# Patent Covering Statin Formulation Invalidated by Federal Circuit

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On December 1, 2011, the Federal Circuit invalidated a patent covering a pharmaceutical formulation comprising a statin and an amine-containing polymer for lack of novelty. This case is *Teva Pharmaceutical Industries Ltd. v. AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals Inc.*

The patent at issue in this case claimed a pharmaceutical composition for the treatment of dyslipidemia, wherein the composition comprises a specific type of statin, and "a stabilizing effective amount of at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound." Teva submitted that they conceived of and reduced the claimed invention to practice in December of 1999.

Teva filed a claim against AstraZeneca for infringing this patent in view of the product Crestor®, a statin formulation marketed for the treatment of dyslipidemia. This formulation included crospovidone, an amido-group containing polymeric compound. Interestingly, AstraZeneca conceded infringement[1] in order to present an argument of invalidity under 35 U.S.C. § 102(g): although they did not appreciate crospovidone's role as a stabilizer in the formulation, AstraZeneca alleged that it had actually reduced the claimed invention to practice months before Teva did.

AstraZeneca's preparation of the statin formulation prior to Teva was undisputed. Teva, however, took the position that AstraZeneca was unable to have anticipated the claim because it was unaware of the stabilizing effect of crospovidone at the time of invention. Any other interpretation, according to Teva, was a "misapplication" of 102(g).

The court disagreed. Citing multiple prior Federal Circuit cases dealing with novelty and infringement, the court took the position that the prior artist needs to demonstrate that it appreciated that it had invented a working composition, but it is not required to demonstrate that it understood how each of the elements of the composition worked: "[t]o establish prior invention, the party asserting it must prove that it appreciated what it had made. The prior inventor does not need to know everything about how or why its invention worked. Nor must it conceive of its invention using the same words as the patentee would later use to claim it." Thus, in order to establish prior invention, AstraZeneca's inventors had to appreciate that the formulation was stable and what the components of the formulation were, but did not need to appreciate that

crospovidone was responsible for the stability. The court accordingly held that AstraZeneca had established prior invention and held the claim to be anticipated.

The Federal Circuit recently made a similar ruling on functional language in a claim with respect to an obviousness rejection in *In re Kao* (2011), in which an applicant unsuccessfully argued that the prior art did not explicitly make obvious a claimed dissolution profile of a pharmaceutical composition that was measured using a particular technique: "it should be clear that it makes no difference… whether the hypothetical person of ordinary skill in the art would have understood the claimed dissolution profile…The claimed subject matter is not presumed to change as a function of how one elects to measure it."

An understanding of the functional characteristics of a new pharmaceutical invention is critical to proper claim and application drafting, especially in the pharmaceutical arts. For example, functional language such as "stabilizing amount" can be critical in providing breadth in coverage of excipients and/or ranges that provide a newly discovered property in a formulation. However, the *Teva* case serves as a reminder that such characterizing language cannot serve as the basis for a novelty argument, if it can be shown that a prior composition inherently displays those characteristics. Further, whether the prior innovator was aware of the functional role of any given individual component is irrelevant, provided the innovator appreciated the existence and overall function of the composition at the time of invention.

It is worth noting that the *Teva* case does not, in any way, prohibit claiming an *entirely new* method of using a known composition, provided that new use is not taught or suggested in the prior art. See, for example, *Eli Lilly v. Actavis Elizabeth* (2011), in which a claim to a new method of treatment using a previously known compound was upheld as nonobvious by the Federal Circuit.

If you have any questions about this case, or any other aspect of chemical/pharmaceutical patent law, please contact your Lathrop Gage attorney or the authors listed on this alert.

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[1] *This concession of infringement removed many issues from this case, such as whether AstraZeneca's drug was an embodiment within the scope of the claim, whether the amount of crospovidone falls within a "stabilizing effective amount," and whether the doctrine of inherency applies to priority under § 102(g).*