UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRAY SQUARE PHARMACEUTICALS, LLC
Petitioner,
v.

POZEN INC.
Patent Owner.

Case IPR2016-00191
Patent 7,332,183

Request for Rehearing Under 37 C.F.R. § 42.71(d)

Pursuant to 37 C.F.R. § 42.71(d), Gray Square Pharmaceuticals, LLC ("**Petitioner**") respectfully requests rehearing of the Board's Decision (Paper No. 10, entered May 6, 2015; "**Dec**.") denying institution of Petitioner's petition for *inter partes* review of claims 1-2 of the '183 Patent ("**Pet**."). The Board reviews a request for rehearing for an abuse of discretion. An abuse of discretion "occurs when a court misunderstands or misapplies the relevant law or makes clearly erroneous findings of fact." *Renda Marine, Inc. v. U.S.*, 509 F.3d 1372, 1379 (Fed. Cir. 2007).

I. The Board's construction of "dissolve independently" overlooked an express teaching from the specification that this limitation can be "achieved by placing the individual layers in a side-by-side arrangement."

The Board construed the phrase "dissolution of said naproxen occurs independently of said triptan" (hereinafter, the "dissolve independently" limitation) as follows: "a dissolution profile such that complete dissolution of naproxen and triptan when the drugs are given in the combination tablet requires the same amount of time ± 10% as when the same amount of naproxen or triptan is given alone." (Dec. p. 8). This construction was not proposed either the Petitioner or the Patent Owner.

The Board adopted this construction on the ground that the Patent Owner purportedly "acted as its own lexicographer by defining 'dissolve independently' in the Specification." (Dec. at 6). For support, the Board relied upon the following

passage from the specification:

> The layers should be arranged such that the individual therapeutic agents dissolve independently of one another, i.e., dissolution should occur at approximately the same rate as would occur if the drugs were given separately. In this context, "approximately the same rate" indicates that the time for complete dissolution of agent when drugs are given in the combination tablet should require the same amount of time ±10% as when the same amount of agent is given alone.

(Dec. p. 6, quoting Ex. 1001, 2:46-54).

However, the Board overlooked the critical sentence immediately following this passage, and in so doing, the Board misapprehended the Patent Owner's express definition of the "dissolve independently" limitation. Specifically, the Board overlooked the sentence in **bold** below:

> The layers should be arranged such that the individual therapeutic agents dissolve independently of one another, i.e., dissolution should occur at approximately the same rate as would occur if the drugs were given separately. In this context, "approximately the same rate" indicates that the time for complete dissolution of agent when drugs are given in the combination tablet should require the same amount of time ±10% as when the same amount of agent is given alone. **This can be achieved by placing the individual layers in a side-by-side arrangement,** as opposed, for example, in a single layer tablet matrix containing both agents or one layer forming a core surrounded by the other layer.

(Ex. 1001, 2:46-58).

This sentence (in **bold**) is part of the Patent Owner's purported definition of "dissolve independently." In other words, even if the Patent Owner defined "dissolve independently" to mean "complete dissolution of agent when drugs are given in the combination tablet should require the same amount of time ±10% as when the same amount of agent is given alone," as construed by the Board, the Patent Owner expressly and unequivocally also defined how this limitation can be achieved: "This can be achieved by placing the individual layers in a side-by-side arrangement."

The Board's misapprehension of the full scope of Patent Owner's lexicography of the "dissolve independently" limitation was material to its decision denying institution. The Board faulted each of Petitioner's proposed grounds of unpatentability for the same reason: because the Petitioner allegedly failed to identify evidence to meet the Board's construction of "dissolve independently." The Board repeatedly stated:

> Petitioner fails to identify sufficient evidence demonstrating that [Ouali (p. 10, ground 1); Elger (p. 12-13, ground 2); Desai (p. 16, ground 4)[1]] discloses or suggests bilayer tablets having a dissolution

[1] For ground 3, rather than repeating the quote above again, the Board stated:

> profile such that complete dissolution of the ingredients when given in the combination tablet requires approximately the same amount of time as when the ingredients are given alone.

(Dec. pp. 10, 12-13, 16).

The Board reasoned that Petitioner failed to identify sufficient evidence demonstrating its construction of "dissolve independently" because Petitioner did not identify evidence comparing dissolution rates of ingredients in a multilayer tablet versus dissolution rates for those ingredients alone. The Board repeatedly stated:

> Petitioner does not direct us to any test results comparing dissolution rates of [Ouali's (p. 10, ground 1); Elger's (p. 13, ground 2); Desai's (p. 16, ground 4)[2]] ingredients combined in a multilayer tablet with dissolution rates of those same ingredients on their own.

(Dec. p. 10, 13, 16).

But this evidence is not necessary. Test results, or similar evidence comparing dissolution rates of ingredients combined in a multilayer tablet with

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"Petitioner's argument is no more persuasive here than it was when presented in combination with Plachetka." (Dec. p. 14).

[2] For ground 3, rather than repeating the quote above again, the Board stated: "Petitioner's argument is no more persuasive here than it was when presented in combination with Plachetka." (Dec. p. 14).

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