BIOBUSINESS BRIEFS

PATENT WATCH

US Supreme Court revises patent claim construction standards

The US Supreme Court handed down another practice-changing decision in its ruling on Teva Pharmaceuticals versus Sandoz in January, mandating that the US Federal Circuit must defer to facts found by trial courts when the meaning of the scope of patent claims is determined during trial.

In an earlier case, Markman versus Westview Instruments, the Supreme Court decided that the scope and meaning of patent claims were matters of law to be reviewed *de novo* by the Federal Circuit — that is, without any deference to the rulings of the trial court. In practice, and as established by the Cybor Corp. versus FAS Technologies case, the Federal Circuit decided that it would not only give no deference to the legal determinations regarding what the claims meant, but also give no deference to any 'factual' matters that formed the basis for the trial court's legal determinations.

In the Teva case, the issue was the meaning of the term 'molecular weight' as used in the claims. Teva's drug, glatiramer acetate (Copaxone) — which is approved for the treatment of multiple sclerosis — is a random tetramer of Glu, Ala, Lys and Tyr, and thus each molecule has a range of potential molecular weights. Teva brought suit against Sandoz and Mylan, both of which had applied for regulatory approval of their generic versions of Copaxone. Approval for these versions was stayed for 30 months while the lawsuit was pending. The trial court considered expert testimony that there are three meanings for the term 'molecular weight' used by persons in this art. They are: the 'peak average molecular weight' (M_p; defined as the weight of the molecule that is most prevalent in a mixture); the 'number average molecular weight' (M_n; defined as the average weight of all the different-sized molecules in the mixture); or the 'weight average molecular weight' (M_w; determined by calculating the average weight of all the molecules in the mixture while giving heavier molecules a weight-related bonus).

The trial court had decided that in this case the term meant the 'peak average molecular weight' and thus that the claim was sufficiently definite that it was not invalid. Sandoz appealed the decision on invalidity to the Federal Circuit and, during those proceedings, the Federal Circuit came to its own conclusions regarding the meaning of 'molecular weight' without regard to the trial court's determination. Under the Federal Circuit's construction, the term was indefinite (owing to the various meanings for 'molecular weight') and thus the claim was found to be invalid.

Teva appealed this decision to the Supreme Court, arguing that the Federal Circuit should give deference to trial court determinations of the 'subsidiary' facts on which it based its legal decisions of claim construction. The Supreme Court agreed and reversed the Federal Circuit's decision, holding that the Federal Circuit must give deference to trial court decisions related to these 'subsidiary' facts. The Court further noted that no such deference is required when the trial court restricts its consideration to the 'intrinsic' evidence (that is, the claim language, the specification and the written record before the US Patent and Trademark Office), but that any factual determinations by the trial court based on evidence outside that record (such as expert testimony) must be given deference by the appellate court and reversed only if the reviewing court finds clear error (that is, an actual mistake) in the factual findings.

The Supreme Court made this decision in order to bring patent claim construction practice for reviewing mixed questions of law and fact in line with the standards used by other appellate courts. The Supreme Court grounded this decision in the trial court's "greater opportunity to engage its capabilities of assessing the credibility of the witnesses and its capacity to immerse itself in the technical minutiae attendant upon construing claims in the first place."

The decision has resolved a question that has bedeviled the Federal Circuit since the Cybor decision. Case after case has been decided purely on *de novo* review of the claims, including the trial courts' factual determinations. This practice has been criticized by legal commentators and has even raised dissent among members of the Federal Circuit, because in practice this lack of deference has encouraged an appeal of every patent decision. As a result, trial court decisions have often been reversed in these appeals, frequently because the Federal Circuit came to a different conclusion on the facts.

The clearest potential drawback to this decision is that US patent practice could lose some of the harmonizing effect that was the principal motivation for — and the primary benefit of — having a specialized appellate court for patents. Matters of claim construction are often very dependent on the types of 'factual' evidence for which the Federal Circuit must now give deference. In addition, parties in patent litigation will probably try to make as much of the claim construction process before the trial court as possible dependent on expert testimony and other 'subsidiary' fact-finding, which should reduce the likelihood of having the trial court decision overturned on appeal.

Although it is too soon to tell, future patentees may try to limit the opportunity for such fact-finding by providing explicit definitions in their specifications. For highly complex technologies, however, it is also likely that trial court judges will need expert or other testimony to understand the language of the claims even with such express definitions. The Teva decision will thus shift the focus of cases related to patent claim construction towards the trial courts and away from the Federal Circuit.

As for Teva versus Sandoz, the case has been sent back to the Federal Circuit for reconsideration; ironically, the legal question at issue — invalidity due to indefiniteness — is itself a question of law and it remains to be seen whether the Federal Circuit can decide the claims are indefinite, even deferring to the trial court's definition of 'molecular weight'. For now, Copaxone will remain protected from generic competition until the case is resolved in favour of the generic challengers, or until the patent protecting the drug expires.

Kevin Noonan is a partner at McDonnell, Boehnen, Hulbert & Berghoff LLP, 300 South Wacker Drive, Chicago, Illinois 60606-6709, USA.
e-mail: noonan@mbhb.com

The author declares no competing interests.

FURTHER INFORMATION

US Supreme Court decision on Teva Pharmaceuticals versus Sandoz: http://www.supremecourt.gov/opinions/14pdf/13-854_o7jp.pdf
Markman versus Westview Instruments: https://supreme.justia.com/cases/federal/us/517/370/case.pdf
Cybor Corp. versus FAS Technologies: http://caselaw.findlaw.com/us-federal-circuit/1097487.html
PatentDocs blog: http://www.patentdocs.org/

ALL LINKS ARE ACTIVE IN THE ONLINE PDF