



MAYNE PHARMA ANNOUNCES PATENT LAWSUIT AGAINST SUN PHARMACEUTICAL

25 July 2024, Adelaide, Australia: Mayne Pharma Group Limited (ASX: MYX), today announced the filing of a patent infringement suit against Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (Sun Pharma) on 24 July 2024, in the United States District Court for the District of New Jersey.

In its suit, the Company alleges infringement by Sun Pharma of all twenty Orange Book listed patents relating to IMVEXXY® (estradiol vaginal inserts). This lawsuit arises from a notification that Sun Pharma submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking approval to market a generic version of IMVEXXY®, including a Paragraph IV certification challenging the Company's Orange Book listed patents. This action formally initiates the litigation process under the Hatch-Waxman Act and triggers a 30-month stay of any potential FDA approval for Sun Pharma's ANDA.

Mayne Pharma's CEO, Mr. Shawn Patrick O'Brien said, "This lawsuit reflects Mayne Pharma's commitment to protecting our intellectual property rights. As one of the top two specialised women's healthcare companies in the United States, intellectual property is important to our business, and we are confident in our ability to vigorously defend the IMVEXXY® franchise for the benefit of our patients."

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Authorised for release to the ASX by the Chair

About IMVEXXY

IMVEXXY® (estradiol vaginal inserts) is approved in the US for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause. IMVEXXY® is the only product in its therapeutic class to offer a 4mcg and 10mcg dose. The 4mcg dose represents the lowest approved dose of vaginal estradiol available. Mayne Pharma acquired an exclusive license agreement for IMVEXXY® in the United States from TherapeuticsMD, Inc. (NASDAQ:TXMD) in December 2022.

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel pharmaceuticals, offering patients better, safe and more accessible medicines. Mayne Pharma is a leader in dermatology and women's health in the United States and also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40-

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year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit maynepharma.com.

IMVEXXY® is a registered trademark of TherapeuticsMD, Inc.

