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Federal Circuit Patent Bulletin: *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*

August 7, 2014

"[I]t is not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) 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."

On August 6, 2014, in *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, the U.S. Court of Appeals for the Federal Circuit (Newman, Bryson,* Moore) affirmed-in-part, vacated-in-part, and remanded the district court's summary judgment that Tyco did not violate the antitrust laws by filing suit alleging Mutual's infringement inter alia of U.S. Patent No. 5,211,954, which related to temazepam for insomnia treatment that Tyco markets as Restoril, or by filing a "citizen petition" with the U.S. Food and Drug Administration (FDA) seeking to bar Mutual from obtaining FDA permission to market its generic version of one of Tyco's drugs. The Federal Circuit stated:

A party is ordinarily exempt from antitrust liability for bringing a lawsuit against a competitor. That principle is known as "Noerr-Pennington immunity . . . . There is a recognized exception to Noerr-Pennington immunity for "sham litigation," which the Supreme Court has defined as litigation that (1) is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" (the objective element), and (2) is motivated by a desire "to interfere directly with the business relationships of a competitor" (the subjective element).

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On appeal, Mutual asserts that there is a disputed issue of fact concerning whether Tyco's infringement suit was "objectively baseless" so as to fall within the sham-litigation exception to Noerr-Pennington immunity. . . . Mutual's argument [ignores precedent] that could give a patentee in Tyco's position a reasonable expectation of a favorable outcome even though the generic manufacturer's ANDA application describes a generic drug with characteristics that take it outside the patent's claims. The question [is] whether the product that the ANDA applicant will likely market if its application is approved will infringe. That can occur in spite of the ANDA specification if, for example, the ANDA is based on faulty testing or screening procedures. . . . Therefore, we agree with Tyco that it is not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) 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.

That does not end our inquiry into whether Tyco's section 271(e)(2)(A) infringement claim was objectively baseless, however. Tyco's infringement claim is based on its theory that Mutual's use of 40°C as the outgassing temperature was inappropriate and that 105°C—the temperature at which Tyco and Sandoz tested Restoril—should have been used instead. The parties do not disdispute that the specific surface area of Mutual's temazepam falls within the infringing range when the outgassing temperature is set at 105°C. However, expert testimony and other evidence, including images from a scanning electron microscope, suggest that exposing Mutual's temazepam to a temperature of 105°C physically alters the temazepam material itself, resulting in larger temazepam particles and decreased specific surface area.

In addition, testimony from Mutual's expert tends to establish that lower outgassing temperatures result in measurements that underestimate specific surface area. If that is true, the difference between the actual specific surface area of the tested product and the infringing range would actually be greater than indicated by the measurement of the tested product obtained at a lower outgassing temperature. According to Mutual's expert, increasing the outgassing temperature merely serves to accelerate the removal of contaminants from the surface of the tested material. If full outgassing is not achieved, the measured specific surface area may be reduced, because less surface area is available for the test gas to adsorb to. It therefore stands to reason that, barring physical alteration to Mutual's temazepam, Tyco's demand that Mutual increase the outgassing temperature would not decrease—but would potentially increase—the specific surface area measurement due to the removal of more surface contaminants. Barring physical alteration of the material, an increased outgassing temperature would thus make it more likely that Mutual's commercial product would measure outside of the infringing range, not more likely that it would measure within the infringing range, as Tyco suggests. Tyco's theory of why Mutual's as-marketed ANDA product will infringe therefore appears to be based on a theory contrary to what the underlying scientific principles dictate. Put simply, even if Mutual's specific surface area measurements are wrong, they would appear to be wrong in a way that does not help Tyco.

Based on the evidence of record and this analysis, we conclude that further inquiry is needed into the effect of the outgassing temperature on the specific surface area of Mutual's generic product. We leave it to the district court to determine whether that inquiry can be performed within the context of a summary judgment proceeding or requires a trial. Accordingly, on remand, the district court should determine whether Tyco's factual theory of infringement is objectively baseless. If necessary, the court should then determine whether Mutual has shown that the subjective element of the sham-litigation test has been satisfied. . . .

We conclude that Mutual has not met its burden to establish that Tyco's validity arguments were objectively baseless, even though those arguments were ultimately unsuccessful. We therefore affirm the district court's grant of summary judgment for Tyco with respect to the invalidity portion of Mutual's sham-litigation counterclaim.

Mutual next argues that the district court erred by granting summary judgment for Tyco with respect to Mutual's claim that Tyco's citizen petition to the FDA was a sham that stripped Tyco of its Noerr-Pennington immunity. Because the district court applied the wrong legal standard and because disputed issues of material fact remain, we vacate that portion of the district court's judgment. . . . Particularly probative of whether the citizen petition was reasonable is the FDA's response, which denied the petition in terms indicating that, in the FDA's view, it was wholly without merit. The FDA found that Tyco had "provided no evidence from clinical trials, pharmacokinetic studies, bioequivalence testing, or any other source . . . .Instead the petition relies entirely on uncorroborated generalities and theoretical speculation to support its critical point." The FDA also concluded that the petition "fail[ed] to provide any evidence at all about the existence, extent, or significance of surface area variations for any other generic temazepam products at any dosage strength." Furthermore, the FDA noted that it has not required generic manufacturers to demonstrate additional bioequivalence criteria except in "very rare instances," all of which have involved "complex extended-release or otherwise modified-release products for which there was a known and clinically significant connection between release characteristics and clinical performance" and that"[t]emazepam is not such a drug." . . .

There remains an open issue, however, as to whether the filing of the citizen petition caused any antitrust injury to Mutual. In this court, neither party has pointed to anything in the record establishing that the citizen petition was the cause of a delay in the approval of the ANDA. In support of its contention that the FDA's approval was delayed "solely because of Tyco's petition," Mutual cites only the ANDA approval letter. The letter, however, does not say anything about a delay due to the citizen petition. On remand, the district court should determine whether Mutual suffered an anticompetitive harm in the form of a delay in the approval of its ANDA due to the filing of Tyco's citizen petition with the FDA. Tyco would be entitled to summary judgment if

there is no evidence that the citizen petition caused a delay in the approval of Mutual's ANDA.