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Paper No. 12
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LTD.,
Petitioner,

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner.

Case IPR2018-00163
Patent 7,923,536 B2

Before JEFFREY N. FREDMAN, RAMA G. ELLURU, and SUSAN L. C. MITCHELL, *Administrative Patent Judges.*

ELLURU, *Administrative Patent Judge*.

DECISION
Request for Rehearing
37 C.F.R. § 42.71

Petitioner, Cipla LTD., filed a request for rehearing (Paper 11, "Req.") of the Decision Denying Institution (Paper 10, "Dec.") of an *inter partes* review of claims 1–16 of U.S. Patent No. 7,923,536 B2 (Ex. 1001, "the '536 patent"). Petitioner seeks rehearing on both of its anticipation and obviousness challenges. Req. 1. Specifically, Petitioner contends the Decision misapprehended or overlooked that

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> (1) the Petition argues anticipation based on what Desai discloses to a POSA, and not necessarily inherency (§ II.A.1 below); (2) the law does not limit anticipation to *ipsis verdis* disclosure and inherency (§ II.A.2 below); (3) Dr. Berkland's testimony, which the Decision cites as supporting Patent Owner's position, actually refutes it (§ II.A.3 below); (4) Dr. Desai's letter submitted during prosecution of an Indian Patent Application is irrelevant and excludable (§ II.A.4 below); and (5) for both anticipation and obviousness, the Board misapplied Rule 42.108(c) by crediting Patent Owner's declarants over Petitioner's declarant (§§ II.A.5 and II.B.1 below).

Id. at 1–2. After reviewing Petitioner's request for rehearing, we find that we did not misapprehend or overlook any matter set forth in the Petitioner, and therefore, the request for rehearing is denied.

ANALYSIS

When rehearing a decision on institution, the Board will review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The applicable standard for a request for rehearing is set forth in 37 C.F.R. § 42.71(d), which provides in relevant part:

> A party dissatisfied with a decision may file a request for rehearing, without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

(A)(1) - Desai Anticipation

Petitioner asserts that its anticipation challenge is "based on two premises. First, Example 1 of Desai indisputably teaches the mixing of paclitaxel (30 mg) and albumin (270 mg)—literally a 9:1 ratio. Pet. at 27–28. Second, a POSA would not expect any change in the final ratio after

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completing the process of Example 1. *Id*. at 32[.]" Req. 3. Petitioner contends that we misapprehended Petitioner's main argument as one of inherency. *Id*. at 4. In support, Petitioner asserts: "Whether the process of Example 1 inherently produces a final 9:1 weight ratio is irrelevant to Petitioner's anticipation argument: Regardless of inherency, a POSA reading Example 1 in light of his or her knowledge and experience would understand the final ratio to be 9:1. See Pet. at 27–28." *Id*.

We find Petitioner's argument unpersuasive. We interpret the "weight ratio" phrase as "the ratio of albumin to paclitaxel in the final composition, i.e., the composition injected into the patient." Dec. 7. Thus, in order for Desai to anticipate, it is not sufficient for Desai to simply mix paclitaxel and albumin in a particular ratio, but rather Desai must formulate the composition into particles as well because a particle formulation is required for the final pharmaceutical composition that is injected into patients (*see* '536 patent, Claim 1).

Example 1 of Desai does show a mixture of 30 mg of paclitaxel to 270 mg of human serum albumin. *See* Ex. 1006, 60:25–27[1]. However, that mixture is not the final pharmaceutical composition because the mixture is then homogenized to form a crude emulsion at low RPM, emulsified in a high pressure homogenizer, and subjected to a rotary evaporator in order to obtain the particulate form. *See Id*. at 60:27 to 61:6. Example 4 of Desai disclosed a further filtering step to obtain a sterile composition. *See Id*. at 63:23–25. Examples 1 and 4 of Desai provide no information regarding the

[1] Cites to Ex. 1006 refer to original page numbers.

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final paclitaxel/albumin ratio found in the final pharmaceutical compositions in particulate form relative to the starting ratio. *See Id*. at 61:8–12, 64:1–3.

The Decision, therefore, analyzes the evidence regarding whether the initial ratio shown in Example 1 remained within the scope of the claim after final formulation into particulate form as required by Claim 1. The Decision contrasts Petitioner's argument, supported by Dr. Berkland's unsubstantiated opinion, that Example 1 of Desai does not result in any paclitaxel loss (*see e.g*., Dec. 13 (citing Ex. 1002 ¶ 106)) with Patent Owner's experimental evidence that paclitaxel was lost during processing such that a starting 9:1 albumin/paclitaxel ratio resulted in a final 13.3:1 albumin/paclitaxel ratio after formulation *(see* Dec. 19 (citing Ex. 2069 ¶¶ 5, 9)). In essence, Petitioner contends that a skilled artisan would have understood that there was no paclitaxel loss in the 9:1 albumin/paclitaxel starting ratio of Desai's Example 1 and relies solely on Dr. Berkland's unsubstantiated opinion for that assertion.

Thus, the evidence of record does not support, but instead contradicts Petitioner's assertion that "a POSA would not expect any change in the final ratio" after completing the process of Example 1. Req. 6. In fact, the Desai Declaration states the "weight ratio of albumin to paclitaxel in the starting components was 9:1. . . . Taking into account loss of paclitaxel during the nanoparticle preparation process, the estimated albumin/paclitaxel ratio in the resulting nanoparticle albumin-bound paclitaxel composition was about 13.3:1." Ex. 2069 ¶ 5. The Desai Declaration similarly shows that Example 16 starts with a 13:1 ratio of albumin/paclitaxel but obtains a final 19:1 ratio of albumin/paclitaxel. *See id*. ¶¶ 9–10.

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To the extent that inherency was at issue, the Decision found inherency inapplicable because "Dr. Desai's statements expressly rebut any reading of either of Desai's Examples 1 or 16 as *necessarily* resulting in a final composition with an 'about 1:1 to about 9:1' weight ratio of albumin to paclitaxel.." Dec. 19.

(A)(2) - Law of Anticipation

Petitioner asserts the "Board misapprehended the law of express anticipation by treating express anticipation as requiring *ipsis verbis* disclosure in the prior art." Req. 5.

We do not agree that the Decision misapprehended the anticipation analysis. *See* Dec. 8–9. We recognize Petitioner's point that the prior art need not "'expressly spell out' all limitations combined as in the claim if a POSA would 'at once envisage' the arrangement or combination." *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069 (Fed. Cir. 2017). However, "anticipation is not proven by 'multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.'" *Id*.

In the instant case, under the proper anticipation standard that we applied in our decision on institution, Petitioner does not identify a disclosure in Desai of a ***final*** pharmaceutical formulation of albumin and paclitaxel that satisfies the requirements of claim 1 of the '536 patent for a pharmaceutical composition for injection with a 9:1 ratio of albumin/paclitaxel and a formulation comprised of particles less than 200 nm. *See* Ex. 1001, 37:20–29. There is also no sufficient persuasive evidence that the person of ordinary skill would "at once envisage" a ***final***

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