FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Allergan, Inc. v. Alcon Labs., Inc., 02-1449 (Fed. Cir. Mar. 28, 2003) (Per Curiam)

The court held that a recent panel opinion, Warner-Lambert v. Apotex, 316 F.3d 1348 (Fed. Cir. Jan. 16, 2003), precluded an inducement infringement claim under 35 U.S.C. §271(e)(2) when: (i) an ANDA requests approval to produce a generic drug for use to treat a particular condition; (ii) the generic drug is medically effective when used to treat a second, different condition; and (iii) the patentee, while having a patent for use of the drug to treat the second condition, does not have FDA approval under a NDA to market the drug for such second use. Judge Schall separately wrote a lengthy concurrence in the judgment, acknowledging that Warner-Lambert controlled, but arguing that it contravened the plain meaning and intent of various Hatch-Waxman Act provisions, and, therefore, the inducement claim should be allowed. In addition, Judge Linn wrote a short concurrence expressing agreement with Judge Schall's view, noting that while the Warner-Lambert court's conclusion is sensible policy, it disregards congressional intent. Judge Clevenger joined Judge Schall's concurring opinion.

Allergan holds patents for use of the public domain drug brimonidine, one for a method of treatment to protect the optic nerve (U.S. Pat. No. 6,194,415), the other for a method of neural protection (U.S. Pat. No. 6,248,741). These treatments are beneficial for "open-angle" glaucoma. Allergan's brand name brimonidine is called Alphagan. Both the '415 and '741 patents issued in 2001. That same year, Allergan subsequently associated them with Alphagan in the FDA's "Orange Book."

Alcon's Abbreviated New Drug Application ("ANDA") sought approval to produce and market a generic brimonidine for reducing intraocular pressure, a method of use in the public domain. Allergan's concern, and motivation for bringing an inducement infringement claim, is the worry that once generic brimonidine is available to a doctor, she will use it to protect optic nerves or administer neural protection, directly infringing Allergan's two method patents. The direct infringement possibility raises the inducement claim for Alcon – the question being whether that inducement claim can be brought upon filing of the ANDA under §271(e)(2), or whether it must wait until the generic drug is actually in commercial use.

The court overruled the district court's rulings that: (i) §271(e)(2) was merely a jurisdictional statute, i.e., a "hook" for a patent case and was symmetric with §271(e)(1) – meaning that it only authorized infringement suits against actions that would otherwise fall into §271(e)(1)'s exceptions to infringement; and (ii) that §271(e)(2) could not generally "serve as an umbrella for a claim of induced infringement for a method of use patent." Section 281(e)(2) creates an "act of infringement" and its language "does not limit the reach of the statute to direct infringement actions to the exclusion of actions for induced infringement." Further, the constitutional "case or controversy" requirement is not a barrier to §271(e)(2) inducement claims: "[while such a claim] may be speculative, it is not sufficiently so to contravene the . . . requirement."

While generally §271(e)(2) inducement claims are not barred, this particular type of claim is barred under the Warner-Lambert interpretation of §271(e)(2). The court recounted that case as follows.

> [A] method of use patent holder may not sue an ANDA applicant for induced infringement of its patent, if the ANDA applicant is not seeking FDA approval for the use claimed in the patent and if the use claimed in the patent is not FDA-approved. . . . "because an ANDA may not seek approval for an unapproved or off-label use of a drug under 21 U.S.C. § 355(j)(2)(A)(i), it necessarily follows that 35 U.S.C. § 271(e)(2)(A) does not apply to a use patent claiming only such a use." . . . [T]he Warner-Lambert court expressed concern that permitting a cause of action under section 271(e)(2) for off-label method of use patents would "confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." Warner-Lambert, 316 F.3d at 1359. The court also expressed concern about the threat of abuse by a patent holder attempting to extend its patent exclusion.