

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD., ACRUX LIMITED, and
ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

KAKEN PHARMACEUTICAL CO., LTD. and VALEANT
PHARMACEUTICALS INTERNATIONAL, INC.,
Patent Owner.

Case IPR2017-00190¹
Patent 7,214,506 B2

Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION
Motions to Strike and to Exclude
37 C.F.R. § 42.64

¹ Case IPR2017-01429 has been joined with the instant proceeding.

Kaken Pharmaceutical Co., Ltd. and Valeant Pharmaceuticals International, Inc. (collectively, “Patent Owner”) filed a Motion to Strike,² *see* Paper 46, to which Acrux DDS PTY Ltd. and Acrux Limited (collectively, “Petitioner”) filed an opposition, *see* Paper 48. Patent Owner also filed a Motion to Exclude, *see* Papers 58, to which Petitioner filed an opposition, *see* Paper 63, and Patent Owner filed a reply, *see* Paper 76. Petitioner filed a Motion to Exclude, *see* Paper 51, to which Patent Owner filed an opposition, *see* Paper 70, and Petitioner filed a reply, *see* Paper 75.

Patent Owner’s Motion to Strike

Patent Owner seeks to strike significant portions of three declarations, Exhibits 1509–1511, which Petitioner submitted with its Reply, and portions of Petitioner’s Reply that Patent Owner contends presents new legal theories in violation of 37 C.F.R. § 42.23(b). Paper 46, 4–12. Patent Owner suggests that the three declarations are an attempt by Petitioner to circumvent the word limit for its reply “by pushing most of its evidence and argument into declarations that are not cited with particularity. Rather, Petitioner [improperly] incorporates by reference into the Reply large sections of its declarations without explaining their specific relevance.” *Id.* at 2. Patent Owner also asserts that Petitioner uses these declarations as the “sole vehicle” for introducing many of the new exhibits that Patent Owner seeks to have struck. *Id.* Patent Owner also seeks to strike Exhibits 1512 and 1514–1660 as either not relied upon by Petitioner or only cited in “bulk form.” *Id.* at 9–12. Patent Owner provides a detailed analysis of which

² We authorized Patent Owner to file a motion to strike. *See* Paper 43, 3.

paragraphs and exhibits should be struck as either not relied upon by Petitioner in its Reply or were cited “in bulk.” *Id.* at 13–15.

Concerning Petitioner’s alleged new theory of obviousness, Patent Owner states:

Petitioner argues in its Reply that earlier Kaken patents (Exs. 1007 and 1505) are genus patents covering the use [of] efinaconazole in treating mycosis. Petitioner concludes for the first time in the Reply that it would be obvious to use efinaconazole in treating a species of mycosis—onychomycosis—based on the generic disclosure of treating any type of mycosis in Exs. 1007 and 1505. Petitioner concludes that these earlier patents allegedly undermine evidence of commercial success for Jublia®, the marketed topical efinaconazole product for treating onychomycosis (*see* Reply at p. 9).

Paper 46, 11.

Petitioner responds that the three additional expert declarations are properly supported by documentary evidence and “are directly responsive to arguments raised by [Patent Owner’s] experts and in the [Patent Owner Response].” Paper 48, 1. Petitioner details how its use of the declarations and exhibits in its Reply constitutes appropriate rebuttal evidence and its Reply contains no new legal theory. *See id.* at 3–15. Specifically, Petitioner states that its rebuttal evidence at issue here includes (1) publications by PO’s expert, Dr. Elewski, that Petitioner alleges contradict her declaration testimony (Exs. 1512 & 1518); (2) Petitioner’s experts’ rebuttal of new issues introduced by Dr. Elewski’s declaration (Exs. 1509–1511), and (3) evidence rebutting Patent Owner’s secondary considerations evidence (Exs. 1515–1517, 1523–1660). Paper 48, 2.

Petitioner asserts that it made no new argument to support its obviousness grounds because the argument in questions merely “observes

the PO's prior efinaconazole patents recite the same preferred amount of antifungal agent as the '506 patent and the cited art: JP '639," a fact that Petitioner notes was reflected in the Decision on Instituted. Paper 48, 14, (citing Instit. Dec. 9, 16). Finally, Petitioner asserts that its assertions regarding to blocking patents is appropriate rebuttal to Patent Owner's proffer of secondary considerations evidence. *Id.* at 14–15.

Our rules mandate that a “reply may only respond to arguments raised in the corresponding opposition or patent owner response.” 37 C.F.R. § 42.23(b). We agree with Petitioner that its three rebuttal declarations and the exhibits that are cited as support in those declarations are appropriate rebuttal to the Patent Owner Response. *See* Paper 48, 11–14 (explaining how Petitioner's experts relied on the challenged exhibits); 37 C.F.R. § 42.65 (stating “[e]xpert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight”).³ We also agree that Petitioner raises no new legal theory in its Reply.

In reviewing the declarations of Dr. Walters and Dr. Weinberg at issue in Patent Owner's Motion to Strike, both declarants were responding to specific assertions made by Dr. Elewski cited as support in the Patent Owner Response. *See generally* Exs. 1509, 1510. For instance, Dr. Walters addresses Dr. Elewski's claim construction and her characterization of the teachings of the asserted art. *See, e.g.*, Ex. 1509 ¶¶ 7–71. Dr. Weinberg also addresses Dr. Elewski's characterization of the teachings of the asserted art. *See, e.g.*, Ex. 1510 ¶¶ 31–45. In his declaration, Mr. Staines addressed

³ Petitioner agrees to withdraw Exhibit 1635 as it was inadvertently included. *See* Paper 48, 11 n.3.

Patent Owner's arguments concerning secondary considerations. *See generally* Ex. 1511. As such, these declarations, along with the evidentiary exhibits cited in support, are appropriate rebuttal evidence.

That is not to say, however, that we will review the declarations and exhibits cited therein independent of Petitioner's reliance on them in its Reply. As Petitioner admits "[t]o the extent that both parties' expert declarations contain information not expressly cited, the Board is, of course, free to ascribe whatever weight it deems appropriate." Paper 48, 2.

We also agree with Petitioner that it has not presented a new legal theory in its Reply. Petitioner's arguments were in direct response to Patent Owner's assertions as to how one of skill in the art would have viewed the use of efinaconazole to treat onychomycosis. *See* Reply 3 (responding to PO's arguments that efinaconazole was a 'breakthrough' and that prior art topical agents did not work); *id.* at 9 (citing two of Patent Owner's patents to validate preferred amounts of efinaconazole).

Therefore, we deny Patent Owner's Motion to Strike.

Petitioner's Motion to Exclude

Petitioner moves to exclude paragraph 9–11 and 20–30 of the Declaration of Vincent A. Thomas, CPA, CVA, CFF, ABV (Exhibit 2028) and supporting evidence exhibits, Exhibits 2093, 2095, 2098, and 2099. Paper 51, 1; *see* Paper 75. Petitioner moves to exclude these paragraphs of Mr. Thomas' Declaration under Federal Rule of Evidence 702 as conclusory and unsupported by sufficient facts or data. *Id.* Petitioner moves to exclude the exhibits because they are "incomplete as providing partial information preventing Petitioners from testing the sufficiency of the information

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