Paper 9

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Petitioner,

v.

ALLERGAN, INC.
Patent Owner

IPR2018-00608
Patent 9,161,926 B2

PATENT OWNER PRELIMINARY RESPONSE

I. INTRODUCTION

The Petition should be denied because (*a*) Petitioner presents no evidence that the claimed copolymer was known to be capable of replacing Garrett's Carbopol to form microparticulate dapsone; (*b*) Petitioner ignores Nadau-Fourcade's express teaching to avoid crystallization; and (*c*) Petitioner fails to show that evidence it relies on is prior art.

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II. DISCUSSION OF CHALLENGES

A. Ground 1 — Garrett and Nadau-Fourcade

1. Petitioner does not show that the claimed copolymer was known to have the properties required for it to replace Garrett's Carbopol.

Petitioner argues that Garrett's Carbopol® 980 carbomer ("Carbopol") could have been replaced by Sepineo P 600 ("Sepineo") because Sepineo was known to include the claimed acrylamide/sodium acryloyldimethyl taurate copolymer ("copolymer") and was included in a list of gelling agents with Carbopol by Nadau-Fourcade. Pet. 31–32. But Petitioner presents no evidence that a person of ordinary skill in the art would have known that the claimed copolymer possessed properties that made it a suitable substitute for Garrett's Carbopol. Petitioner thus fails to demonstrate a rationale in the prior art for its proposed modification.

Garrett expressly teaches that it is the addition of the Carbopol "thickener component" to the dapsone component of its gel formulation that "immediately result[s] in the formation of crystalline microparticles."

Ex. 1004, 24:33–34.[1] Petitioner's witness Dr. Michniak-Kohn agrees, testifying that Garrett's Carbopol is the "thickening agent" and that "the thickening agent plays a role in the formation of the microparticulate dapsone." Ex. 1002 ¶¶ 81–82 (cited at Pet. 46, 47).

Petitioner offers no evidence, however, that its proposed Carbopol substitute—Sepineo (a product which includes the claimed copolymer)—was also recognized at the time of the invention as being capable of "play[ing] a role" in the formation of microparticulate dapsone. Petitioner's evidence shows, at best, that Sepineo was included with Carbopol in Nadau-Fourcade's listing of gelling agents, *e.g.* Pet. 32 (citing Ex. 1005, 47:12–32 and 48:1–7), but not that these agents were known to be interchangeable for the function of dapsone microparticulate formation.

Petitioner cites prior cases for the unremarkable proposition that "[w]here two known alternatives are interchangeable for a desired function, an express suggestion to substitute one for the other is not needed to render a

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[1] Patent Owner follows Petitioner's convention of citing exhibits by page numbers added to the exhibits by Petitioner, instead of to page numbers already present in the document.

substitution obvious." Pet. 32 (citations omitted). But Petitioner has not in fact offered any evidence that Carbopol and Sepineo were known alternatives interchangeable for the function that Garrett and Petitioner demand of Carbopol, specifically, dapsone microparticulate formation.

Even if Carbopol and Sepineo were "interchangeable for use in a topical composition with a water-insoluble drug," as Dr. Michniak-Kohn asserts without evidentiary support (Ex. 1002 ¶ 57), Petitioner cites no evidence that they were "interchangeable" for the specific function that the Carbopol is called upon to perform: dapsone microparticulate formation. Without putting forward evidence that Sepineo was known to be capable of this function, Petitioner provides no basis to argue that one of ordinary skill in the art even would have thought of Sepineo as a potential substitute for Carbopol in forming microparticulate dapsone.

Although Petitioner bases its arguments on Garrett's microparticulate dapsone reservoir embodiments, Petitioner does not establish a reason to modify the very component that it says "plays a role" in triggering those reservoirs. Ex. 1002 ¶ 81 (cited at Pet. 46–47). Petitioner acknowledges that Garrett teaches a "'pharmaceutical carrier system comprising a dermatological composition that is a semi-solid aqueous gel, wherein dapsone

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