

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ALMIRALL, LLC,
Patent Owner.

Case IPR2018-00608
U.S. Patent No. 9,161,926 B2

**PETITIONERS' REPLY IN SUPPORT OF THEIR MOTION TO
EXCLUDE EVIDENCE**

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Amneal's motion to exclude showed that Almirall's uncited evidence was both irrelevant and prejudicial. Almirall failed to rebut either point. Amneal established that the mountain of Almirall's uncited evidence should be excluded as irrelevant. Almirall did not explain why its uncited evidence made a *fact of consequence* more or less probable (*see* FRE 401(b)) and instead asks the Board to "simply not rely on" it. The Board should exclude the uncited evidence.

Next, Almirall did not rebut the prejudice to Amneal from the uncited evidence; it opted instead to incorrectly claim that Amneal "fail[s] to explain how these paragraphs are unfairly prejudicial to Petitioners." Paper 39, 3, 5. Amneal explained the prejudice of both (1) dealing with this evidence on appeal and (2) Almirall far exceeding its word limits by retaining this evidence without properly citing or discussing it. Paper 39, 1-2, 4-5. Almirall simply ignores these points.

Almirall concedes that EX2044 should be excluded, but opposes exclusion of EX2043. EX2043 is improper because it is either used for its truth to "corroborate" other evidence, or it is irrelevant. Almirall is wrong that EX2043 is "self-authenticating" under FRE 901. But FRE 902 governs self-authentication; Almirall's reading of FRE 901 would render FRE 902 meaningless.

I. Almirall's uncited evidence is irrelevant and prejudicial.

Almirall's uncited evidence is irrelevant and prejudicial, and Almirall has come forward with no meaningful basis to not exclude them. Almirall's reliance on

SK Hynix Inc. v. Netlist, Inc., IPR2017-00562, Paper 36 (PTAB Jul. 5, 2018) is misplaced. There, the Board did not exclude uncited evidence because the Petitioner specifically explained (1) why each paragraph/exhibit was submitted but not cited, (2) why the evidence was relevant, and (3) why the evidence was not unfairly prejudicial. *SK Hynix*, Paper 36 at 48. Almirall did none of this.

First, Almirall never explains why the uncited evidence was submitted but not cited, and its unsupported claim of relevance falls short. Almirall argues “relevance” through bullet points that vaguely describe the uncited evidence. Paper 39, 3-4 (stating that certain paragraphs offer “conclusion,” “context,” “background,” or an expert’s “understanding”). But describing those paragraphs, without connecting them to any fact in this case, does not make any fact of consequence more or less probable.

This deficiency is crystallized by Almirall’s misstatement of FRE 401. To be relevant, evidence must both (1) have a tendency to make a fact more or less probable than it would be without the evidence; *and* (2) that fact must be “of consequence in determining the action.” FRE 401. Almirall’s opposition ignores the second prong of FRE 401. Almirall’s uncited evidence is not consequential because Almirall never explained how this evidence has any bearing on its case. Paper 39, 3-5. Almirall still fails to offer any explanation for how its uncited evidence makes a fact of consequence more or less probable, and thus has waived

its opportunity to establish relevance. For example, Almirall stated that paragraphs 202-217 of Dr. Klivanov's declaration (EX2003) are relevant to respond to Amneal's expert testimony that the "unexpected results" evidence submitted during prosecution is factually and legally flawed. Paper 39, 3. But Dr. Klivanov's paragraphs cannot be relevant; Almirall did not argue any objective indicia of nonobviousness in its Patent Owner Response. Paper 23, 27-28.

Second, Amneal explained that allowing Almirall to maintain the uncited evidence in this proceeding is unfairly prejudicial to Amneal because (1) failure to exclude the evidence allows Almirall the potential opportunity to rely upon the evidence during appeal, and (2) Almirall would have vastly overshot the word limits if the evidence was cited and meaningfully discussed. Paper 34, 2, 4-5; *see Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014) ("Incorporation by reference amounts to a self-help increase in the length of the brief.") (quotations and citations omitted). Almirall's sole response was to repeat that Amneal "fail[ed] to explain how these paragraphs are unfairly prejudicial." Paper 39, 3, 5. That is false, so Amneal's prejudice is un rebutted.

Almirall next, to divert attention away from its own failings, argues (for the first time) that Amneal's papers contain uncited evidence, which should similarly be excluded. Paper 39, 7. But Almirall waived any such argument by not moving on this basis. Moreover, Amneal's "uncited" exhibits are relevant: it was either

cited directly or indirectly in its papers, or, in the case of AMN1006, was a legally required submission under 37 C.F.R. § 42.63(b). Conversely, Almirall's uncited exhibits are often cited only in its uncited expert testimony. *Compare* Paper 39, 6 (listing paragraphs citing exhibits) *with id.*, 2-5 (uncited paragraphs). This leaves both Amneal and the Board to work "like pigs, hunting for truffles buried in" the record. *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991).

Almirall's uncited evidence should be excluded under FRE 401-403.

II. Exhibits 2043 and 2044 should be excluded.

Amneal objected to EX2043 and EX2044 on relevance, hearsay, and authentication grounds. Almirall consents to exclusion of EX2044, but contends that EX2043 should not be excluded because it is (1) relevant, (2) authentic, and (3) not hearsay. Almirall is wrong for at least the reasons below.

First, Amneal demonstrated both that (1) the "date of report" on the face of EX2043 was hearsay and (2) EX2043 was irrelevant if Almirall could not establish that it had been published before the '926 patent's priority date. Paper 39, 5-7.

Unable to rebut this showing, Almirall shifts to now argue that EX2043 is relevant because it "corroborat[es]" other unchallenged exhibits, and that "the date is not being presented for the truth of the matter asserted." Paper 39, 7. Both assertions are wrong. Dr. Harper expressly relied on the "publication date." EX2022, ¶144, n.6. And in order to "corroborate" Almirall's other exhibits, EX2043 must

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