

District of New Jersey Resets KUDCo's ANDA's Final Approval in Protonix Litigation, Notwithstanding Outstanding Defenses of Teva and Sun

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On August 13, 2010, the United States District Court for the District of New Jersey granted a motion for reconsideration and entered an order pursuant to 35 U.S.C. § 271(e)(4)(A) against KUDCo Ireland, Ltd. ("KUDCo"), a defendant generic pharmaceutical company in the consolidated Protonix[®] litigation, resetting the date of any final approval of KUDCo's Abbreviated New Drug Application ("ANDA") to a date not earlier than January 20, 2011, the date on which the plaintiffs' pediatric exclusivity period for the Protonix[®] patent ends. *Altana Pharma AG and Wyeth v. Teva Pharmaceuticals USA, Inc.*, No 04-2355, slip. op. (D.N.J. August 13, 2010). The Order was entered despite the fact that 1) other defendants in that same consolidated action still had outstanding unenforceability defenses and 2) KUDCo had already obtained final approval of its ANDA in March 2009.

Starting in May 2004, Altana Pharma AG (now known as Nycomed GmbH) and Wyeth (acquired last year by Pfizer) (collectively, "Plaintiffs") sued three generic pharmaceutical companies, Teva Pharmaceuticals USA, Inc. ("Teva"), Sun Pharmaceuticals Industries, Ltd. ("Sun"), and KUDCo, for patent infringement in the United States District Court for the District of New Jersey in response to their applications to the FDA seeking approval for generic versions of Plaintiffs' ulcer drug Protonix[®]. These cases were consolidated "for all purposes" in February 2007. Paul Hastings, along with co-counsel, represented Plaintiffs during a two-and-a-half week trial that commenced on April 5, 2010. At the time of trial, Teva, Sun, and KUDCo's ANDAs had all received final approval, and Teva and Sun had launched their generic products at risk in late-2007 and early-2008, respectively, thereby exhausting their 180-day exclusivity period.

On April 23, 2010, the jury returned a verdict in favor of Plaintiffs, finding the Protonix[®] patent to be valid, and rejecting the defendants' obviousness and obviousness-type double patenting defenses. On July 16, 2010, Judge Linares denied numerous post-verdict motions filed by Teva, Sun, and KUDCo regarding their obviousness and obviousness-type double patenting defenses, and also independently found the Protonix[®] patent to be valid. Final judgment was entered against KUDCo at that time since the company had no remaining challenges to the validity or enforceability of the Protonix[®] patent.

On July 16, 2010, Judge Linares also denied Plaintiffs' motion for relief under Section 271(e)(4)(A) seeking an order mandating that the effective dates of each of the defendants' ANDAs be set for a

date after the expiration of the Protonix[®] patent and Plaintiffs' six-month pediatric exclusivity period. Although final judgment had been entered against KUDCo, the Court denied the motion as to all three defendants based on the fact that Teva and Sun still had outstanding unenforceability defenses.

Plaintiffs sought reconsideration of the denial of Section 271(e)(4)(a) relief only as to KUDCo, for whom final judgment had been entered. Plaintiffs argued, *inter alia*, that KUDCo should not be in a better position having challenged the Protonix[®] patent and lost than that of the many generics who had chosen to respect the valid Protonix[®] patent, and who could not now enter the market until the conclusion of Plaintiffs' pediatric exclusivity period.

On August 13, 2010, Judge Linares granted Plaintiffs' motion for reconsideration of the decision with respect to KUDCo "so as to prevent manifest injustice to Plaintiffs." (*Id.* at 4.) The Court determined that since the patent was found valid, KUDCo stipulated to infringement, and KUDCo's sole counterclaim relating to unenforceability was dismissed with prejudice, Section 271(e)(4)(A) required the court to "order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." (*Id.* at 4 (citations omitted).) Furthermore, since Plaintiffs complied with 21 U.S.C. § 355a and received a period of pediatric exclusivity, the Court found that case law supported the conclusion that it was also within the Court's power to enforce the grant of the six-month pediatric exclusivity period. The Court thus ordered the effective date of the KUDCo's ANDA be set to a date not earlier than the expiration of that pediatric exclusivity period, January 20, 2011. (*Id.* at 6.)



If you have any questions concerning these developing issues, please do not hesitate to contact the following Paul Hastings lawyer:

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