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ANDA Automatic Stay of FDA Approval Does Not Defeat Standing in Sham Litigation Antitrust Counterclaim

September 20, 2011 by Don T. Hibner, Jr.

The District of Delaware recently denied a motion to dismiss an antitrust counterclaim in a patent infringement action in the wake of defendant Mylan, Inc. ("Mylan") having filed an Abbreviated New Drug Application ("ANDA") with the Federal Drug Administration ("FDA"). *Shionogi Pharma, Inc. v. Mylan, Inc.*, United States District Court, District of Delaware, Civil Action No. 10-1077, August 31, 2011. The decision raises a host of interesting and provocative issues relating to the "sham" exception for petitioning activity immunity under the *Noerr* doctrine. *See Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961) ("Noerr") and *Professional Real Estate Investors v. Columbia Pictures Industries*, 508 U.S. 49 (1993) ("PRE"). In essence, the court held that plaintiff and counter-defendant Shionogi Pharma, Inc. ("Shionogi") could not maintain that Mylan lacked standing to prosecute an antitrust counterclaim by virtue of Shionogi's filing of the underlying patent infringement action, which automatically triggered an ANDA automatic 30-month stay of FDA approval of Mylan's submission.

Shionogi is the owner and/or owner of exclusive licensing rights to U.S. Patent No. 6,740,341 BI. ("'341 patent"), entitled "Taste Masking Rapid Release Coating System." The '341 patent relates to the tablet design for masking a pharmaceutical's ill taste. Shionogi holds and is listed in the FDA "Orange Book"

as the owner of a new drug application for Orapred ODT®, an orally disintegrating tablet.

Mylan filed an ANDA with the FDA for a "prednisolone phosphate orally disintegrating tablet", which it intended to market as a therapeutic equivalent to, or generic formulation of, Shionogi's patented Orapred ODT® product. Upon receiving notice of Mylan's FDA filing for a non-infringing proposed product before the expiration of the '341 patent, Shionogi filed suit alleging '341 infringement. Mylan had attached to its certification that the proposed product has no "spacing layer", and would not infringe the '341 patent. This is because the '341 patent allegedly excludes tablets without a "spacing layer". Shionogi received samples from Mylan, which confirmed the absence of a spacing layer. In response to Shionogi's patent infringement action, Mylan filed an antitrust counterclaim alleging that the infringement action was a "sham" and constituted monopolization and attempted monopolization under Section 2 of the Sherman Act, and a combination and conspiracy in restraint of trade in violation of Section 1.

Shionogi moved to dismiss the amended antitrust counterclaim on the ground that Mylan lacked "antitrust standing". It argued that Mylan was neither a consumer or competitor in a relevant market, and therefore lacked antitrust standing, and had failed to properly allege "antitrust injury". The linchpin of Shionogi's argument was that, upon the filing of Shionogi's patent infringement complaint, the FDA was statutorily unable to grant tentative approval to Mylan's ANDA application, and therefore Mylan could not demonstrate that it was ready to enter the market. Accordingly, Shionogi argued Mylan lacked standing, and could not have suffered "antitrust injury". By this argument, one would conclude that even if Shionogi had filed a sham patent infringement action designed to misuse the adjudicatory process, Mylan would be unable to assert an antitrust counterclaim, simply because Shionogi's complaint automatically triggered an FDA stay of approval. Mylan argued that the filing of the '341 infringement action was "objectively baseless", and intended to harm Mylan as a potential

competitor in the relevant market by imposing anticompetitive barriers to entry, citing the Supreme Court's seminal decision in *PRE*. In *PRE*, the Supreme Court held that a petitioning lawsuit is "objectively baseless" if no reasonable litigant could expect a favorable outcome on the merits. The *PRE* test is whether the petitioning plaintiff has probable cause to sue. 508 U.S. at 63.

In denying Shionogi's motion to dismiss the amended antitrust counterclaim, the District Court noted first that "antitrust standing" is a "prudential, rather than constitutional" limitation on its jurisdiction. The court noted Shionogi's argument that the absence of FDA approval of Mylan's proposed product, rather than Shionogi's monopolistic behavior, impeded Mylan's entry into the market. The court observed, however, that this argument was at odds with its recent decision in *In re Metoprolol Succinate Direct Purchaser Antitrust Litigation*, Civ. A. Nos. 06-52 (GMS), 2010 WL 1485328, D. Del. April 13, 2010. There, it was held that the FDA approval process was simply one element of a factual analysis of antitrust standing. In support, it cited *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799 (D.C. Cir. 2001) and *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 994 (D.C. Cir. 1977).

> [I]ndicia of preparedness include adequate background and experience in the new field, sufficient financial capability to enter it, and the taking of actual and substantial affirmative steps toward entry. *Id.* at 807, quoting *Hecht, Id.* at 994.

The Delaware District Court held that it would suffice for Mylan to allege that although FDA approval was a regulatory prerequisite to entering the market, it could allege that it had the intent and preparedness to enter the market, by claiming that FDA approval was probable. Not discussed, but nevertheless a presence, were the allegations by Mylan that its ANDA certification clearly claimed that its proposed product had no "spacing layer", and thus would not infringe the terms of the '341 patent, which specifically excluded products formulated without such a "spacing layer". These allegations would clearly raise

the specter that Shionogi's argument was "too cute by half", and that it was on notice that Mylan's ANDA certification could not "plausibly" be infringing, or that Mylan was not poised for entry into the market. *See also Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998), for an exhaustive treatment of the interrelationship between the various aspects of the *Noerr* "sham" exception to the concept of petitioning activity immunity.

The *Shionogi* court noted that Mylan had alleged in its ANDA its intention and preparedness to enter the market, and had demonstrated that it was a potential competitor. Mylan also alleged a sufficient causal connection between the alleged violation – the patent litigation itself, and the alleged harm to the competitive process, which was artificially keeping Mylan out of the market, and thus preventing the transfer of producer rents for the benefit of augmenting consumer welfare through the lower prices of generics. The court also noted the absence of more direct victims who could file suit, and the lack of any potential of duplicative recovery.