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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. IPR2018-00174
Patent No. 9,730,900

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,730,900

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I. INTRODUCTION

Mylan Technologies, Inc. ("Mylan") requests review of U.S. Patent No. 9,730,900 to Mantelle ("the '900 patent," EX1001), which issued on August 15, 2017. PTO records indicate that the '900 patent is assigned to Noven Pharmaceuticals, Inc. (Patent Owner, "PO"). This Petition demonstrates that there is a reasonable likelihood that claims 1-23 of the '900 patent are unpatentable for failure to distinguish over the prior art asserted herein. An additional petition is being filed simultaneously to address similar claims of related U.S. Patent No. 9,724,310, also assigned to PO.

These patents are 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 them. The patch comprises a backing layer, and 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 '900 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 more of 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 can be achieved by increasing the amount of hydrophiles 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 claims 1 and 16 and their dependent claims 2, 8, 10-15, and 18-22. 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, and a coat weight above 10 mg/cm^2. Moreover, Mueller teaches that it provides a constant release of estradiol over a period of 72 hours, and achieves an estradiol flux of 0.015 mg/cm^2/day, within the claimed range of "from about 0.0125 to about 0.05 mg/cm^2/day." Mueller Example 3 achieves a higher estradiol flux than was reported for the prior art Vivelle-Dot® patch. Mueller expressly teaches that higher flux permits the use of smaller patches to deliver a given amount of estradiol.

The prior art also teaches that increasing the coat weight of the drug-matrix layer of a patch results in an increased flux per-unit-area. For example, Chien, which was not of record during prosecution, explicitly teaches that increasing estradiol drug loading, or the coat weight of the adhesive polymer matrix of an estradiol patch, directly increased flux. EX1009, FIGS. 4-5. Yet, during prosecution, PO obtained allowance for the '900 patent by repeatedly asserting that it was "surprising and unexpected" that increasing the amount of estradiol per-unit-area (increasing the coat weight) of the drug-containing matrix would increase the flux of the patch. *See*, *e.g.*, EX1004, 0010; *see also id.*, 0169-70, 0194, 0269, 0541-2.

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