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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN TECHNOLOGIES, INC.,
Petitioner,

v.

NOVEN PHARMACEUTICALS, INC.
Patent Owner.

Case No. IPR2018-01119
Patent No. 9,833,419

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,833,419

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I. INTRODUCTION

Mylan Technologies, Inc. ("Mylan") requests review of U.S. Patent No. 9,833,419 to Mantelle ("the '419 patent," EX1001), which issued on December 5, 2017. PTO records indicate that the '419 patent is assigned to Noven Pharmaceuticals, Inc. (Patent Owner, "PO"). This Petition demonstrates that there is a reasonable likelihood that claims 1-15 of the '419 patent are unpatentable for failure to distinguish over the prior art asserted herein.

The '419 patent is directed to a monolithic (single drug-containing layer) transdermal drug delivery system (*i.e.*, a transdermal patch) for the administration of estradiol, and to conventional methods of making and administering the same. The patch comprises a backing layer, a single drug-containing adhesive polymer matrix, and, optionally, a release liner. The claims specify parameters for coat weight, drug loading (dose per-unit-area), and estradiol flux (permeation over time) that were each known in the prior art.

The art of transdermal delivery of estradiol using monolithic patches was well developed by the time of the '419 patent's earliest claimed priority in July, 2008. In fact, PO had obtained FDA approval for one patch system, termed Vivelle®, as early as 1994. EX1008 (Vivelle® Label); EX1034 (Orange Book Listing), 0175. In 1999, PO received FDA approval for a second-generation patch system with higher estradiol flux, termed Vivelle-Dot®, which permitted the

delivery of the same amount of estradiol as Vivelle®, but in smaller patches. EX1006 (Vivelle-Dot® Label); EX1034, 0175. The art made clear that smaller adhesive patches were desirable for a number of reasons, both aesthetic and practical (*e.g.*, reduced skin irritation, better adhesive properties, improved patient satisfaction, improved compliance, and reduced packaging costs).

Thus, before July 2008, it was well recognized in the art that one could deliver a drug more efficiently, and reduce the patch size for a given dose, by increasing the flux of a patch. The prior art described several methods for increasing the flux of monolithic transdermal patches, including for estradiol. For example, the prior art taught that higher flux could be achieved by increasing the amount of hydrophile within the adhesive polymer matrix or by using increased amounts of penetration enhancers. EX1005, ¶¶3, 5, 17-18, 27, 31; EX1007 (Kanios), ¶¶118-22, 126-28.

The prior art Mueller reference (EX1005) describes a monolithic transdermal estradiol delivery system in Example 3 that satisfies each of the elements of independent claim 1 and its dependent claims 2, 8, and 10-15. The Mueller system comprises a single drug-containing adhesive polymer matrix layer, a backing layer, and a release liner. Mueller teaches that the polymer matrix comprises greater than 0.156 mg/cm^2 estradiol, acrylic and silicone adhesives, soluble polyvinylpyrrolidone (PVP), dipropylene glycol as a penetration enhancer,

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