

Sham-Wow! Antitrust Liability May Attach to Sham Administrative Petitions: Tyco Healthcare Group LP v. Mutual Pharm. Co., Inc.

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Addressing whether the “sham” exception to Noerr-Pennington immunity is limited to sham litigation in courts, the U.S. Court of Appeals for the Federal Circuit vacated a lower court’s summary judgment of no antitrust liability, finding that antitrust liability can attach to sham administrative petitions and that the sham litigation exception is not limited to court litigation. *Tyco Healthcare Group LP v. Mutual Pharm. Co., Inc.*, Case No. 13-1386 (Fed. Cir., Aug. 6, 2014) (Bryson, J.) (Newman, J., dissenting).

Tyco Healthcare acquired patents relating to temazepam, an insomnia drug marketed as Restoril. Seeking Food and Drug Administration (FDA) approval to manufacture and sell generic temazepam, Mutual Pharmaceutical filed an Abbreviated New Drug Application (ANDA), certifying that its generic product would not infringe any patents. Tyco disagreed and sued Mutual for infringement under the Hatch-Waxman Act. The district court rejected this claim, reasoning that products manufactured to the ANDA’s specification could not infringe. Tyco then filed a citizen petition with the FDA, urging new guidelines to require generic temazepam

manufacturers to more extensively demonstrate bioequivalence to Restoril. The FDA denied Tyco's citizen's petition "indicating that, in the FDA's view, it was wholly without merit."

In response to Tyco's infringement suit, Mutual brought antitrust counterclaims, including allegations that Tyco's suit and citizen petition were shams. In other words, Mutual argued that Tyco used illegitimate means to keep Mutual's product off the market. On summary judgment, the district court rejected these counterclaims, holding that it was reasonable for Tyco to proceed with its infringement action and that antitrust liability for sham claims cannot apply to filing administrative petitions because the exception "is expressly limited to litigation." Mutual appealed.

The Federal Circuit vacated the rulings on antitrust issues and remanded for further consideration. With regard to Tyco's Hatch-Waxman claim, the Federal Circuit found that it was not unreasonable for a patent owner to allege infringement under Hatch-Waxman if the patent owner has evidence that the as-marketed commercial ANDA product will infringe, even though the hypothetical product specified in the ANDA could not infringe. The Court concluded that further inquiry was necessary to determine if Tyco's factual theory of infringement was objectively baseless. With regard to the administrative proceeding, the Court found that the sham exception to Noerr-Pennington is not limited to court litigation, and that it has been applied to administrative petitions, including FDA citizen petitions. Accordingly, it remanded this counterclaim for resolution of fact issues regarding whether the citizen petition was objectively baseless and motivated by a subjective desire to directly interfere with Mutual, as well as whether Mutual suffered any anticompetitive injury.

Judge Newman dissented from the court's conversion of routine patent litigation into antitrust violations, arguing that "[e]nforcement of a presumptively valid patent against a product that infringes by statute [Hatch-Waxman] cannot be deemed objectively baseless" and patent holders have "the right to communicate with the FDA concerning public information on matters within the agency's authority and responsibility without incurring antitrust liability."

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