IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI INC., and ASTRAZENECA LP, *Plaintiffs*, v. DEXCEL, LTD., DEXXON, LTD., DEXCEL PHARMA TECHNOLOGIES, LTD., and DEXCEL PHARMA TECHNOLOGIES *Defendants.*	Civil Action No. 06-358 (SLR)

PLAINTIFFS' MOTION FOR LEAVE TO FILE A SUR-REPLY IN OPPOSITION TO DEFENDANTS DEXCEL'S MOTION TO TRANSFER OR DISMISS

On November 30, 2006, Defendants ("Dexcel") filed their reply brief in support of their motion to transfer or dismiss (D.I. 60). Plaintiffs ("AstraZeneca") respectfully seek leave of Court to file a sur-reply of no longer than 5 pages. The basis for this motion is that Dexcel's reply brief contains incorrect and inflammatory assertions, and relies upon authority that has been vacated on appeal. For example:

(1) Dexcel's sole basis for urging transfer to Virginia is that this dispute should be decided before the expiration of two of the three patents-in-suit in April 2007. Dexcel accuses AstraZeneca of seeking "to delay resolution of this action, including by litigating in this Court," which it says is "too busy" to bring this case to trial (and decide it) in the eleven-month time frame it wants. Dexcel says that it "is entitled to its day in Court" on the schedule it demands (D.I. 60 at 1). In fact, Dexcel dictated the timing of

this litigation. Dexcel has been selling its omeprazole product outside of the United States for about five years (Fulton Sur-Reply Decl. Exh A at 7-8). But Dexcel did not apply for FDA approval to market omeprazole in the United States until 2006.

(2) Dexcel says that the Virginia Court has "previously indicated that it could try this action as early as January 2007" (D.I. 60 at 1) and that the case should be in a Court "that can actually conduct a trial" before two of the patents expire in April 2007 (*id.* at 7). The Virginia Court has entered a stay to allow this Court to determine the proper venue (D.I. 52, Fulton Decl. Exh. 64). Moreover, that Court recently declined to vacate that stay, and indicated that it was not likely to be able to try the case any sooner than this Court would, given the need to complete discovery and the technical complexities of the case (Fulton Sur-Reply Decl. Exh. B at 8-12). Indeed, fact discovery is far from complete. Dexcel has failed to produce its documents and the parties have yet to take a single merits deposition. Expert discovery has not begun. Moreover, it is not the trial – but the entry of judgment – that would lift the 30-month stay. Dexcel does not suggest that any Court would be in a position to enter judgment four months from now, particularly given what remains to be done in the case.

(3) Dexcel rented an office in Virginia for the sole purpose of trying to force this litigation to Virginia, where it has no operations. Yet Dexcel labels any action by AstraZeneca – which is located in Delaware – that is inconsistent with Dexcel's plan as "manipulat[ing] the courts," "an extreme miscarriage of justice," "abusive procedural tactics" and an "abuse of process" (D.I. 60 at 1, 6, 7).

(4) Dexcel argues in support of its "delay" and "abuse of process" allegations that plaintiffs "likely still would not have filed a brief" but for Dexcel's

emergency email to the Court (D.I. 60 at 8), even though a briefing schedule already had been agreed upon before then, as recited in the email itself.

(5) Although Dexcel argues that it is critical that this case be tried by April, it provides no reason to believe that the FDA will approve its New Drug Application ("NDA") before October 2007. Dexcel filed its application as an NDA rather than as an Abbreviated New Drug Application ("ANDA"). The FDA will not approve an NDA until it has made a thorough evaluation of the safety and efficacy of the new drug being proposed. Thus, even if Dexcel were cleared of infringement in an early trial, it provides no reason to expect that it could be on the market before October 2007. In fact, as set forth in an exhibit to its reply brief, Dexcel's distributor has announced that it expects to begin shipping Dexcel's product "no sooner than 2008" (D.I. 61, Mehta Decl., Ex. 1).

(6) Dexcel recognizes the unique jurisdictional aspects of the Hatch-Waxman Act, but draws the wrong conclusions from them (D.I. 60 at 10-11). The courts in *Abbott Labs. v. Mylan Pharm., Inc.*, 2006 WL 850916 (N.D. Ill. 2006), and *Purdue Pharma L.P. v. Impax Labs., Inc.*, 2003 WL 22070549 (S.D.N.Y. 2003), exercised jurisdiction on facts analogous to those here. Dexcel's attempts to distinguish these cases are unavailing.

(7) Even as it accuses AstraZeneca of "an apparent attempt to mislead this court" with respect to personal jurisdiction (D.I. 60 at 12), Dexcel relies upon authority that has been vacated. Dexcel cites *Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics Corp.*, 293 F. Supp. 2d 423 (D. Del. 2003) (D.I. 60 at 11), to support its position that there is no basis for general jurisdiction, but ignores that the Federal Circuit vacated that decision and remanded for further proceedings, based upon the determination that the stream of commerce theory applied to 10 *Del. C.* §3104(c)(4). *Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics Corp.*, 395 F.3d 1315 (Fed. Cir. 2005). Under the circumstances, AstraZeneca requests the opportunity to discuss the relevant law on personal jurisdiction that applies here.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Leslie A. Polizoti

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
Leslie A. Polizoti (#4299)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Plaintiffs

OF COUNSEL:
Errol B. Taylor
Robert J. Koch
Jay I. Alexander
Enrique D. Longton
MILBANK, TWEED, HADLEY & McCLOY LLP
1850 K Street NW
Washington, DC 20006
(202) 835-7500

Dated: December 4, 2006

CERTIFICATE PURSUANT TO LOCAL RULE 7.1.1

I hereby certify, pursuant to D. Del. LR 7.1.1, that the foregoing motion has been discussed with counsel for Dexcel and that the parties have not been able to reach agreement thereon.

/s/ *Leslie A. Polizoti* (#4299)
Leslie A. Polizoti

CERTIFICATE OF SERVICE

I hereby certify that on December 4, 2006, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to Richard D. Kirk.

I further certify that I caused to be served copies of the foregoing document on December 4, 2006 upon the following in the manner indicated:

BY HAND & E-MAIL

Richard D. Kirk (rkirk@bayardfirm.com)
Ashley B. Stitzer (astitzer@bayardfirm.com)
The Bayard Firm
222 Delaware Avenue
Suite 900
Wilmington, DE 19899

BY E-MAIL

Robert F. Green (rgreen@leydig.com)
David M. Airan (dairan@leydig.com)
Saumil S. Mehta (smehta@leydig.com)
Leydig, Voit & May
Two Prudential Plaza
180 N. Stetson Avenue, Suite 4900
Chicago, IL 60601

/s/ Leslie A. Polizoti
Leslie A. Polizoti (#4299)
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Wilmington, DE 19801
(302) 658-9200
lpolizoti@mnat.com