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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 B2

Before DONNA M. PRAISS, JO-ANNE M. KOKOSKI, and JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

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I. INTRODUCTION

Gray Square Pharmaceuticals, LLC ("Petitioner") filed a Request for Rehearing of our Decision (Paper 10, "Dec.") denying *inter partes* review of claims 1 and 2 of U.S. Patent No. 7,332,183 B2 (Ex. 1001, "the '183 patent"). Paper 11 ("Req. Reh'g"). In our Decision, we determined that Petitioner had not established a reasonable likelihood of prevailing with respect to any of the challenged claims of the '183 patent. Dec. 2.

For the reasons that follow, Petitioner's Request for Rehearing is *denied.*

II. STANDARD OF REVIEW

The party challenging a decision in a request for rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d). A request for rehearing "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed." *Id.* Upon a request for rehearing, the decision on a petition will be reviewed for an abuse of discretion. 37 C.F.R. § 42.71(c).

III. DISCUSSION

1. Construction of "dissolution of said naproxen occurs independently of said triptan"

Claim 1 of the '183 patent requires a multilayer tablet wherein "said first layer and said second layer are in a side by side arrangement such that the dissolution of said naproxen occurs independently of said triptan." Ex. 1001, 18:35–37. At page 8 of our Decision, we stated that

> the broadest reasonable interpretation of the phrase "dissolution of said naproxen occurs independently of said triptan" is a

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> 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. 8. We based our construction on a specific portion of the Specification that we determined to be Patent Owner's definition of "dissolve independently." *Id.* at 6 (citing Ex. 1001, 2:46–54).

Petitioner contends that the Board overlooked a "critical sentence" in the Specification when construing the phrase "dissolution of said naproxen occurs independently of said triptan" in claim 1 and, therefore, misapprehended the express definition of "dissolve independently." Req. Reh'g 3. This "critical sentence" is shown in bold in the passage from the Specification reproduced 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 (emphasis added).

In our Decision, we considered Patent Owner's definition of "dissolve independently" to include only the first two sentences of the passage reproduced above. Dec. 6. Petitioner, however, contends that the sentence shown in bold is part of Patent Owner's definition of "dissolve independently" such that the proper construction of the phrase "dissolution

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of said naproxen occurs independently of said triptan" includes the sentence "[t]his can be achieved by placing the individual layers in a side-by-side arrangement." Req. Reh'g 4, 6.

We are not persuaded by Petitioner's argument that we misapprehended the express definition of "dissolve independently" by overlooking the alleged "critical sentence" identified by Petitioner. The sentence in question explains *how* one can achieve independent dissolution (as acknowledged by Petitioner (*id.* at 4)), not *what* it means to "dissolve independently." To the contrary, the first two sentences in the passage reproduced above—the portion of the Specification we identified in our Decision as containing Patent Owner's definition of "dissolve independently"—squarely addresses what that term means. Dec. 6; Ex. 1001, 2:46–54.

Further, we note that the sentence in question indicates independent dissolution "*can be* achieved by placing the individual layers in a side-by-side arrangement," which is different from requiring that a person of ordinary skill in the art must achieve it that way. Ex. 1001, 2:54–55 (emphasis added). Thus, because Patent Owner chose to describe the side-by-side configuration as an optional way to achieve independent dissolution in the Specification, we are not persuaded that the definition of "dissolve independently" should expressly include that configuration. This is especially true considering that claim 1, as Petitioner recognizes (Req. Reh'g 6–7), separately requires that the multilayer tablet have a side-by-side configuration in addition to requiring that the naproxen and triptan dissolve independently.

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Nor are we persuaded that the construction adopted in the Decision is inconsistent with the Patent Owner's teaching in the Specification, or that it requires that the limitation that "dissolution . . . occurs independently" cannot be met by placing the individual layers in a side by side configuration. *See* Req. Reh'g. 7. To the contrary, in view of the optional language provided in the Specification, independent dissolution is not necessarily tied to any specific configuration. In order to establish unpatentability of claim 1 in view of prior art, however, Petitioner has the burden of demonstrating that the prior art discloses or suggests both independent dissolution and a side-by-side configuration, as required by claim 1.

2. Whether the limitation "such that the dissolution . . . occurs independently" is a patentable distinction over the prior art

Petitioner contends that the Board overlooked and misapprehended its argument that the limitation requiring ingredients to be arranged side-by-side "such that dissolution . . . occurs independently" is not a patentable distinction. Req. Reh'g 11. For the reasons set forth below, we disagree.

In the Petition, Petitioner argued that the limitation requiring independent dissolution is not a patentable distinction because "[p]ersons of ordinary skill knew that 'independent' dissolution of the ingredients in the respective layers of a bilayer tablet was an inherent property of that formulation." Pet. 38. As Petitioner acknowledges (Req. Reh'g 14), we addressed this argument directly in our Decision, noting that Petitioner failed to provide evidence sufficient to demonstrate that the property of independent dissolution is necessarily present in bilayer tablets. Dec. 11 (citing *Akamai Technologies, Inc. v. Cable & Wireless Internet Services*, 344 F.3d 1186, 1192 (Fed. Cir. 2003)). The lack of proof demonstrating that

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