AstraZeneca's Best Defense is a Good Offense in Recent Infringement Litigation Victory

Last month, the Federal Circuit affirmed a Pennsylvania District Court's grant of summary judgment in favor of AstraZeneca in a patent infringement suit concerning the popular cholesterol drug CRESTOR®. *Teva Pharm. Indus. v. Astrazeneca Pharms. LP*, 100 U.S.P.Q.2D (BNA) 1852 (Fed. Cir. 2011). AstraZeneca obtained this victory by conceding infringement for the limited purpose of seeking summary judgment of prior invention pursuant to 35 U.S.C. § 102(g)(2).

Plaintiff Teva Pharmaceutical Industries Ltd. ("Teva"), alleged that AstraZeneca's CRESTOR® prescription drug products infringed certain claims of Teva's U.S. Patent No. RE39,502 ("the '502 patent"). The pharmaceutical composition disclosed in the '502 patent is a "statin," a class of compounds useful for treating persons suffering from high cholesterol. Statins are an inherently unstable and must be manufactured in stabilized formulations in order to be medically viable. The '502 patent discloses a statin compound stabilized by

> *a stabilizing effective amount* of at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof, wherein said stabilized pharmaceutical composition does not contain a stabilizing effective amount of another stabilizer or a combination of other stabilizers.

'502 patent col.16 ll.17-33.

AstraZeneca's CRESTOR® product is also a stabilized statin formulation for the treatment of high cholesterol. Unlike the invention disclosed in the '502 patent, however, CRESTOR® was not designed to be stabilized by "at least one amido-group containing polymeric compound ("AGCP") or at least one amino-group containing polymeric compound" within the meaning of the '502 patent's claims. Rather, AstraZeneca employed a different compound to act as a stabilizer in the CRESTOR® formulation. AstraZeneca's CRESTOR® formulation does include an AGCP compound employed by the drug's inventors as a disintegrant, but AstraZeneca did not appreciate the stabilizing function of this AGCP compound in the formulation at the time of invention.

Teva maintained that, although it was undisputed that AstraZeneca reduced its drug to practice prior to Teva's first conception of the '502 patent's asserted claims, AstraZeneca could not establish priority of invention under § 102(g)(2) because AstraZeneca did not appreciate the stabilizing function of the AGCP compound employed in CRESTOR®. The Federal Circuit rejected Teva's argument, reaffirming the rule that

> To 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.

Teva Pharm, 100 U.S.P.Q.2D (BNA) 1852, 2011 U.S. App. LEXIS 23874* 14 (citations omitted). This established principal of Federal Circuit law sealed the '502 patent's fate.

Whether prior art includes a particular claim limitation is a question of fact that a party asserting invalidity must establish by clear and convincing evidence. *See, e.g., Sandt Tech., Ltd. v. Resco Metal & Plastics Corp*., 264 F.3d 1344, 1350 (Fed. Cir. 2001). Thus, in order to establish that the '502 patent's asserted claims were invalid under section 102(g)(2), AstraZeneca would have had to prove that CRESTOR® was a statin compound stabilized by "a stabilizing effective amount" of the AGCP compound AstraZeneca employed as a disintigrant in the CRESTOR® formulation.

Because AstraZeneca designed CRESTOR® to be stabilized by another non-AGCP substance, whether CRESTOR® contained a stabilizing effective amount of its AGCP compound would likely have presented a question of fact ripe for a battle of the experts. In fighting this battle, Teva would have been armed with the presumption of patent validity. *E.g., id*. However, AstraZeneca's limited concession of infringement, combined with Teva's infringement allegations, "took any such factual dispute off the table." *Teva Pharm,* 2011 U.S. App. LEXIS 23874* 18. By conceding that CRESTOR® fell within the scope of the '502 patent's claims, AstraZeneca effectively removed the '502 patent's fundamental limitation from the scope of the Court's section 102(g)(2) analysis.

It is unclear when Teva learned the date on which AstraZeneca first reduced its CRESTOR® formulation to practice, but presumably such information was revealed in discovery long before AstraZeneca filed its summary judgment motion. Had Teva extracted itself from the litigation before the summary judgment phase, the '502 patent would likely still be a part of Teva's patent portfolio. Indeed, the Federal Circuit hinted that Teva could have saved the '502 patent by abandoning its infringement allegations. *See Teva Pharm,*, 2011 U.S. App. LEXIS 23874* 8.