

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIOACTIVE LABORATORIES,  
Petitioner,

v.

BTG INTERNATIONAL INC.,  
Patent Owner.

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Case IPR2015-01305  
Patent 8,048,414 B1

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Before TONI R. SCHEINER, LORA M. GREEN, and  
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

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

On January 11, 2016, Petitioner filed a Request for Rehearing (Paper 20, “Rehearing Request” or “Reh’g Req.”) of our Decision denying institution of an *inter partes* review (Paper 19, “Decision” or “Dec.”) of claims 1–22 of U.S. Patent No. 8,048,414 B1 (Ex. 1001, “the ’414 patent”). In the Decision, we determined that Petitioner had failed to establish a reasonable likelihood of prevailing in showing the unpatentability of claims 1–22 of the ’414 patent. Dec. 20.

We deny the Rehearing Request for the reasons set forth below.

#### ANALYSIS

When considering a request for rehearing, the Board reviews its decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The party requesting rehearing bears the burden of showing that the decision should be modified, and “[t]he request must specifically identify all matters the party believes the Board misapprehended or overlooked.” 37 C.F.R. § 42.71(d).

In the Petition, Petitioner contended that claims 1–7, 9–18, 21, 22 are anticipated by, and claims 8 and 19 are unpatentable over U.S. Patent No. 4,489,352 (Ex. 1004, “the ’352 patent”). Petitioner acknowledged that the ’352 patent “is listed in the priority chain on the face of the ’414 patent” (Pet. 5), and that the specifications of the ’352 patent and the ’414 patent are identical (*id.* at 29), but argued that:

[T]he ’352 patent is in fact prior art because not one application in the ’414 patent’s alleged priority chain complies with the requirements of 35 U.S.C. § 112. In particular, the ’414 patent’s priority applications do not describe or enable the full scope of the claimed invention. Therefore, the ’414 patent’s priority claim fails under 35 U.S.C. § 120 and the ’352 patent qualifies as prior art under 35 U.S.C. § 102(b).

*Id.* at 5.

Essentially, Petitioner advanced the position that, broadly construed, the challenged claims “encompass nearly unlimited compositions that are defined almost exclusively by their function,” and the ’352 specification does not describe or enable the full scope of the claims. Pet. 22, 29. Petitioner contended that the ’352 patent nevertheless “disclose[s] at least one specific or subgeneric embodiment” that anticipates or renders obvious the challenged claims. *Id.* at 29.

After reviewing the arguments and evidence presented in the Petition, however, we were not persuaded that Petitioner had shown that the ’352 patent fails to provide proper written description support or enablement for the claims of the ’414 patent. Accordingly, we were not persuaded that the ’352 patent is prior art to the claims of the ’414 patent and declined to institute an *inter partes* review on grounds based on the ’352 patent. Dec. 10–11.

In requesting rehearing, Petitioner contends that our decision was “solely based upon an improperly narrow construction” of the claim phrase: “[t]he [or said] antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the *Crotalus* genus.” Reh’g Req. 1, 3; see Ex. 1001, claims 1, 19, 20. Specifically, Petitioner contends that we “misapprehended or overlooked the prior broad (and contradictory) construction offered by the patent owner and accepted by the U.S. International Trade Commission (“ITC”)” for the claim phrase.<sup>1</sup> *Id.* at 1. That is, Petitioner contends that “[t]he claim construction adopted by the

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<sup>1</sup> The ’414 patent was the subject of an investigation before the ITC: *Certain Antivenom Compositions and Products Containing the Same* (ITC Investigation No. 337-TA-903) (“the ITC investigation”).

Board under the Broadest Reasonable Interpretation standard (“BRI”) is impermissibly *narrower* than that previously urged by patent owner . . . and accepted by the ITC.” *Id.* at 2.

We are not persuaded. In the Petition, Petitioner contended “during the ITC investigation, the Patent Owner argued that there is no requirement that the Fab fragments by themselves in the . . . composition of claim 1 neutralize the lethality of the *Crotalus* venom.” Pet. 17 (citing Ex. 1009,<sup>2</sup> 19). We agree that that much is supported by the evidence of record. According to the claim construction order issued in the ITC investigation, Patent Owner, in its initial *Markman* brief, argued that “[t]he claim does **not** require that the ‘Fab fragments,’ by themselves, neutralize the lethality of the venom, and Respondents’ construction would improperly re-write the claim language in . . . a manner” that would “improperly . . . limit the term to require that only the Fab fragments neutralize the lethality of the snake venom.” Ex. 1009, 17.

Petitioner, however, went further—contending “[i]n other words, the Patent Owner argued that the Fab fragments in the . . . composition *can be in any amount or not have any activity.*” Pet. 17 (emphasis added). This interpretation of the claim phrase was at the root of Petitioner’s contention that the challenged claims “encompass nearly unlimited compositions that are defined almost exclusively by their function,” and its contention that the ’352 specification does not describe or enable the full scope of the claims

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<sup>2</sup> Order 23: Construing the Terms of the Asserted Claims of the Patent at Issue, issued in ITC Investigation No. 337-TA-903 (May 21, 2014) (Ex. 1009, “the claim construction order”).

“[s]ince there is no description of the amount or structure of any active component of the claimed antivenom compositions.” Pet. 22, 24.

Nevertheless, these “other words” were Petitioner’s, not Patent Owner’s, and we did not agree that arguing that there is no requirement that the Fab fragments accomplish the neutralization by themselves is the same as arguing that the Fab fragments need have no neutralizing activity at all. We were not then persuaded that Petitioner’s interpretation of Patent Owner’s argument before the ITC is supported by the evidence of record, nor are we now.

Moreover, to the extent that the claimed compositions can comprise, in addition to Fab fragments, other components that contribute to venom neutralization, we noted that the ’353 patent and the ’414 patent identically describe highly purified F(ab)<sub>2</sub> fragments and IgG, which demonstrated, or were expected to demonstrate, “better protection against venom-induced pathophysiology than the [prior art] commercial antivenin.” Dec. 4–5 (citing Ex. 1001, 3:22–30, 32–37, 4:43–48, 54–59).

As we explained in our Decision:

[W]e agree with Patent Owner that “construing the limitation to include compositions in which the Fab or Fab/F(ab)<sub>2</sub> fragments do not neutralize the lethality of *Crotalus* venom is not reasonable in light of the specification.” . . . That is, we agree that “[p]roperly construed, the claims cover a composition in which Fab fragments neutralize venom, either alone or in combination with F(ab)<sub>2</sub> fragments.”

Dec. 10–11 (citing Prelim. Resp. 25).

Accordingly, we are not persuaded we misapprehended or overlooked any of Petitioner’s arguments or evidence regarding the meaning of the

claim phrase “[t]he [or said] antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the *Crotalus* genus.”

Petitioner further contends that we misapprehended or overlooked the distinction between the claim terms “binds specifically to” and “binds to.”

Reh’g Req. 11. In the Petition, Petitioner argued that

The term “binds to,” found in independent claim 19, is the broader of the two terms, and refers to *the basic ability of the “Fab and F(ab)<sub>2</sub> fragments” in the claimed antivenom pharmaceutical composition to interact with Crotalus venom.* In contrast, the term “bind specifically to” found in independent claims 1 and 20 . . . is narrower, and refers to *“Fab fragments” in the claimed composition that only bind to Crotalus venom and not to other antigens.*

Pet 15.

Petitioner further contended that:

Claim 19 requires that the Fab fragment *composition* “binds to a venom of a snake of the *Crotalus* genus.” In contrast, claim 1 is narrower in its requirement that any *Fab fragment* “bind *specifically* to a venom of a snake of the *Crotalus* genus” . . . At best, however, the priority applications disclose certain embodiments of a *composition comprising Fab fragments* that *specifically bind* to snake venom. Because the language in claim 1 is narrower, the term “binds to” in claim 19 should be construed to be broader than the narrower claim 1 embodiment of “bind specifically to.”

Pet. 27 (citing Ex. 1001, 13:17–23).

Finally, Petitioner contended that “the plain language of claim 19 shows that neither the Fab nor the F(ab)<sub>2</sub> fragments of the composition need to actually bind venom at all” but “[t]here is no support in the priority applications for a composition containing Fab and F(ab)<sub>2</sub> fragments that do not bind venom at all, much less such a composition that comprises

fragments that do not specifically bind venom.” *Id.* at 12 (citing Pet. 28; Ex. 1001, 14:21-34; Ex. 1002 ¶ 63).

We considered these arguments in reaching our decision, but explained, “[f]or the reasons discussed above, we are not persuaded that the ’352 patent lacks written description support and enablement for an antivenom pharmaceutical composition comprising Fab fragments and F(ab)<sub>2</sub> fragments ‘wherein said antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the *Crotalus* genus.’”

Dec. 12. Again, those reasons were:

[W]e agree with Patent Owner that “construing the limitation to include compositions in which the Fab or Fab/F(ab)<sub>2</sub> fragments do not neutralize the lethality of *Crotalus* venom is not reasonable in light of the specification.” . . . That is, we agree that “[p]roperly construed, the claims cover a composition in which Fab fragments neutralize venom, either alone or in combination with F(ab)<sub>2</sub> fragments.”

Dec. 10–11 (citing Prelim. Resp. 25). Whether “binds specifically to” is narrower than “binds to” is irrelevant in this context, and we found it unnecessary to expressly construe the terms for purposes of our decision. *See* Dec. 7.

## CONCLUSION

We have considered Petitioner’s request for rehearing, but are not persuaded we misapprehended or overlooked any of Petitioner’s arguments or evidence, or abused our discretion in declining to institute an *inter partes* review.

ORDER

It is

ORDERED that Petitioner's request for rehearing of the Decision denying institution of an *inter partes* review of claim 1–22 of U.S. Patent No. 8,048,414 B1 is *denied*.

IPR2015-01305  
Patent 8,048,414 B1

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