# IP Alert: Federal Circuit Holds Claims Indefinite Based on Prosecution History in Teva Pharmaceuticals USA v. Sandoz, Inc.


# FEDERAL CIRCUIT HOLDS CLAIMS INDEFINITE BASED ON PROSECUTION HISTORY IN TEVA PHARMACEUTICALS USA V. SANDOZ, INC.

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On June 18, 2015, the United States Court of Appeals for the Federal Circuit released its decision in Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.[i] The case was on remand from the Supreme Court, which vacated the Federal Circuit's earlier determination regarding the definiteness of claims directed towards Copaxone®, Teva's market-approved treatment for multiple sclerosis.[ii]The Supreme Court held that claim construction is a question of law subject tode novo review, and that the underlying factual findings are subject to clear error review.[iii] Based on the Supreme Court's guidance in Teva and Nautilus, Inc. v. Biosig Instruments, Inc.,[iv] the Federal Circuit held the claims under review indefinite and therefore invalid.[v]

## BACKGROUND

Teva, which markets Copaxone®, sued Sandoz for submitting Abbreviated New Drug Applications for generic versions of Copaxone®. Claim 1 of U.S. Patent No. 5,800,808 (the '808 patent) recites a method of making "copolymer-1 having a molecular weight of about 5 to 9 kilodaltons." Claim 1, however, does not specify what measure of molecular weight to use, nor does the specification expressly define "molecular weight." At least three industry-accepted norms exist for measuring molecular weight: peak average molecular weight

($M_p$), number average molecular weight ($M_n$), and weight average molecular weight ($M_w$).[vi] Further, neither party identified any portion of the '808 patent's prosecution history relevant to the construction of "molecular weight."[vii]

The '808 patent includes multiple continuation applications, including U.S. Patent No. 6,620,847 (the '847 patent) and U.S. Patent No. 6,939,539 (the '539 patent). During the prosecution of the '847 patent, Teva argued that "'one of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight,' i.e. $M_w$."[viii] But during prosecution of the '539 patent, Teva argued that "a person 'of ordinary skill in the art, upon reviewing the specification, would understand that 'average molecular weight' refers to' . . . $M_p$."[ix]

**ANALYSIS**

In remanding Teva back to the Federal Circuit, the Supreme Court explained that "it was proper to treat the ultimate question of the proper construction of the patent as a question of law in the way that we treat document construction as a question of law."[x] Further, in Nautilus, the Supreme Court clarified, "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."[xi]

On remand, the Federal Circuit acknowledged that "[t]he definiteness requirement must take into account the inherent limitations of language," and that "[s]ome modicum of uncertainty is the price of ensuring the appropriate incentives for innovation."[xii] At the same time, however, "a patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them."[xiii]

In light of the Court's guidance, the Federal Circuit reevaluated the claims at issue in Teva. The opinion explained, "[t]o the extent that Teva argues that the meaning of 'molecular weight' in the context of [the] patents-in-suit is itself a question of fact, it is wrong. A party cannot transform into a factual matter the internal coherence and context assessment of the patent simply by having an expert offer an opinion on it."[xiv] Further, the Federal Circuit drew a distinction between: (1) the understanding of one of skill in the art from the patent and intrinsic evidence and (2) the understanding of the skilled artisan from outside the patent documents. "The meaning one of skill in the art would attribute to the term molecular weight in light of its use in the claims, the disclosure in the specification, and the discussion of this term in the prosecution history is a question of law."[xv] By contrast, "[u]nderstandings that lie outside the patent documents about the meaning of terms to one of skill in the art . . . are factual issues."[xvi]

Important to the Federal Circuit's determination regarding the definiteness of the claims were the "[s]tatements made during prosecution history."[xvii] Specifically, "[d]uring prosecution of the related '847 and '539 patents, which with respect to molecular weight have identical specifications, examiners twice rejected the term 'molecular weight' as indefinite for failing to disclose which measure of molecular weight to use ($M_p$, $M_n$, or $M_w$). And the patentee in one instance stated that it was $M_w$ and in the other it was $M_p$."[xviii] Therefore, the Federal Circuit held that "claim 1 is invalid for indefiniteness by clear and convincing evidence because read in light of the specification and the prosecution history . . . there is not reasonable certainty that molecular weight should be measured using $M_p$."[xix]

**CONCLUSION**

The Federal Circuit in Teva provided further guidance regarding the application of Nautilus's standard for evaluating allegedly ambiguous claims. Most significantly, "[s]tatements made during prosecution history are relevant to claim construction."[xx] As the dissent pointed out, "a single statement by Teva during prosecution of the '847 patent — made years after the '808 patent issued — [was] deemed dispositive on the question of whether the '808 patent is sufficiently definite."[xxi]

Based on Teva, therefore, practitioners involved in both patent prosecution and litigation should pay special attention to the prosecution history of an application or issued patent. During prosecution, for example, a prosecutor should consider how a particular claim term — and arguments regarding that term — might be construed not only in the present application, but also in any related patents in the family.

The Federal Circuit's full opinion is available here.

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[i] Teva Pharm. USA, Inc. v. Sandoz, Inc., No. 2012-1567, slip op. at 1 (Fed. Cir. June 18, 2015).
[ii] Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 843 (2015).
[iii] Id. at 837-38, 841-42.
[iv] Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014).
[v] Teva, No. 2012-1567, slip op. at 3.
[vi] Id. at 4.
[vii] Id. at 13.
[viii] Id. at 15.
[ix] Id. at 16-17.
[x] Teva, 135 S. Ct. at 837.
[xi] Nautilus, 134 S. Ct. at 2124.
[xii] Teva, No. 2012-1567, slip op. at 9 (citing Nautilus, 134 S. Ct. at 2128).
[xiii] Id. (citing Nautilus, 134 S. Ct. at 2129).
[xiv] Id. at 12.
[xv] Id.
[xvi] Id. at 13.
[xvii] Id.
[xviii] Id. at 17.
[xix] Id. at 18.
[xx] Id. at 13.
[xxi] Teva Pharm. USA, Inc. v. Sandoz, Inc., No. 2012-1567, slip op. at 5 (Fed. Cir. June 18, 2015) (Mayer, J., dissenting)

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