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COMMENTARY

Patent Litigants Feeling Effects of *Teva* in Claim Construction Decisions on Appeal

In January 2015, the U.S. Supreme Court handed down its decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, holding that underlying factual disputes related to a district court's claim construction should be reviewed for clear error instead of *de novo*, as the Federal Circuit had long held. In three recent decisions issued over the span of just a few days, the Federal Circuit has grappled with just how to apply the *Teva* ruling. (Our prior coverage of the *Teva* decision can be found here.) This brief *Commentary* provides a look at those decisions and what they may mean for future patent litigation.

Cephalon v. Abraxis

On June 17, 2015, in *Cephalon, Inc. v. Abraxis Bioscience, LLC*, a unanimous Federal Circuit panel affirmed a district court judgment of noninfringement in a case involving Celgene's Abraxane® breast cancer drug. (Disclosure: Jones Day represented defendants-appellees Abraxis Bioscience and Celgene Corp. in this case.) In affirming the district court's construction of the claim terms "nanoparticles" and "microparticles," the court, quoting the Supreme Court's decision in *Teva* as holding that "'how the art underst[ands] [a] term … [is] plainly a question of fact,'" concluded that "[t]he terms 'microparticles' and 'nanoparticles' are technical words, and how the relevant scientific community understands them is therefore a question of fact reviewable for clear error." The court found no clear error in the district court's construction, because it was supported by definitions found in contemporaneous treatises and textbooks, and in other patents in the same field that are owned by the patentee. The court further noted that the contrary construction proposed by the patent owner would have made the patent internally incoherent (by making some claim terms superfluous and at least one claim redundant), and was contradicted by certain representations made in the patent's prosecution history.

Teva on Remand

The very next day, June 18, 2015, the Federal Circuit handed down its decision on remand in the *Teva* case itself. By a 2–1 decision, the Federal Circuit stuck to its original view that the district court had erred in holding the term "molecular weight" definite. This decision was premised on claim construction: The district court had held that the term "molecular weight" (which in the abstract could refer to any of various types of molecular weight, including "number average," "weight average," and "peak average" molecular weight) actually referred to peak average molecular weight, based on

expert testimony that peak-average molecular weight was the only kind of molecular weight that could be obtained from the size-exclusion-chromatography data (a chromatogram and calibration curve) set forth in the patent's Example 1.

The Federal Circuit agreed that the term "molecular weight" does "not have a plain meaning to one of skill in the art." And the majority upheld, as not clearly erroneous, "[t]he district court's determination about how a skilled artisan would understand the way in which [size-exclusion-chromatography]-generated chromatogram data reflects molecular weight." But the court said that it did not follow that the meaning of "molecular weight," as used in the claims, had to accord with this not-clearly-erroneous finding. The problem, according to the majority, was that a correct claim construction has to be one that a skilled artisan would give to the claim term—in the words of the Supreme Court's decision in *Teva*—"in the context of the specific patent claim under review." As the majority explained, "accepting these fact findings does not, as Teva suggests, mean that there now exists a presumption regarding the meaning of the claim term in the art in general or in the context of this patent."

The context of the patent, including the prosecution history, highlighted the problem. Even though a skilled artisan might understand the meaning of "molecular weight" to be "peak average molecular weight" based on the data provided in Example 1, the patentee had also said, during prosecution of the patent (to overcome an examiner's rejection for indefiniteness), that "molecular weight" meant "weight average molecular weight." And this, the majority concluded, meant that "there is not reasonable certainty that molecular weight should be measured using [peak average molecular weight]."

The majority was not willing to let the "weight average" representation in the intrinsic record be overcome by expert testimony or factual findings that this statement was scientifically erroneous. In the majority's view, it is the court's job, as a matter of law, to determine whether a proffered construction is consistent with the context provided by the entire patent, such that the document is internally coherent: "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." Thus, the majority held that the district court's not-clearly-erroneous findings still could not compensate for the absence of reasonable certainty in the intrinsic record, and the claim was indefinite.

Senior Judge Mayer, who has historically urged deferential review of district courts' claim constructions, dissented. He would have found the claim term definite based on the district court's factual findings, giving those findings considerable deference in light of the evidence and testimony reviewed by the district court.

Lighting Ballast on Remand

The final case—*Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, decided on June 23, 2015—was, like *Teva*, also on remand from the Supreme Court, and also involved claim construction in the context of the definiteness requirement. Previously in *Lighting Ballast*, the Federal Circuit, acting *en banc*, had confirmed its view that the entirety of claim construction is reviewed *de novo*. Barely a month after the Federal Circuit's *en banc* decision in *Lighting Ballast*, the Supreme Court granted review in *Teva* on the same question of appellate deference, eventually reaching a different holding than did the *en banc Lighting Ballast* court. The Supreme Court then granted the pending petition in *Lighting Ballast*, vacated the Federal Circuit's prior judgment and remanded the case to the Federal Circuit for further consideration in light of *Teva*.

On remand, the unanimous Federal Circuit panel departed from its original (and also unanimous) decision that the claim was indefinite—and the district court's factual findings made all the difference. In its new opinion, applying clear-error review to the district court's factual findings, the panel explained that the district court did not err in relying on extrinsic evidence (expert testimony) to find the claims definite because those findings and extrinsic evidence were not used to contradict any unambiguous meaning in the intrinsic record. Rather, the extrinsic evidence explained how one of skill in the art would understand that record. The appellate court thus deferred to the district court's findings and upheld the definiteness of the claims.

The opinions on remand in *Teva* and *Lighting Ballast* were both issued by newly constituted panels—this was because then-Chief Judge Rader, now retired, had been assigned to the prior panels, and because a visiting district court judge had sat by designation on the *Teva* case.

The Decisions in Conjunction

It is still early in the post-*Teva* world. The cases that are making their way to the Federal Circuit at this time—these three are notable examples—are cases that were tried in the district court under pre-*Teva* law, where all aspects of claim construction were treated as matters of law for *de novo* review on appeal. But some patterns are emerging from these post-*Teva* decisions. All three decisions gave clear-error review to certain factual findings made in the context of claim construction. But, as *Cephalon* and *Teva* underscore, this is not always the end of the inquiry—those factual findings, even if not clearly erroneous ones, also should be tested against the context of the patent and the intrinsic record. And, where the intrinsic record would yield a different or inconsistent conclusion, the factual findings may either yield to the coherence of the intrinsic record, or may—as was the case in *Teva*—demonstrate that the patent claim is indefinite. As more Federal Circuit decisions apply the *Teva* standard of review, we will learn just how different the post-*Teva* world is from the world that existed before.

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