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Paper No. 9
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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 IPR2018-00173
Patent 9,724,310 B2

Before JAMES T. MOORE, SUSAN L. C. MITCHELL, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Mylan Technologies, Inc. ("Petitioner") requests an *inter partes* review of claims 1–15 of U.S. Patent No. 9,724,310 B2 ("the '310 patent," Ex. 1001). Paper 1 ("Pet."). Noven Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314(b) may not institute review on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018).

Applying those standards, and upon consideration of the information presented in the Petition and the Preliminary Response, we determine that Petitioner has not demonstrated a reasonable likelihood of success in proving that any claim of the '310 patent is unpatentable. We, therefore, deny the Petition and do not institute an *inter partes* review.

II. BACKGROUND

A. Related Matters

Petitioner identifies *Noven Pharmaceuticals, Inc. v. Alvogen Pine Brook LLC*, No. 1:17-cv-01429-LPS (D. Del.) as a related matter under 37 C.F.R. § 42.8(b)(2). Pet. 20. Petitioner also petitioned for an *inter partes* review of U.S. Patent 9,730,900 B2 ("the '900 patent"), owned by Patent Owner, which has been designated Case IPR2018-00174. *Id.* at 20. Petitioner states that the '310 and the '900 patents both claim the benefit of

priority to U.S. Application No. 12/216,811, filed on July 10, 2008, now U.S. Patent No. 8,231,906 ("the '906 patent"). Petitioner identifies both pending and terminated litigations involving the '906 patent. *See id.* at 20–21 (identifying *Noven Pharmaceuticals Inc. v. Mylan Technologies Inc.*, No. 1:15-cv-00328 (D. Del.) (terminated); *Noven Pharmaceuticals Inc. v. Mylan Technologies Inc.*, 1:15-cv-00069 (N.D.W.V.) (terminated), *Noven Pharmaceuticals Inc. v. Actavis Laboratories UT, Inc.*, Nos. 1:15-cv-00249-LPS and 1:16-cv-00465-LPS (D. Del.) (pending); *Alvogen Pine Brook LLC v. Noven Pharmaceuticals, Inc.*, No. 1:16-cv-00395-LPS (D. Del.) (pending)).

B. The '310 Patent

The '310 patent, titled "Transdermal Estrogen Device and Delivery," issued on August 8, 2017. Ex. 1001, [45]. The '310 patent relates to transdermal drug delivery systems for the transdermal administration of estrogen. *Id.*, Abstract. In one embodiment, the transdermal drug delivery system is a patch comprising a single adhesive polymer matrix layer of adhesive polymer matrix and estradiol. *Id.* at 2:10–16.

According to the '310 patent, "a patch comprising a pressure-sensitive adhesive containing a drug, as a means of delivering drug through the skin is well known." *Id.* at 1:20–22. But formulation of viable commercial embodiments has been difficult, in part due to patient preference for patches having a small surface area. *Id.* at 1:55–2:6. The '310 patent explains that "size, e.g., surface area at the site of application, is often dictated and limited by other physical and pharmacokinetic requirements, such as desired drug delivery rates and daily dosages." *Id.* at 1:55–60. Thus, "it is easier to develop a relatively 'large' transdermal drug delivery system that will

achieve drug delivery at target therapeutic levels over an intended duration of therapy, than it is to develop a smaller transdermal drug delivery system that still exhibits acceptable pharmacokinetic properties." *Id.* at 1:60–65.

The '310 patent refers to the target delivery rate of a drug as "flux," *id.* at 3:39, and explains that "Applicant surprisingly discovered that increasing the coat weight of the drug-containing adhesive layer resulted in an increased flux per unit area, and thus permitted the development of smaller transdermal drug delivery systems that achieve comparable daily dosages" to larger patches, *id.* at 3:56–60. Although "it was known in the art to increase coat weight to provide delivery over a longer period of time," the '310 patent continues, "it was not known that increasing coat weight could increase delivery rate or flux, and thus permit the development of a smaller system while maintaining daily dosage." *Id.* at 3:63–67.

The '310 patent provides an example of a polymer matrix composition comprising, *inter alia*, acrylic adhesive, silicone adhesive, povidone (PVP), and estradiol. *Id.* at 15:8–19 (Example 1). In one example, the polymer matrix was applied to a release liner at a coat weight of 12.5 mg/cm^2 (Example 1), and in a second sample, at a coat weight of 15 mg/cm^2 (Example 1a). *Id.* at 15:21–22. Human cadaver permeation studies were then performed to compare the estradiol flux of these samples to that of commercial embodiment Vivelle-Dot®. *Id.* at 15:23–43. As shown in Figure 1, below, "the systems according to the invention have a greater flux than the Vivelle-Dot® product and are able to achieve therapeutic daily dosages despite their significantly smaller size." *Id.* at 15:44–47.

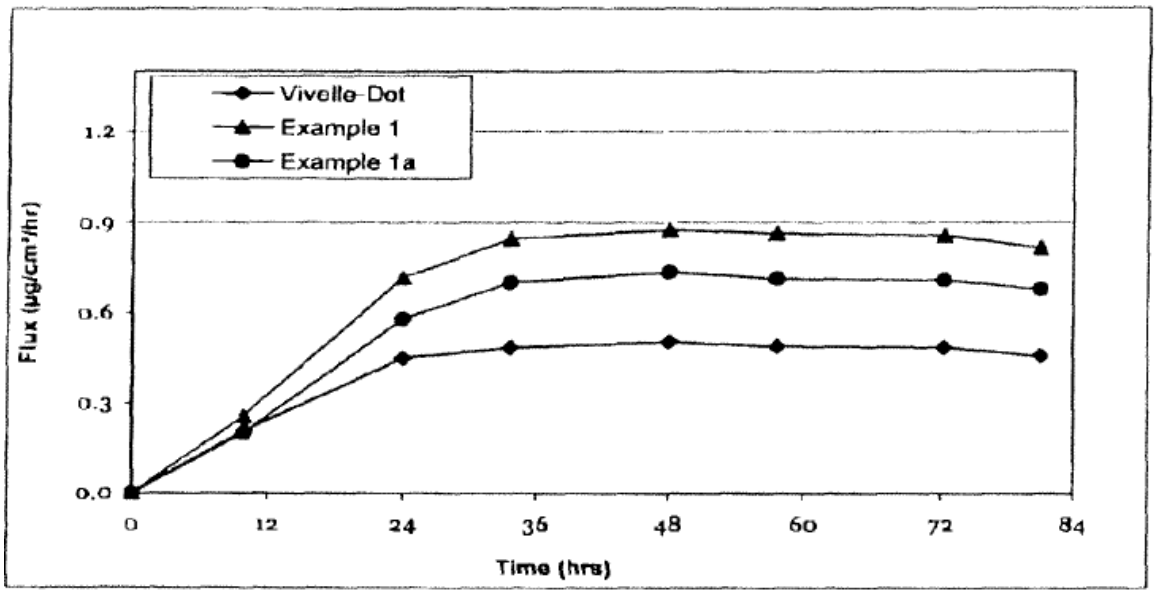

Figure 1 illustrates the estradiol flux (µg/cm^2/hr) over time (0–81 hours) from transdermal delivery systems according to the invention (Examples 1 and 1a) as compared to Vivelle-Dot®. Ex. 1001, 3:24–26.

C. Illustrative Claim

Of the challenged claims, claim 1 is independent. Claim 1 is illustrative of the claimed subject matter and recites:

> 1. A monolithic transdermal drug delivery system for estradiol, consisting of (i) a backing layer, (ii) a single adhesive polymer matrix layer defining an active surface area and, optionally, (iii) a release liner, wherein the single adhesive polymer matrix layer comprises an adhesive polymer matrix comprising estradiol as the only drug, wherein the adhesive polymer matrix layer has a coat weight of greater than about 10 mg/cm^2 and includes greater than 0.156 mg/cm^2 estradiol, and the system achieves an estradiol flux of from about 0.0125 to about 0.05 mg/cm^2/day, based on the active surface area.

Ex. 1001, 15:50–16:3.

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