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An Update On Appellate Review Of Indefiniteness

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Law360, New York (May 12, 2016, 11:12 AM ET) -- To what extent will a district court's indefiniteness determination receive deference? In last year's panel opinion in the Dow Chemical case, the Federal Circuit arguably treated all aspects of the indefiniteness inquiry as purely legal issues, and applied de novo review without appearing to give any deference to the jury's underlying factual findings.[1] But in denying Dow's petition for rehearing en banc, a separate opinion joined by five judges sought to clarify that "the panel's opinion does not alter U.S. Supreme Court and our own precedent that fact findings made incident to the ultimate legal conclusion of indefiniteness receive deference on appeal."[2]

Given that indefiniteness can implicate issues seemingly at different places on the "fact-law" spectrum, the standard of review can be as unpredictable as it is dispositive. And given the increased interest in raising indefiniteness defenses since the Supreme Court's Nautilus opinion, this unpredictability may increase the uncertainty generally associated with patent litigation, at least until the Supreme Court or Federal Circuit further develops the post-Nautilus law of indefiniteness.

As stated in Nautilus, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention."[3] Patents are presumed valid, so indefiniteness, like all invalidity defenses, must be shown by clear and convincing evidence.[4] But in contrast to the other invalidity defenses, courts frequently address indefiniteness as part of claim construction, with the judge resolving any underlying factual inquiries. In Teva, the Supreme Court reaffirmed that claim construction is a legal issue that can include underlying factual determinations by the district court, and that any such judicial fact-finding is reviewed under the clearly erroneous standard.[5] Teva also clarified that evaluation of the intrinsic evidence is a legal issue reviewed de novo, whereas evaluation of extrinsic evidence (such as expert testimony) is a factual issued reviewed under the clearly erroneous standard.[6]

This dual status of indefiniteness — as an invalidity defense and a claim construction issue — can create confusion in how to apply burdens of persuasion and standards of review. As briefly explained below, this confusion can be prevented by sorting indefiniteness issues into two different "species" which tend to fall on opposite sides of the fact/law divide. In some cases, the court must determine whether a particular term has any objective meaning at all, or whether the only reasonable constructions, in light of the specification and prosecution history, are nonsensical or facially subjective. The entire indefiniteness inquiry in these cases is subject to de novo review.

In other cases, the claim term facially appears to have objective boundaries, but the court must determine if multiple methods exist to determine if the term is satisfied, such that the choice of method could be dispositive of infringement in a given case. If that is the case, the facially objective claims may "fail[ ] to inform, with reasonable certainty, those skilled in the art about the scope of the invention."[7] Although the standard of appellate review in these cases is more complicated, the dispositive issues would normally be findings of fact reviewed with deference, even if the ultimate conclusion of indefiniteness is — similar to the ultimate conclusion of obviousness — subject to de novo review.

Facially Subjective, or Nonsensical, Claim Terms

The first variety of indefiniteness, for the most part, presents purely legal issues and is reviewed by an appellate court de novo. Although there may be some preliminary fact finding to limit the universe of reasonable constructions, the ultimate question of whether any particular construction could offer coherent and objective boundaries is readily treated as an issue of law. As the Federal Circuit recognized in its Teva remand opinion, "[t]he internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law."[8]

For example, in Halliburton Energy Services Inc. v. M-I LLC, the claim term at issue was "fragile gel," which the specification defined as "a 'gel' that is easily disrupted or thinned, and that liquifies or becomes less gel-like and more liquid-like under stress."[9] The Federal Circuit, reviewing the district court's indefiniteness determination de novo, affirmed that claims containing the term "fragile gel" were indefinite "because it is ambiguous as to the requisite degree of the fragileness of the gel, the ability of the gel to suspend drill cuttings (i.e., gel strength), and/or some combination of the two."[10]

Andrulis Pharmaceuticals Corp. v. Celgene Corp. is another example of this type of indefiniteness.[11] The claims at issue recited an "enhanced combination" of two active pharmaceutical ingredients.[12] The court found that the only reasonable interpretation of "enhanced" was "synergistic" or "greater than additive," but that the patentee had disclaimed such a narrow definition in prosecution.[13] As a result, the court was wholly unable to determine what the term "enhanced combination" meant, in light of the specification and prosecution history, and found the claims indefinite.[14] Because the indefiniteness holding — currently on appeal — did not involve any judicial fact-finding, it will also likely be reviewed de novo.

Multiple Methods of Determining Infringement

The second variety of indefiniteness requires answering two questions. First, are there multiple methods by which to determine whether a particular limitation is satisfied? Second, if there are multiple methods, could the choice of method affect the infringement outcome? The first question is sometimes, and the second question almost always, a factual question. Especially because the second question is key in many of these cases,[15] appellate review should be under the clearly erroneous standard.

As to the first question, whether multiple methods exist to determine if a particular limitation is satisfied is a question of law if apparent from the intrinsic evidence, but is a question of fact if the court must consult extrinsic evidence.[16] Teva was a paradigmatic case in this regard. The claim limitation at issue there was "a molecular weight of about 5 to 9 kilodaltons."[17] Both parties agreed that persons of skill in the art used three different measures of "molecular weight," and they also agreed that the choice of measure could be dispositive of infringement, thereby resolving the "dispositive of infringement issue."[18] But they disputed whether the patent actually referenced each of these three measures, or

whether the patent was properly limited to a single measure of molecular weight.[19] The district court had found that "molecular weight" in the context of the patent was limited to a single measure, and made extensive factual findings to that effect in support of its holding that the claims were not indefinite.[20]

The Federal Circuit reversed and held the claims indefinite under de novo review, without disturbing the district court's underlying factual findings.[21] Based solely on the specification of the patent at issue and the prosecution history of related patents, the Federal Circuit found as a matter of law that "molecular weight" could not possibly be understood as referring to a single measure.[22]

On the other hand, whether the choice of method is dispositive of infringement — a point conceded in Teva — is entirely a question of fact and therefore subject to deferential review. For example, in Honeywell, the process claims recited a "drawn yarn" with a particular "melting point elevation."[23] Depending on which of four different methods is used to prepare the yarn sample, the calculated melting point elevation could vary.[24] The Federal Circuit affirmed the agency's holding of indefiniteness, recognizing as a "finding of fact" the agency's determination "that the choice of sample preparation method is critical to discerning whether a particular product is made by a process that infringes the ... patent claims."[25] In other words, a person of skill in the art could not understand the scope of the claims without knowing the method of sample preparation — an issue for which the intrinsic evidence provided no guidance.

Dow

The Dow case, which fractured the Federal Circuit, involved the second type of indefiniteness — whether multiple methods exist to determine if a polymer has "a slope of strain hardening coefficient greater than or equal to 1.3" such that the choice of method is dispositive of infringement of the claims.[26] In the district court, a jury instructed on the pre-Nautilus "insolubly ambiguous" standard for indefiniteness had found that the claims at issue were not indefinite.[27] The Federal Circuit panel reviewed this indefiniteness holding following the Nautilus Supreme Court decision.[28]

The panel assumed that three different methods existed in the art to measure the maximum slope of strain hardening coefficient, thereby disposing of the first inquiry.[29] The key remaining inquiry was whether "the method chosen ... could affect whether or not a given product infringes the claims."[30] One could argue that, as in Takeda and Honeywell, this was a factual issue that must be decided, in the first instance, by the district court. Nevertheless, the Federal Circuit, applying de novo review, reversed the district court and found the claims indefinite, and afforded no deference to any aspect of the district court's conclusion.[31]

In applying de novo review, the Federal Circuit noted the similarities between Dow and Teva and found that "[t]he claims here are even more clearly indefinite than those in Teva."[32] But while de novo review in Teva was justified because both parties conceded the "dispositive of infringement" issue, this concession did not exist in Dow. And the various opinions generated by the en banc petition in Dow made clear that there is still some uncertainty in how the Federal Circuit will review indefiniteness issues in future cases. For example, while concurring in the denial of en banc review, Judge Kimberly Moore suggested that the Dow panel failed to afford the required deference to a clearly factual issue.[33] In contrast, the judges from the Dow panel wrote at the en banc stage to clarify that the panel opinion did directly apply the principles referenced by Judge Moore "that findings of fact by juries are entitled to deference" and "that knowledge of someone skilled in the art may be pertinent to the indefiniteness question."

In March 2016, Dow filed a petition for a writ of certiorari, presenting the question of "[w]hether factual findings underlying a district court's determination on the definiteness of a patent claim ... like a district court's factual findings underlying construction of a patent claim, are subject to appellate review only for clear error or substantial evidence rather than de novo review." In its petition, Dow seeks only to have the Supreme Court to clarify that the existing Teva standard of review applies to indefiniteness as well as claim construction. This would not, however, squarely address the difficulty in identifying "fact" and "law" issues presented by an indefiniteness defense. Thus, whether or not the Supreme Court takes up the Dow case, until clearer lines between "fact" and "law" issues are drawn in this area, it will be unclear how the key indefiniteness issues in a given case will be reviewed.

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[1] Dow Chemical Co. v. Nova Chemicals Corp. (Canada), 803 F.3d 620, 633–35 (Fed. Cir. 2015).

[2] Dow Chemical Co. v. Nova Chemicals Corp. (Canada), 809 F.3d 1223, 1224 (Fed. Cir. 2015) (Moore, J., concurring in denial of petition for rehearing en banc).

[3] Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014).

[4] Microsoft Corp. v. i4i Ltd. P'Ship, 131 S. Ct. 2238, 2242 (2011).

[5] Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 835 (2015).

[6] Id. at 841.

[7] Nautilus, 134 S. Ct. at 2124.

[8] Teva Pharms. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1342 (Fed. Cir. 2015).

[9] 514 F.3d 1244, 1251 (Fed. Cir. 2008).

[10] Id. at 1249, 1256.

[11] See Civ. A. No. 13-1644, 2015 WL 3978578 (D. Del. June 26, 2015).

[12] Id. at *2.

[13] Id. at *3–4.

[14] Id. at *5.

[15] See, e.g., Takeda Pharm. Co. v. Zydus Pharms. USA, Inc., 743 F.3d 1359, 1366–68 (Fed. Cir. 2014); Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332, 1338–42 (Fed. Cir. 2003).

[16] See Teva, 135 S. Ct. at 841.

[17] 789 F.3d at 1338.

[18] Id. at 1341.

[19] Id.

[20] Id. at 1338.

[21] Id. at 1344–45.

[22] Id.

[23] 341 F.3d at 1335.

[24] Id. at 1336.

[25] Id. at 1339–40.

[26] 803 F.3d at 631.

[27] Id. at 625.

[28] Id.

[29] Id. at 633.

[30] Id. at 634.

[31] Id. at 635.

[32] Id.

[33] See 809 F.3d at 1228.

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