

Life Sciences MVP: Fish & Richardson's Jonathan Singer

By Jeff Overley

Law360, New York (December 17, 2013, 6:56 PM ET) -- Fish & Richardson PC's Jonathan E. Singer in 2013 sealed a major Federal Circuit victory directing courts to look at all objective facts when deciding the obviousness of drug patents, one of several high-profile triumphs that scored him a spot among Law360's Life Sciences MVPs.

Singer cemented his win for Cephalon Inc. when the U.S. Supreme Court declined to review the appellate court's ruling, and the significance was evident in complaints from petitioner Mylan Inc. that the outcome "has the potential to disrupt the availability and affordability of generic medications."

At issue was muscle relaxant Amrix, which boasted a novel extended-release formulation but whose active ingredient was nothing new. To show that the formulation was nonetheless deserving of protection, Singer called a witness who described how a laboratory with exceptional prowess in creating extended-release products had invested \$10 million to produce a long-acting version of the muscle relaxant, but ultimately failed.

Nonetheless, a district judge found that the longer-acting version was obvious. "What the lower court did was look at the technical documents and say, 'You just did A plus B, and that's obvious because anybody could do A plus B,'" Singer recalled.

At the Federal Circuit, however, Singer persuaded judges to take a more expansive view and recognize that other drugmakers had tried and failed to create a long-lasting form of cyclobenzaprine.

"You've got to give weight to the real world," Singer told Law360.

While Mylan raised concerns about putting up roadblocks in front of generics, Singer countered by suggesting the district court's ruling could have discouraged development of products offering more convenience.

"If you really can't get a patent on any kind of extended-release drug, you will [impede] innovations to create them," Singer said. "People will say, 'Forget it.'"

Another closely followed case involved patents on Allergan Inc.'s eyelash growth stimulant Latisse, or bimatoprost, whose hair-growth properties were discovered by accident during development of a glaucoma drug.

A key issue in the case was whether Latisse's patent claims were anticipated by earlier patents and presentations, and were therefore invalid. A North Carolina federal judge balked at that contention from Apotex Inc. and other generics makers, finding that eyelash-related side effects among some glaucoma patients were not enough to conclude that the earlier medicine was a suitable hair growth treatment.

"The mere fact that bimatoprost, when applied through an eye drop, may contact the skin and cause eyelash growth, does not mean that such an effective application is inherent in the [glaucoma drug] patent," the judge wrote.

That finding has important implications for drugmakers that stumble across unexpected benefits of their molecules, Singer said.

"What it shows is that things discovered by accident like this ... if they're beneficial, they can be pursued as inventions without running afoul of a host of technical issues [under patent law]," he said.

In another suit involving Amrix, Singer in February again prevailed at the Federal Circuit, this time successfully short-circuiting what he labeled a "breathtaking argument" by Impax Laboratories Inc. to become the exclusive seller of the muscle relaxer's generic version.

The convoluted case began when Impax settled a patent infringement suit brought by Cephalon. Under the terms of the deal, Impax would be licensed to sell a generic as soon as any other company — except for the generics maker that won 180-day exclusivity — was authorized to sell a generic version.

Later, Mylan launched a generic on an at-risk basis, and Cephalon responded by launching its own generic. An injunction ended up taking both those generics off the market, but Impax said its agreement had been triggered by Cephalon's launch, and that it should be able to start selling its generic.

Singer convinced a Delaware federal judge to reject that logic. "Having reviewed the contract on the whole, it is clear that the parties did not intend for Impax to receive any sort of windfall whereby it became the sole generic company on the market," the judge wrote in a decision that was affirmed by the Federal Circuit.

That decision included an important takeaway for branded-drug companies, Singer said, because had the language of Cephalon's deal with Impax been different, it's possible the unusual legal argument would have prevailed.

"These settlements are very common, so it taught people to be very careful how you word them," he said.

Others wins in 2013 included convincing a Delaware federal judge that Mylan had infringed patents for Cephalon's cancer drug Fentora, and a Federal Circuit victory along with co-counsel Juanita Brooks, also of Fish & Richardson, that protected Allergan's glaucoma drug Lumigan.

All in all, 2013 provided "terrific chances to shine in multiple different cases," Singer said, crediting the many successes to "an enormous number of talented, younger lawyers [at Fish] who are very hungry to learn this area of the law."

The heavy workload made things something of a blur, Singer added, with the impressive scorecard

coming into focus only when the year wound to a close.

"To be honest," he said, "I lost track."

--Additional reporting by Ryan Davis. Editing by Katherine Rautenberg.

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