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## Lord, Bissell & Brook Leads The Way For Apotex's Victory In Paxil® Appeal

Lord, Bissell & Brook LLP scored another victory for Apotex, Inc. On April 8, 2005, the Federal Circuit ruled for the second time that a patent claim covering crystalline paroxetine hydrochloride hemihydrate, the active ingredient in GlaxoSmithKline's ("GSK") highly successful antidepressant Paxil®, is invalid. The Federal Circuit's decision is the latest ruling in a long complex legal battle that began in 1998 and included a highly publicized trial in 2003. The decision allows Apotex to continue marketing its lower-cost paroxetine alternative, which it began marketing in September 2003.

GSK's U.S. Patent No. 4,721,723 ("the '723 patent") was the first in a long line of paroxetine-related patents on which GSK relied to prevent generic competition for Paxil®, which had U.S. sales of approximately \$2.2 billion in 2002. Lord, Bissell & Brook attorneys represented Apotex during a successful three-week trial regarding the '723 patent in 2003. In May 2003, Circuit Judge Richard A. Posner, sitting by designation in the United States District Court for the Northern District of Illinois, ruled that Apotex's then-proposed anhydrous paroxetine hydrochloride product would not infringe claim 1 of the '723 patent and that claim 1 would be invalid under GSK's view of the allowable coverage. A three-judge panel of the Federal Circuit affirmed the district court on April 23, 2004, but on alternate grounds. Specifically, the Federal Circuit (1) construed claim 1 of the '723 patent to cover any amount of paroxetine hydrochloride hemihydrate, even a single crystal; (2) held, based on an inference by the district court that Apotex probably had some undetectable hemihydrate in its product, that Apotex would infringe the '723 patent; but (3) held that GSK's '723 patent was invalid based on GSK's use of the hemihydrate in public U.S. clinical trials more than one year prior to the filing date of the '723 patent application.

GSK petitioned the Federal Circuit for rehearing *en banc*, arguing that only the issue of invalidity based on public use should be

reviewed and claiming that GSK was entitled to an experimental-use exception to its invalidating public use. Apotex opposed GSK's petition, but filed a conditional petition for rehearing *en banc*, arguing that the court should consider the intertwined claim construction, non-infringement, and invalidity issues.

In an interesting procedural move, the Federal Circuit issued an order on April 8, 2005 vacating the 2004 opinion, granting the petition for *en banc*, and remanding the matter to the original panel for the limited purpose of reconsidering its 2004 opinion. The original panel issued an opinion that same day.

In its revised opinion, the panel reaffirmed its construction of claim 1 of the '723 patent and, using that construction, reaffirmed its holding that Apotex's paroxetine hydrochloride anhydrous product would infringe the '723 hemihydrate patent based on an inference that Apotex's product might contain a trace amount of the hemihydrate. But the Federal Circuit also held that claim 1 of the '723 patent is invalid for inherent anticipation (*i.e.*, that the claimed hemihydrate is not a novel compound) because a person, carrying out the teachings of the prior-art paroxetine patent (filed a decade before the '723 patent), also would have inevitably obtained paroxetine hydrochloride containing at least a trace amount of the hemihydrate. Lord, Bissell & Brook attorneys on the appeal were Hugh L. Moore, Keith D. Parr, Scott B. Feder, Hugh S. Balsam, and Kevin M. Nelson.

### ABOUT THE AUTHORS

Hugh L. Moore, Keith D. Parr, Scott B. Feder and Kevin M. Nelson represent pharmaceutical industry companies in litigation, intellectual property and regulatory matters. Hugh S. Balsam is an attorney in the firm's appellate group.