

ACRUX ANNOUNCES COURT RULING ON AXIRON® PATENT FAMILIES

Axiron® patent litigation

On 22 August 2016, in the United States (23 August Melbourne AEST), the United States District Court for the Southern District of Indiana ruled the formulation and axilla application patents granted by the US Patent Office for Axiron® have been invalidated and therefore would not be infringed by the commercialisation of generic versions of Axiron® by the generic companies that have challenged these patents. The applicator patent is valid but not infringed by the majority of parties.

Acrux and Lilly are disappointed with the U.S. District Court's ruling that the Axiron® formulation and axilla application patents are not valid and would not be infringed by generic competitors. Acrux and Lilly will review the Court's decision and consider whether to appeal the ruling.

The launch of generic competition to Axiron® in the United States will cause a material decline in Axiron's net sales and the resulting royalties received by Acrux.

For further information, contact

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About the litigation

Acrux (ASX: ACR) and our partner Eli Lilly and Company have filed lawsuits against 1) Perrigo Israel Pharmaceuticals Limited ("Perrigo"), 2) Watson Laboratories Inc. ("Actavis"), 3) Amneal Pharmaceuticals LLC ("Amneal") and 4) Lupin Pharmaceuticals Inc. ("Lupin"), each of which filed an Abbreviated New Drug Application ("ANDA") for a generic version of Axiron, for infringement of certain issued US patents. Formal trial proceedings began June 2016 in the United States District Court for the Southern District of Indiana against these generic companies.

About Acrux

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising branded and generic topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and licensed a number of pharmaceutical products in the US and Europe using the Patchless Patch™, a fast-drying and invisible topical application technology. Marketed products include Axiron®, Evamist® and Lenzetto®. More recently, in addition to specialty products, Acrux has identified and initiated development of a range of generic products. Acrux is leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring more products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

For further information on Acrux, visit www.acrux.com.au

