

ACRUX AND ELI LILLY TO APPEAL PATENT RULING ON AXIRON®

On 23 August 2016, in the United States (24 August Melbourne AEST), Eli Lilly and Company and Acrux announced that they will appeal yesterday's decision by the United States District Court for the Southern District of Indiana, in which the Axiron® formulation and axilla application patents granted by the US Patent and Trademark Office were held invalid, and in which the applicator patent was held valid but not infringed by the majority of parties.

The decision allows FDA-approved generic versions of Axiron® to enter the U.S. marketplace "at risk," pending an appeal. A favourable ruling would have provided patent protection for Axiron® until the formulation and axilla application patents expired in 2017 and 2027, respectively. "At-risk" generic launches refer to when FDA approved generics are launched while patent litigation is ongoing. In the event that the decision is overturned during the appeal, and the courts determine that the patents are valid and infringed, the generics would be withdrawn from the market and the brand company can seek monetary damages.

Lilly and Acrux continue to believe that the Axiron® formulation and axilla application patents are valid and enforceable, and would be infringed by a generic competitor prior to the expiration of exclusivity. Lilly and Acrux are committed to asserting their intellectual property rights for Axiron®. Lilly and Acrux are represented by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP which is a firm with significant expertise in patent litigation in the United States.

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. On 22 August 2016, 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 Court also ruled that the applicator patent is valid but not infringed by the majority of parties.



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

