IP Alert | Federal Circuit to Decide if Patentee is Bound by Earlier Statement to PTAB

By Sarah A. Kagan, Ph.D.

Should a patentee be held to all statements it makes about its claims? Does prosecution history estoppel flow from a patentee's arguments no matter when and where they are made in an administrative or judicial setting? Will a patentee's statements limit a claim's scope even if the Patent Trial and Appeal Board (PTAB) rejected the statements?

A panel of the U.S. Court of Appeals for the Federal Circuit consisting of Judges Alan Lourie, Kimberly Moore, and Kara Stoll grappled with these questions at an oral hearing on Sept. 5, 2019, in an appeal of Abbreviated New Drug Application (ANDA) litigation from the District Court of Delaware.[1] The court has yet to issue its opinion.

Galderma Laboratories filed an infringement suit against Amneal Pharmaceuticals for its proposed generic version of Oracea® capsules, a once daily, 40 mg capsule for delivering doxycycline to treat acne rosacea. Galderma asserted eight patents against Amneal's proposed generic version. One set of the patents relates to a pharmaceutical composition of doxycycline with an immediate release and a delayed release component. The second set of the patents relates to a method of treating rosacea with doxycycline in an amount that results in no reduction in skin microflora. Here we focus only on the first set.

The first set of patents was challenged in an inter partes review (IPR) proceeding in which Galderma argued for a narrow claim construction of its claims but the PTAB did not adopt that construction. Instead, the PTAB interpreted the claims more broadly. Specifically, Galderma argued that "delayed release" means no substantial release of doxycycline in the acidic stomach environment. The PTAB rejected that claim construction because it found that it was not supported in the specification.

Amneal asserted during oral arguments that a patentee is liable for all its statements regarding the scope of its claims. Judge Moore pushed back against this assertion because the PTAB's rejection of Galderma's construction was so clear. Judge Moore was concerned that a person of skill in the art reading the record of the patent might be confused and think that the PTAB's rejection of Galderma's construction released Galderma from its statement. Amneal countered that a rule that always held a patentee to its statements would lead to less confusion. Galderma argued that no reasonable competitor could rely on Galderma's statements about its claims because the PTAB so clearly rejected them.

Judge Stoll showed concern that a patentee has no formal mechanism to change a position that it took in an IPR because the PTAB controls the papers filed in an IPR and might not permit the filing of miscellaneous papers. Judge Stoll asked each party what mechanism a patentee might use to change its position on the record. Galderma simply stated that it was not aware of any such mechanism. Amneal said that a party could at least try to supplement the record to withdraw its prior position, noting that Galderma had not tried.

Galderma argued that if the court held Galderma to its statements, it would create the anomaly that Galderma would be held to both the accepted and rejected claim constructions. It further noted that Amneal's position on estoppel leads to the anomaly that the literal scope of the claims is broader than the scope of the claims under the doctrine of equivalents because of the operation of the urged prosecution history estoppel.

The judges and parties discussed American Piledriving Equipment, Inc. v. Geoquip, Inc., 637 F.3d 1324 (Fed. Cir. 2011) as perhaps the most relevant precedent. In American Piledriving, the Federal Circuit held that applicant's statements made during prosecution may lead to a disavowal of claim scope, regardless of whether the examiner agreed with or relied on them. The judges noted that American Piledriving involved a claim construction issue rather than a doctrine of equivalents issue as in Galderma v. Amneal. Will that difference lead to a different rule? If the rule is to lead to clearer understanding of a claim's scope by influencing a patentees' behavior during prosecution and post-grant proceedings, then distinguishing the effect based on the issue that is later litigated seems counterproductive.

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[1] Galderma Laboratories, L.P. v. Amneal Pharmaceuticals LLC (2019-1021).

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