabine was not mentioned in the Patent.

The Comptroller's refusal of the application was based on Takeda Chemical Industries Ltd's SPC Applications (No.3)[2004] RPC 1, [2003] EWHC 649 (Pat), where the Patents Court upheld a refusal of SPC applications on lansoprazole in combination with other named antibiotics. Council Regulation (EEC) No. 1768/92 concerning the grant of SPC applications requires in Art 3(a) that a certificate shall only be granted if the product for which it is applied is protected by the basic Patent in force. The judge held in Takeda that the patent did not protect the combination, since the claims only mentioned lansoprazole.

The Comptroller in Gilead indicated that the specification of the Patent should at least provide a clear pointer to the specific combination product. Kitchin J rejected this test, holding at paragraph 33 that the test applicable to a combination of ingredients...

"is to identify the active ingredients of the product which are relevant to a consideration of whether the product falls within the scope of a claim of the basic patent. It is those ingredients, and only those ingredients, which can be



said to be protected within the meaning of the Regulation. So, in the case of a product consisting of a combination of ingredients A and B and a basic patent which claims A, it is only A which brings the combination within the scope of the monopoly. Hence it is A which is protected and not the combination of A and B. ... The product comprises two active ingredients... It falls within the scope of claims 1 and 25 only because of the presence of (one of those compounds). Hence, on the Takeda test, claims 1 and 25 do not protect the product within the meaning of the Regulation. However, claim 27 is directed to a composition comprising (the first compound) together with a carrier and optionally other active ingredients. The product falls within this claim too and it does so, in so far as the claim is directed to a combination, as result of the presence of both (compounds).”

Hence the presence of claim 27 in the Patent allowed Kitchin J to distinguish from Takeda and allow the Appeal.

The Comptroller has been given leave to appeal the decision.

For more information, please contact Helen Jones or Isobel Davies at Gill Jennings & Every LLP.

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