Life Sciences Litigation Update

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Federal Circuit Affirms Preliminary Injunction in Pharmaceutical Case: In *AstraZeneca LP v. Apotex, Inc.*, 2010 WL 4286284 (Fed. Cir. Nov. 1, 2010), the Federal Circuit affirmed a preliminary injunction entered by the U.S. District Court for New Jersey to prevent Apotex from launching a generic version of AstraZeneca's budesonide inhalation suspension product, marketed as "PULMICORT RESPULES." Each "respule" is a plastic vial containing a single dose of budesonide suspended in sterile liquid. AstraZeneca owns two patents covering its product: United States Patent Nos. 6,598,603 and 6,899,099. Each patent includes method claims directed to administering a budesonide composition once daily and product claims directed toward a kit containing either a budesonide composition or a suspension and labeled to indicate once-daily administration by nebulization.

Apotex sought approval for a twice-daily generic version of AstraZeneca's drug product. To avoid infringing AstraZeneca's patents, Apotex unsuccessfully attempted to obtain approval for a label that did not explicitly mention the once-daily administration of its generic suspension formulation. The FDA, however, required Apotex to include statements regarding the down titration (causing dosage decreases over time) of its generic drug.

Upon approval of Apotex's ANDA, AstraZeneca sued for infringement. It alleged, among other things, that the down-titration statements of Apotex's label would induce infringement of specific method claims in its patents. AstraZeneca also sought a preliminary injunction, arguing that (1) it was likely to prove its inducement of infringement claim; (2) it was likely to suffer irreparable harm without preliminary relief in the form of layoffs and loss of consumer goodwill; (3) the balance of hardships tilted in its favor; and (4) an injunction was in the public interest. The district court agreed.

On appeal, Apotex challenged the district court's finding of inducement of infringement—and ultimately the issuance of the preliminary injunction—by arguing that its instructions did not demonstrate specific intent to cause the users of its product to engage in once-daily dosing. The Federal Circuit rejected those arguments and agreed that the downward-titration instructions would necessarily result in some users engaging in once-daily dosing. Most significantly, the Federal Circuit noted that even though Apotex was well aware of the infringement problems raised by once-daily dosing, it chose to proceed with the filing of its ANDA application.

Obviousness-Type Double Patenting in the Pharmaceutical Context: The Federal Circuit recently revisited the doctrine of obviousness-type double patenting in *Sun Pharmaceutical Indus., Ltd. v. Eli Lilly and Co.*, 611 F.3d 1381 (Fed. Cir. 2010). Eli Lilly obtained U.S. Patent No. 4,808,614 covering the drug gemcitabine, the active ingredient in Lilly's Gemzar® product, as well as a method of using it to treat viral infections. The specification of the '614 patent also disclosed using gemcitabine to treat cancer, but the patent did not claim such use. The '614 patent resulted from a divisional application, filed December 4, 1984, as a continuation-in-part of U.S. Patent Application No. 473,883 ("original '883 application"), filed March 10, 1983. Later, Eli Lilly received U.S. Patent No. 5,464,826, which claimed the method of treating cancer with gemcitabine. Although the '614 and '826 patents were filed as applications on the same day in 1984, the '826 patent issued approximately two-and-a-half years after the '614 patent. Owing to the difference in their dates of issuance, the '614 patent expired in 2010, while the '826 patent was not due to expire until 2012.

After filing its ANDA for approval of a generic version of Gemzar®, Sun Pharmaceuticals sought a declaratory judgment that the '826 patent was invalid and not infringed. Lilly counterclaimed for infringement of the '826 and '614 patents. The district court granted summary judgment that the claims of Lilly's '826 patent were invalid for obviousness-type double patenting in light of the '614 patent. The Federal Circuit affirmed, relying principally on two earlier decisions that addressed double patenting in the context of claims claiming different uses of the same drug compound, *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline, PLC*, 349 F.3d 1373 (Fed. Cir. 2003), and *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008). In *Geneva*, the earlier patent claimed a compound, potassium clavulanate, and the specification disclosed its effectiveness for inhibiting beta-lactamase in humans. The later patent claimed a method of using potassium clavulanate to affect beta-lactamase inhibition in humans or animals. Similarly, in *Pfizer*, the earlier patent claimed several compounds, and the specification disclosed their use in treating inflammation and inflammation-associated disorders. The later patent claimed a method of using the earlier-claimed compounds to treat inflammation. In each case, the claims filed in the two applications were not "patentably distinct," and thus the latter claims were held invalid for obviousness-type double patenting.

Lilly attempted to distinguish them by arguing that the district court should have evaluated the compound claims directed to gemcitabine in the '614 patent based on the original '883 application. The '883 application disclosed only gemcitabine's antiviral use, not its anticancer use. Lilly had added a description of gemcitabine's anticancer use to the specification in a continuation-in-part application that eventually resulted in the '614 patent. Lilly asked the court to ignore the '614 patent's description of gemcitabine's use in cancer treatment because that disclosure was not part of the original '883 application. The Federal Circuit rejected its argument, reasoning that the scope of the claims at issue must be understood in light of the entire issued patent, and not be limited to the disclosure in an early version of the specification that may have been substantially altered during prosecution.