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Challenging Therapeutics IP After Fed. Circ. Drink Can Ruling

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Law360 (February 3, 2021, 5:29 PM EST) -- The U.S. Court of Appeals for the Federal Circuit's Dec. 31 opinion in Ball Metal Beverage Container Corp. v. Crown Packaging Technology Inc.,[1] though nonprecedential, raises important considerations for pharmaceutical and biologics patents, a context in which patent challengers regularly allege the indefiniteness of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."[2]

In Ball Metal, the Federal Circuit vacated and remanded a district court's ruling that two beverage can patents[3] 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.[4]

The Federal Circuit's Ruling on Indefiniteness in Ball Metal

The claims at issue in Ball Metal concerned the structure of the bottom portion, or can end, of an aluminum beverage can.[5] At issue in the Federal Circuit's ruling was the angled portion of the claimed can end, which the asserted claims recited as a line between a first point and second point falling within a specified angle range relative to a line perpendicular to the central panel of the can end structure.

For example, claim 14 of U.S. Patent No. 6,935,826 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]

The U.S. District Court for the Southern District of Ohio granted the accused infringers' motion for summary judgment on the grounds that the claim term "second point" was indefinite under Title 35 of the U.S. Code, Section 112, Paragraph 2.[7] But on appeal, the Federal Circuit vacated the grant of summary judgment on indefiniteness and remanded to the district court for further proceedings.[8]

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.[9]

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.[10]

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 Section 112, Paragraph 2 merely because it includes a parameter that is sensitive to the method used to measure or locate it.[11]

Rather, for such a method-sensitive term to be indefinite, the different available measurement methods must lead to materially different outcomes,[12] such that, under realistic circumstances,[13] 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.[14]

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.[15]

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°.[16]

For the second point measurement methods to be materially different, the accused infringers would thus 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.[17]

Because the district court did "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 deemed incomplete.[18]

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. Indefiniteness challenges to such measurement terms are common in Hatch-Waxman Act, Biologics Price Competition and Innovation Act and other patent disputes.[19] 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 of 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 that 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.

The reasoning of Ball Metal may also have procedural implications. The Federal Circuit has characterized indefiniteness as an issue of law that is reviewed de novo but may include subsidiary fact findings reviewed for clear error.[21]

At the district court level, a genuine factual dispute regarding whether variations in a measurement method-sensitive term are materially different could potentially preclude some early findings of indefiniteness at the summary judgment or claim construction stages.

And at the appellate level, fact-intensive disputes regarding whether measurement outcomes are materially different might be subject to greater Federal Circuit deference if addressed by the court below or lead to remand if, as in Ball Metal, the issue was not fully considered below.

To avoid or limit measurement-based 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.[22] By doing so, the patentee can potentially avoid the thornier task of generating evidence and expert testimony to address whether multiple measurement methods result in materially different outcomes.

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[1] Ball Metal Bev'g Container Corp. v. Crown Packaging Tech., Inc., No. 2020-1212, 2020 WL 7828776 (Fed. Cir. Dec. 31, 2020) ("Ball Metal").

[2] Id. at *3.

[3] U.S. Patent Nos. 6,935,826 ("the '826 patent") and 6,848,875 ("the '875 patent").

[4] Ball Metal at *3-4.

[5] Id. at *1 (reproducing Fig. 4 of the '875 patent).

[6] Id. at *1-2. The '875 patent used the equivalent terms "first location" and "transition" in place of "first point" and "second point." Slip Op. at *1.

[7] Id. at *2.

[8] Id. at *1, 4.

[9] Id. at *2.

[10] Id. at *2-3.

[11] Id. at *3 ("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)).

[12] Ball Metal at *3; see also id. ("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.").

[13] Id. at *3 ("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.").

[14] Id.

[15] Id. at *4.

[16] Id.

[17] Id.

[18] Id.

[19] See, e.g., Hospira, Inc. v. Amneal Pharms., LLC, 285 F. Supp. 3d 776, 802-805 (D. Del. 2018) (whether term "no more than about 2% decrease [in drug concentration]" failed to specify measurement under accelerated or long-term stability testing); Taro Pharm. Indus. Ltd. v. Novitum Pharma, LLC, 2020 WL 1673045, at *6-7 (D.N.J. Apr. 6, 2020) (whether term "20% sodium bisulfite solution" failed to specify measurement "weight-per-weight" or "volume-per-volume"); iCeutica Pty Ltd. v. Lupin Ltd., 2018 WL 656446, at *4-8 (D. Md. Feb. 1, 2018) (whether claims were indefinite for failing to define the term

"population of healthy adults" in connection with claimed drug plasma profile); Astellas Pharma Inc. v. Actavis Elizabeth LLC, 2018 WL 4776372, at *16-18 (D. Del. Jun. 18, 2018) (whether term "contains less than 0.2% of moisture," in connection with a claimed crystal form of a drug, was to be measured before or after incorporation with carrier ingredients into a pharmaceutical composition).

[20] See Ball Metal at *3-4 (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., Nevro Corp. v. Boston Sci. Corp., 955 F.3d 35, 37 (Fed. Cir. 2020).

[22] 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).