

1 December 2003



# TECHNOLOGY LAW UPDATE

*A report of the latest Federal Circuit updates brought to you by Preston Gates.*

## Ranbaxy Pharms. v. Apotex, Inc.

No. 02-1429 (Fed. Cir. Nov. 26, 2003)

***“[F]oreseeability relates to the equivalent, not to whether an amendment may result in prosecution history estoppel.”***

On November 26, 2003, the Federal Circuit affirmed the district court’s order that denied a preliminary injunction against Ranbaxy for infringement of U.S. Patent No. 5,847,118, which related to a process for preparing amorphous cefuroxime axetil, a broad-spectrum antibiotic used to treat conditions such as tonsillitis, sinusitis, and skin infections. The Federal Circuit stated:

Apotex was required to establish its right to a preliminary injunction in light of four factors: “(1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of the hardships and (4) the impact of the injunction on the public interest.” . . . To show a reasonable likelihood of success on the merits of the infringement claim, Apotex was required to show that “in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove [infringement] and (2) its infringement claim will likely withstand [Ranbaxy’s] challenges to the validity and enforceability of the . . . patent[s].” . . .

Apotex argues that the district court erred in concluding that there had been a narrowing amendment for a substantial reason related to patentability. It contends that because the examiner in the first office action objected to dependent claims 3-7 but stated that they would be patentable if rewritten in independent form, and because claim 11 is nothing more than claims 3, 5, and 7 combined and rewritten in independent form, there was not a narrowing amendment for a substantial reason related to patentability. . . . In this case the surrender is particularly clear. While Apotex was merely rewriting a dependent claim into independent form, the effect on the subject matter was substantial. The dependent claims that were redrafted into independent form did more than simply add an additional limitation; they further defined and circumscribed an existing limitation for the purpose of putting the claims in condition for allowance. The additional language limited “highly polar solvent” to a defined group of solvents [and thus] the patentee is presumed to have surrendered the equivalents that may have been encompassed by “highly polar solvent.”

Having concluded that the district court properly determined that there had been a narrowing amendment for a substantial reason related to patentability, we next turn to whether Apotex can overcome the presumption that it has surrendered equivalents. [This] presumption can be overcome if “[t]he equivalent [was] unforeseeable at the time of the application; the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question; or there [was] some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.” Apotex argues that it was “not foreseeable that the acceptance of the structurally-defined subject matter could constitute surrender of a highly polar organic solvent which is the obvious structural equivalent (homolog) of one of the recited solvents.” Ranbaxy responds that acetic acid is a foreseeable equivalent to formic acid that could have and should have been included in the original claim. . . .

Ranbaxy has the better argument. First, foreseeability relates to the equivalent, not to whether an amendment may result in prosecution history estoppel. Second, the notion that acetic acid was unforeseeable at the time of application flies in the face of the fact that Apotex stated that formic acid and acetic acid, as homologs, are readily known by chemists to exhibit similar properties and are therefore equivalent. If acetic acid was readily known by chemists to be equivalent to formic acid, it would have been foreseeable to literally include acetic acid in the claim. Therefore, at this stage of the litigation, Apotex has not overcome the presumption that it has surrendered coverage of acetic acid.