IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ORTHO-McNEIL PHARMACEUTICAL, INC., *Plaintiff/Counter-Defendant,* v. APOTEX, INC., *Defendant/Counter-Plaintiff.*	Civil Action No. 07-cv-4050 Judge Rebecca R. Pallmeyer Magistrate Judge Arlander Keys

APOTEX'S MOTION TO ENTER JUDGMENT AND TO TERMINATE THE STAY OF FINAL FDA MARKETING APPROVAL

Apotex, Inc., ("Apotex") respectfully moves the Court to enter judgment in this case and to terminate the automatic stay on FDA approval of the Abbreviated New Drug Application ("ANDA") that is the subject of this litigation inasmuch as Apotex believes it is now likely to receive tentative marketing approval for its tramadol/acetaminophen generic drug product in the very near future. Once it receives this tentative approval, all that stands in the way of Apotex being able to bring its generic product to market is the statutory 30-month automatic stay of final approval afforded by 21 U.S.C. §355(j)(5)(B)(iii). However, that statute also provides that the 30-month stay may be shortened if a Court enters a judgment of invalidity. 21 U.S.C. §355(j)(5)(B)(iii)(I)(aa); 21 CFR 314.107(b)(3)(ii) "If before the expiration of the 30-month period, or 71/2 years where applicable, the court issues a final order that the patent is invalid, unenforceable, or not infringed, approval may be made effective on the date **the court enters judgment; . . .**" (emphasis added). The FDA recently applied this provision of the statute in granting Mylan final marketing approval based on this Court's judgment of invalidity in *Ortho-McNeil Pharm. v. Mylan Pharm. et al.*, Case No. 08-1343 (N.D. Ill. May 14, 2008). *See FDA Final Approval Letter* (Sept. 26, 2008) **(Exhibit A)**.

Apotex's currently pending motion for summary judgment of invalidity is based on the alternative bases of (1) collateral estoppel based on the New Jersey court's decision in *Ortho-McNeil Pharm., Inc. v. Kali Labs, Inc.*, 2008 WL 1782283 (D.N.J. April 17, 2008) (now on appeal) holding the '221 patent invalid for obviousness; and (2) an independent review of the evidence establishing that the asserted claims of the '221 patent are invalid for obviousness, and for Rule 54(b) certification. D.I. 79-81. Ortho agrees that Apotex is **entitled to judgment** based on collateral estoppel applying *Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313, 334 (1971), but disputes that Apotex was entitled to judgment of invalidity based on an independent review of the evidence. *E.g.*, *Ortho-McNeil's Memorandum In Response to Apotex's Motion for Summary Judgment*, D.I. 96 at 1 ("Ortho-McNeil has repeatedly told both Apotex and the Court that it **does not oppose judgment** on this basis.") (emphasis added), at 2 ("Ortho-McNeil therefore has **no basis to oppose entry of judgment** based on the collateral estoppel effect of that decision at this time") (emphasis added); *Ortho-McNeil Pharmaceutical, Inc.'s Surreply in Response To Apotex's Motion For Summary Judgment*, D.I. 120 at 1 ("As Ortho-McNeil has made clear repeatedly, it **does not object to entry of judgment** on that basis.") (emphasis added). Accordingly, because Apotex and Ortho both agree that Apotex is now entitled to entry of judgment in its favor on plaintiff's patent infringement claims, and because that judgment is all that stands in the way of Apotex's expected tentative marketing approval becoming final, Apotex asks the Court to enter judgment now and end the thirty month FDA marketing approval stay period. With respect to the form of judgment, if the Court has not reached a decision regarding Apotex's substantive obviousness arguments based on an independent review of the evidence, it still should enter judgment now giving collateral estoppel

effect to the New Jersey Court's invalidity holding so that Apotex can bring its generic product to market.

Apotex further requests that the judgment be made final pursuant to Fed. R. Civ. P. 54(b). Under Rule 54(b) there is no just cause for delay in entering final judgment that the claims of the '221 reissue patent are invalid and to remove any litigation impediments to the FDA's approval of Apotex's pending Abbreviated New Drug Application. As explained in Apotex's motion for summary judgment, final judgment of invalidity need not wait for an adjudication of the remaining claims, all of which either depend from or are obviated by a judgment of invalidity. *Apotex's Memorandum in Support of Motion for Summary Judgment that U.S. Patent RE 39,221 is Invalid and for Entry of Final Judgment Under Fed. R. Civ. Proc. 54(B),* D.I. 80 at 13.

Delaying FDA approval harms Apotex and the public. Apotex cannot sell its product until it receives final FDA approval. As this case is currently postured the FDA will grant only tentative approval (until entry of judgment), which does not permit Apotex to begin selling. Apotex has done everything it needs to do for approval. It cannot begin to recoup the costs and expense of that undertaking until it can sell. The public interest also weighs heavily in favor of terminating the automatic stay in this case. Getting generic drugs to market, when not barred by a valid patent, is one of the central purposes of the entire statutory scheme governing this proceeding. *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.* 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("A central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment to that Act is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'"). The public interest favors competition. The public interest favors access to medicine. Although there may also be a public interest in

favor of protecting valid patent rights, that interest is not implicated here because another Court has already held that the patent is invalid.

CONCLUSION

Wherefore, for the reasons explained above, Apotex respectfully request that the Court enter judgment in this matter and enter an order terminating the thirty-month stay on FDA approval so that the imminent tentative marketing approval Apotex expects from the FDA can be made final. Apotex further requests that the judgment be made final pursuant to Fed. R. Civ. P. 54(b), there being no just cause for delay.

Respectfully submitted,

Dated: November 21, 2008

By: /s/ Sherry L. Rollo

HUSCH BLACKWELL SANDERS WELSH & KATZ
Steven E. Feldman
Philip D. Segrest, Jr.
Sherry L. Rollo
120 South Riverside Plaza • 22nd Floor
Chicago, Illinois 60606
Phone: (312) 655-1500
Fax: (312) 655-1501

Attorneys for Apotex, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2008, a true and correct copy of the foregoing Memorandum was served upon all counsel of record by the CM/ECF system on:

David T. Pritikin
Lisa A. Schneider
Linda R. Friedlieb
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, Illinois 60603
(312) 853-7000

Jeffrey P. Kushan
David A. Steffes
SIDLEY AUSTIN LLP
1501 K Street N.W.
Washington, D.C. 20005
(202) 736-8000

Michael D. Hatcher
SIDLEY AUSTIN LLP
717 North Harwood, Suite 3400
Dallas, Texas 75201
(214) 981-3300

/s/ Sherry L. Rollo
Counsel for Defendant Apotex, Inc.