Teva Pharmaceuticals v. Sandoz: availability of generic glatiramer acetate and the impact to patent litigation claim construction

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In the upcoming case of Teva Pharmaceuticals v. Sandoz, the U.S. Supreme Court will address how much deference the appellate court should afford to a trial court's claim construction ruling. The effect of this decision will be far-reaching, as how claims are construed can determine whether a patent is infringed or not infringed, valid or invalid.

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In the United States, pharmaceutical and technology companies rely heavily on the patent law system to protect their inventions, as a patent gives them 'the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States [1]'. Patent litigation in the United States has reached unprecedented levels. In 2013, plaintiffs filed over 6000 new patent cases, a 12.4% increase over the number of cases filed in 2012 [2]. And massive patent damages awards continue to make headlines. In 2013, a jury awarded Monsanto $1 billion after finding DuPont infringed a patent related to genetically modified seeds [3]. The Supreme Court’s review of patent cases has also reached unprecedented levels, and, as a result, the United States' patent law system is evolving in an uncertain direction.

The monopoly rights granted by a patent are limited by its claims, which define and describe the scope of the invention [4]. It is not surprising then that claim construction, or construing the meaning and scope of a patent’s claims, often drives patent litigation. Under the current system, construing a patent claim is a question of law, that is, a question for a judge, not a jury, to determine [5]. The claim construction process usually happens early in the proceedings at the district court, and often involves the expenditure of significant resources by the parties and the court that culminates in the district court judge’s written opinion construing the disputed claim terms. After the claim terms have been construed, the case may proceed to a trial on the merits, after which, more often than not, the losing party appeals the case to the Federal Circuit, the sole appellate court for patent appeals in the United States. The Federal Circuit then applies 'de novo' review to ‘any allegedly fact-based questions related to claim construction [6]’. This lack of deference has resulted in a high reversal rate – 33 to 44% – on claim construction rulings, as compared to a reversal rate of < 20% on non-claim construction issues [7].

On October 15, 2014, the U.S. Supreme Court will hear the case of Teva Pharmaceuticals USA, Inc. et al. v. Sandoz, Inc. et al. (‘Teva’). At issue in Teva is the claim construction of the drug Copaxone® (glatiramer acetate, Teva Pharmaceuticals) (‘glatiramer’) [8], an injectable multiple sclerosis therapy. The drug is a blockbuster. It earned > $4.25 billion in 2013, which accounted for 21% of Teva’s revenue and 50% of its profit [9]. The fact that the Supreme Court has accepted this
case is important since the Court has discretion to decide what cases to hear, and statistically only accepts about 1% of the cases that are presented to it for review. Historically, the Supreme Court has declined review of many of the Federal Circuit’s decisions; however, during its last four terms [10], the Court has heard many appeals originating from the Federal Circuit and has reversed decisions in an unprecedented number of these cases.

The procedural history for Teva is straightforward. On December 27, 2007, Sandoz filed an abbreviated new drug application (‘ANDA’) seeking approval by the U.S. Food and Drug Administration to manufacture and sell a generic version of glatiramer before the expiration of Teva’s patents. Filing an ANDA is an act of patent infringement [11], and consequently, Teva sued Sandoz in August 2008 for infringing nine of its patents that allegedly cover glatiramer. Mylan filed its own ANDA on June 29, 2009, and Teva sued Mylan, and its partner Natco, in October 2009. These lawsuits were consolidated and various claim terms were construed by the district court judge, including the key phrase ‘average molecular weight’. The defendants argued that this phrase has multiple potential meanings, and therefore it was invalid for indefiniteness [12]. After months of expert discovery, two Markman (claim construction) hearings, and a lengthy written opinion, the district court disagreed with the defendants and construed this term to be a measure of the peak average molecular weight. After further discovery and briefing, the court held a bench trial after which the judge ruled that all nine of Teva’s patents were valid and infringed by the defendants. The court then issued an injunction preventing the generic manufacturers from marketing their generic versions of glatiramer until September 1, 2015, the date the final patent covering the compound is set to expire.

Sandoz and the other generic manufacturers appealed this decision to the Federal Circuit, arguing that the district court’s claim construction should be reversed. Applying de novo review, the Federal Circuit reversed the district court and held that the phrase ‘average molecular weight’ was indefinite. This holding made five of Teva’s patents invalid, including U.S. Patent No. 5,800,808 (‘the ’808 patent’) that was set to expire on September 1, 2015. The remaining patents-in-suit were still valid and infringed; however, they were all set to expire on May 24, 2014.

Teva appealed this decision, and on March 31, 2014, the U.S. Supreme Court granted certiorari [13] (accepted the appeal) to address the following question:

Whether a district court’s factual finding in support of its construction of a patent claim term may be reviewed de novo, as the Federal Circuit requires (and as the panel explicitly did in this case), or only for clear error, as Rule 52(a) requires [14].

There are a few different options for how the Supreme Court may answer this question. The Supreme Court could uphold the de novo standard of review for claim construction and maintain that construction of claim terms is a ‘purely legal’ exercise [15]. However, the Supreme Court’s decision to accept the Teva appeal suggests that this outcome is unlikely [16].

Alternatively, the Supreme Court could determine that the Federal Circuit should afford deference to the district court’s claim construction determination. The amount of deference would depend on the extent to which the Supreme Court revises its previous determination that claim construction is a legal issue. If the Supreme Court holds that claim construction is purely a factual determination, the Federal Circuit would have to give full deference to the fact finder’s [17] construction determination. This would provide greater certainty at the trial stage and drop the reversal rate on claim construction issues. However, this approach would be a radical departure from the status quo. It would also likely increase the amount of forum shopping at the district court – since the claim construction ruling would be difficult to overturn on appeal. For these reasons, we do not believe the Supreme Court will adopt this ‘full-deference’ option.

As such, the Supreme Court will likely rule that a district court’s factual findings on claim construction should be afforded deference, but that the Federal Circuit would retain de novo review over the associated issues of law. This approach elevates the factual determinations of the fact finder, while maintaining the ultimate issue of claim construction – based on the trial court’s factual findings – as a matter of law for the Federal Circuit. This mixed approach should still result in a lower reversal rate on claim construction issues and provide greater consistency to the Markman process. Although this result could also result in increased forum shopping, it could give patent litigants the certainty they need to rely more on the district court’s claim construction ruling to help decide whether to settle or continue to litigate.

In sum, if the Supreme Court decides to increase the deference the Federal Circuit must accord for claim construction, then the case would likely be remanded, with the ultimate result being that Teva’s ’808 patent could be reinstated as valid and infringed. If that occurs, then Teva could once again prevent a generic version of glatiramer from being marketed in the United States until the ’808 patent expires on September 1, 2015.

**Expert opinion**

In Teva, the Supreme Court has the opportunity to provide clarity to the system of patent litigation claim construction. Under the current system, the Federal Circuit disregards the district court’s claim construction analysis (including the factual findings), and starts over with its own analysis. This is unusual, as appellate courts are required under the Federal Rules to afford deference to findings of fact made by a district court.
Moreover, given the ‘alarming levels of appellate reversals’ [18] on claim construction, the Federal Circuit’s current approach has led to inefficiencies and has been costly to the patent system. Having plenary review for claim construction allows for a second ‘bite of the apple’ at the appellate level that can affect how both litigants and district court judges behave. For example, under the current de novo review standard, the ‘rejection of settlement is encouraged, and a decision to appeal is almost compelled, where counsel believes the client’s position is valid, even if debatable’ [19]. Moreover, ‘[s]ome district judges have responded’ to the high Federal Circuit reversal rate ‘by deciding that it is better to provide little or no reasoning for their claim constructions – possibly on the grounds that the Federal Circuit will be conducting their own analysis’ [20].

However, there remain valid reasons to maintain the status quo. For instance, claim construction is the interpretation of a legal document – a patent. Moreover, it is common for the same patent to be litigated in different district courts against different defendants, with different findings of fact in each case. If the Federal Circuit were to apply a deferential standard of review, “the possibility of disparate district court constructions unravels the ‘uniformity in the treatment of a given patent’ … and thus ‘restore the forum shopping that the Federal Circuit was created to avoid’” [21].

In our opinion, the Supreme Court in *Teva* will reverse the Federal Circuit’s decision, and hold that a district court’s factual findings regarding claim construction should be afforded deference, but that the Federal Circuit should retain de novo review over the ultimate legal question of claim construction. The effect of this holding will likely be that the validity of *Teva*’s ‘808 patent will be restored, preventing generic versions of glatiramer from being marketed in the U.S. until September 1, 2015.

**Declaration of interest**

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

**Bibliography**

1. 35 U.S.C. § 154(a)
4. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude’.” (citation omitted)); Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996) (“The claim defines the scope of a patent grant.” (internal quotation marks omitted) (citation omitted))
5. Markman, 517 US at 385
6. Cyber Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc)
8. Glatiramer is a mixture of polypeptides that range in size from 4,700 – 11,000 Daltons. See, e.g., Ctr. for Drug Evaluation and Research, Food & Drug Admin., Appl. No. NDA 20-622/S-015 Final Printed Labeling (2001)
11. 35 U.S.C. § 271(e)(2)
12. A patent claim is invalid for indefiniteness if its language, when read in light of the specification and prosecution history, “fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention”.
14. Rule 52(a)(6) of the Federal Rules of Civil Procedure provides that in matters tried to a district court, the court’s “[i]ndings of fact … must not be set aside unless clearly erroneous”
15. Markman, 517 U.S. at 391
16. The Supreme Court reverses two out of every three cases it chooses to hear. See generally Roy Hofer, Supreme Court Reversal Rates: Evaluating the Federal Courts of Appeals, 2 Landslide (2010) (finding that the Supreme Court affirmed 29 percent of the appeals accepted from 1999-2008). The Supreme Court typically accepts cases that result from a circuit split (where two different circuit courts reach a different conclusion on a legal issue), or when it intends to correct the actions of a lower court. Because appeals in patent law cases are heard by the Federal Circuit, there are no circuit splits in patent law, and so the Supreme Court typically accepts patent cases when it intends to correct law developed by the Federal Circuit. This is apparent in the Supreme Court’s recent...
opinions. From the October 1996 term up through October 2008, the Supreme Court accepted thirteen patent cases, reversing the Federal Circuit in seven, vacating the decisions in four, and affirming in only two cases, one of which rejected the Federal Circuit’s approach to the legal test at issue. John M. Golden, The Federal Circuit and the D.C. Circuit: Comparative Trials of Two Semi-Specialized Courts, 78 Geo. Wash. L. Rev. 553, 557-558 (2010). Thus, the Supreme Court’s recent trend suggests that the Federal Circuit will once again be reversed in Teva.

17. Because ANDA cases usually involve only injunctive relief, and not monetary damages, a jury trial is not available. See, e.g., Granfinanciera v. Nordberg, 492 U. S. 33, 91 (1989) (“If the claim and the relief are deemed equitable, we need go no further: the Seventh Amendment’s jury-trial right applies only to actions at law.”); Tegal Corp. v. Tokyo Electron Am., Inc., 257 F.3d 1331, 1339 (Fed. Cir. 2001) (holding there is no right to a jury trial when the only remedy sought by the plaintiff-patentee is an injunction).


21. Lighting Ballast Control, 744 F.3d at 1286 (citations omitted)

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