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The Federal Circuit's *Ball Metal* Decision Raises Important Considerations for Pharma and Biologics Patents

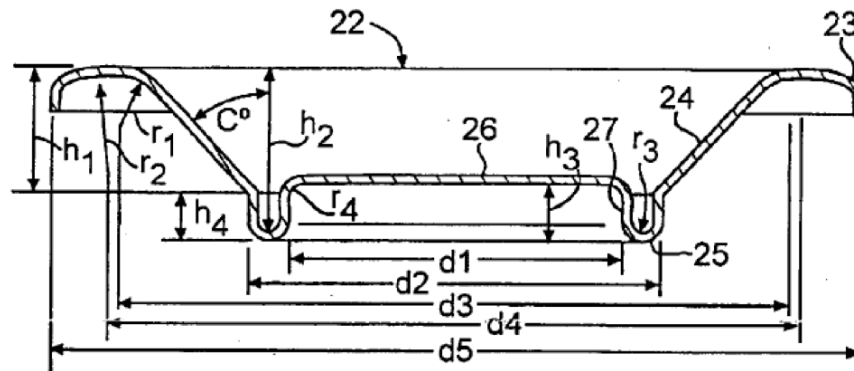
The U.S. Court of Appeals for the Federal Circuit's New Year's eve opinion in *Ball Metal v. Crown Packaging*, though nonprecedential, raises important considerations for pharmaceutical and biologics patents – where patent challengers regularly allege the indefiniteness of “measurement” claim terms that describe pharmacologic or physicochemical properties of the invention. Under *Ball Metal*, even if a “measurement” term is found to allow for multiple different measurement methods that can produce different results, indefiniteness may still be avoided if the challenger cannot show that such differences “matter for determining whether or not [the] claim limitation is met by those who might realistically be practicing the other claim limitations.”¹ See *Ball Metal Bev'g Container Corp. v. Crown Packaging Tech., Inc.*, No. 2020-1212 (Fed. Cir. Dec. 31, 2020). Click [here](#) for a copy of the opinion.

In *Ball Metal*, the Federal Circuit vacated and remanded a district court's ruling that two beverage can patents² were invalid as indefinite for reciting an imprecise “measurement” claim term (“second point”). The Court agreed with the accused infringers that (1) the patentee proffered multiple methods for locating the “second point” on the claimed can structure, and (2) the precise location of the “second point” could differ depending on the measurement method used. Nonetheless, the Court vacated the indefiniteness ruling, because the district court failed to assess whether these various measurement methods would actually yield “**materially different**” results – *i.e.*, whether the selection of a particular measurement method would control whether a product infringes the claims.³

THE PATENTED TECHNOLOGY AND CHALLENGED CLAIM TERMS

The claims at issue in *Ball Metal* concern the structure of the bottom portion (“can end”) of an aluminum beverage can, as exemplified by the patent figure below.⁴ Starting from the outer edge, the wall of the claimed can structure (“chuck wall”) generally features (1) a “peripheral cover

hook” [23]; (2) an angled portion of the wall [24] that extends from a “first point” at the end of the cover hook to a “second point”; (3) an “annular reinforcing bead” [25] located at the “second point”; and (4) a central panel [26].⁵



In particular, the asserted claims require the “angled portion” [24] – *i.e.*, the line between the “first point” and “second point” – to be within certain angle range [C°] relative to a line perpendicular to the central panel [h₂]. For example, claim 14 of the ’826 patent recites “a line extending between said first and second points being inclined to an axis perpendicular to said central panel at an angle of between 30° and 60°.”⁶

In the district court below (S.D. Ohio, Rice, J.), the accused infringers successfully moved for summary judgment of invalidity, on the grounds that the claim term “second point” was indefinite under 35 U.S.C. § 112, ¶ 2.⁷ The patentee appealed the summary judgment ruling to the Federal Circuit.⁸

THE FEDERAL CIRCUIT’S RULING ON INDEFINITENESS

On appeal, the Federal Circuit vacated the grant of summary judgment on indefiniteness, and remanded to the district court for further proceedings.⁹

Conducting its review *de novo*, the Federal Circuit accepted the key factual premises of the accused infringers’ indefiniteness argument. The Court agreed that the patentee’s expert witness had proffered at least three distinct methods for locating the claimed “second point,” including in prior litigations involving the same patents.¹⁰ The Court further found that these different measurement methods “do not necessarily result in the same location for the second point,” and that examples of record confirmed how the identified location for a particular “second point” could differ depending on the measurement method used.¹¹

Despite these facts, the Federal Circuit ruled that the district court did not adequately consider the issue of indefiniteness. As the Court explained, a claim is **not** automatically invalid as indefinite under 35 U.S.C. § 112, ¶ 2 merely because it includes a parameter that is sensitive to the method used to measure or locate it.¹² Rather, for such a method-sensitive term to be indefinite, the different available measurement methods must lead to “**materially different**” outcomes¹³ – such that, under “realistic[]” circumstances,¹⁴ the measurement method selected could control the ultimate question of infringement:

Under our case law ... a claim may be invalid as indefinite when (1) different known methods exist for calculating a claimed parameter, (2) nothing in the record suggests using one method in particular, and (3) application of the different methods result in **materially different outcomes** for the claim’s scope such that a product or method **may infringe the claim under one method but not infringe when employing another method**.¹⁵



Here, the Federal Circuit found that the district court failed to consider whether any method-dependent discrepancies in locating the claimed “second point” were actually “material” to assessing infringement.¹⁶ For the asserted claims, infringement did not turn on the location of the “second point” *per se*, but rather on whether the resulting line connecting the “first point” and “second point” met the claimed angle ranges (e.g., “between 30° and 60°”).¹⁷ For the “second point” measurement methods to be “materially different,” the accused infringers would need to show – for an otherwise “operational” can end – that one measurement method produces an infringing angle, while another method produces an angle outside the claimed range.¹⁸ Because the district court “d[id] not establish in any meaningful way what material difference in angle range outcome, if any, exists among [the patentee’s expert’s] different methodologies” for locating the “second point,” the district court’s indefiniteness analysis was “incomplete.”¹⁹

POTENTIAL IMPACT OF BALL METAL ON CHALLENGES TO THERAPEUTIC PATENTS

While *Ball Metal* involved beverage can technology, it would be wise to keep it in mind when considering future challenges to therapeutic inventions, including patents claiming new pharmaceutical or biologic drug compositions, new methods of treating disease, or new dosing regimens. Such patents often include “measurement” claim terms – defining, e.g., therapeutic effects; adverse events; pharmacokinetic (blood level) profiles; or physicochemical parameters such as dissolution profile or viscosity – and indefiniteness challenges to such measurement terms are common in Hatch-Waxman, BPCIA, and other patent disputes. Tellingly, much of the indefiniteness case law discussed by the Federal Circuit in *Ball Metal* concerned inventions in the therapeutic and chemical fields.²⁰

In light of *Ball Metal*, both patentees and patent challengers for therapeutic inventions should keep in mind that a “measurement” claim term is **not** necessarily indefinite, even if multiple measurement methods are applicable to the term, and the term’s scope or value can vary depending on which of the applicable methods is used. But if such method-sensitive variations in term scope are shown to be “**materially** different” – such that the measurement method selected could control whether or not a realistic, otherwise operational embodiment would infringe the claims – then an indefiniteness challenge may potentially carry more weight.

To avoid or limit such indefiniteness challenges, patentees for therapeutic inventions may also consider whether claim construction can be used to add methodological precision to “measurement” terms. For example, a measurement term may, in some cases, be construed in part or in whole by reference to a specific, defined assay that was referenced in the intrinsic record to distinguish the claimed invention from the prior art.²¹

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¹ *Ball Metal Bev'g Container Corp. v. Crown Packaging Tech., Inc.*, No. 2020-1212 (Fed. Cir. Dec. 31, 2020) (“Slip Op.”) at 8.

² U.S. Patent Nos. 6,935,826 (“the ‘826 patent”) and 6,848,875 (“the ‘875 patent”).

³ Slip Op. at 7-10. Unless otherwise noted, all emphasis is added.

⁴ *Id.* at 3 (reproducing Fig. 4 of the ‘875 patent).

⁵ Slip Op. at 3.

⁶ *Id.* at 3-5. The ‘875 patent used the equivalent terms “first location” and “transition” in place of “first point” and “second point.” Slip Op. at 3-4.

⁷ *Id.* at 5.

⁸ *Id.*

⁹ *Id.* at 2-3, 10.

¹⁰ *Id.* at 6.

¹¹ *Id.* at 6-7.

¹² *Id.* at 7 (“That the record evidence indicates that multiple different methodologies exist for measuring a parameter recited in a claim does not by itself render a claim indefinite.”); *id.* (“We have explained that ‘the mere possibility of different results from different measurement techniques’ does not render a claim indefinite.”) (quoting *Takeda Pharms. Co. Ltd. v. Zydus Pharms. USA Inc.*, 743 F.3d 1359, 1366–67 (Fed. Cir. 2014)).

¹³ Slip Op. at 8; see also *id.* at 7 (“Under such circumstances, the relevant indefiniteness inquiry then becomes whether the differing methodologies lead to **materially different results** in defining the boundaries of the claim.”).

¹⁴ *Id.* at 8 (“Consistent with the purpose of the definiteness requirement, differences in measurement methods **must matter for determining whether or not a claim limitation is met** by those who might **realistically** be practicing the other claim limitations.”).

¹⁵ *Id.* at 8.

¹⁶ *Id.* at 9-10.

¹⁷ *Id.* at 9.

¹⁸ *Id.* at 9-10.

¹⁹ *Id.* at 10.

²⁰ See *id.* at 7-9 (discussing *Takeda Pharms.*, 743 F.3d 1359; *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335 (Fed. Cir. 2015); *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620 (Fed. Cir. 2015); and *Amgen Inc. v. Hoechst Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003)).

²¹ See, e.g., *Galderma Labs., L.P. v. Amneal Pharms. LLC*, No. 16-207-LPS, 2017 WL 1882499, at *2-4 (D. Del. May 9, 2017) (construing term “results in no reduction of skin microflora during a six-month treatment” by reference to specific assay parameters in a patent specification example); *Eisai, Inc. v. Banner Pharmacaps Inc.*, No. 11-cv-901-GMS, D.I. 101, at 1-2 (D. Del. Jul. 2, 2013) (construing term “co-transfection assay” by reference to a specific assay described in the patent specification).