

Teva to uphold Copaxone patent until May 2015

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Singapore: Israel-based Teva Pharmaceuticals has received favourable response in England and Wales regarding the validity of the asserted claims of UK patent 762,888 relating to Copaxone (glatiramer acetate injection), following an appeal brought by UK based Generics, a subsidiary of Mylan Laboratories.

Copaxone is indicated for reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis (RRMS), including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

In the litigation, Generics had applied to the court to revoke the patent and also grant a declaration of non-infringement for its purported generic version of Copaxone. The High Court and the Court of Appeal have now both upheld the validity of the patent and denied the application for a declaration of non-infringement. The patent is not due to expire until May 2015.

Teva's president and CEO, Dr Jeremy Levin, welcomed the court's decision, "This decision upholding the patent strengthens Teva's exclusivity of Copaxone in the UK until at least the date of the patent expiry. Thousands of patients in the UK and elsewhere depend on Copaxone for relief in relapsing-remitting multiple sclerosis, and we are pleased that the English Court of Appeal has upheld the validity of the patent until its expiry in 2015."

Any potential generic version of Copaxone would require a marketing authorization from the Medicines and Healthcare products Regulatory Agency (MHRA) before it could be commercialized.

Given the complexity of Copaxone, unpredictable differences between a proposed generic product and Copaxone could lead to immunogenic effects in patients. The inability to fully characterize the active ingredients of the product leads many experts to believe that the only way to ensure the safety, efficacy and immunogenicity of any purported generic version of Copaxone would be through full-scale, placebo-controlled clinical trials with measured clinical endpoints (such as relapse rate) in relapsing-remitting multiple sclerosis (RRMS) patients.