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)

DECLARATION OF ALLISON FULTON IN SUPPORT OF PLAINTIFFS' MOTION FOR LEAVE TO FILE A SUR-REPLY IN OPPOSITION TO MOTION TO DISMISS OR TRANSFER

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I, Allison Fulton, declare as follows:

1. I am one of the attorneys for plaintiffs AstraZeneca AB, Aktiebolaget Hässle, KBI-E Inc., KBI Inc., AstraZeneca LP (collectively, "AstraZeneca"). I am a member in good standing of the bars of New York and Virginia and am competent to testify to the matters set forth herein, which are based on my personal knowledge. I submit this Declaration in support of Plaintiffs' Motion for Leave to File a Sur-reply in Opposition to Motion to Dismiss or Transfer.

2. Attached as Exhibit A are excerpts from a true and correct copy of Exhibit 6 of Defendants' Opposition to Plaintiffs' Motion for Stay dated August 29, 2006.

3. Attached as Exhibit B are excerpts from a true and correct copy of an official transcript from the oral hearing on Defendants' Motion to Vacate Stay dated November 3, 2006.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 4th day of December, 2006 at Washington, DC.

Allison Fulton

Allison Fulton

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:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

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.	Case No. 1:06cv634 (CMH/BRP)
DEXCEL PHARMA TECHNOLOGIES LTD., Counterclaim-Plaintiff, v. ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE,and ASTRAZENECA LP, Counterclaim-Defendants.	

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR STAY OR TRANSFER

Plaintiffs' misnamed Motion For Stay or Transfer is actually a motion for reconsideration of the Court's August 10, 2006 Order, the entry of which Defendants requested and Plaintiffs opposed. *See* Docket Items 11-12, 16 and 17. Plaintiffs' current motion offers no new argument, facts, or change in the law that would necessitate reconsideration of the Court's issuance of a Scheduling Order. Their request for reconsideration, couched as a request for a "stay" of the proceedings, should be denied on procedural grounds alone.

As to the substance of their request, Plaintiffs themselves caused the duplication about which they now complain. They chose to file identical lawsuits in two different forums, and they

III. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court deny Plaintiffs' motion for transfer or stay of this action.

Date: August 29, 2006

DEXCEL, LTD.,
DEXXON, LTD.,
DEXCEL PHARMA TECHNOLOGIES LTD,
and DEXCEL PHARMA TECHNOLOGIES

By: _____
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Exhibit 6

BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE OMEPRAZOLE PATENT LITIGATION	)	MDL Docket No. 1291

REPLY IN SUPPORT OF MOTION TO VACATE CONDITIONAL TRANSFER ORDER (CTO-8)

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Dated: August 22, 2006

underlying venues without resort to the 28 U.S.C. § 1407; (2) there is no factual overlap between the underlying actions and MDL-1291; and (3) a transfer would not serve the interest of justice.

The AstraZeneca parties do not dispute the first point. Rather, they concede, as they must, that they initiated two identical lawsuits in different venues. The Panel should not consolidate the actions under § 1407 simply because Plaintiffs initiated duplicative litigation. As to the latter two factors, the AstraZeneca parties attempt to sow confusion where none exists. The dispute between the AstraZeneca and Dexcel parties has no facts in common with the actions previously tried in MDL-1291. As to the interest of justice factor, the AstraZeneca parties willfully misrepresented the relevant facts in order to distinguish the Panel's precedent.

A. Transfer of This Action Will Not Serve the Interest of Justice

The Panel's precedent establishes that a transfer should promote the just and efficient conduct of the litigation. *See In re Cable Tie Patent Litigation*, 487 F.Supp. 1351 (J.P.M.L. 1980). Incredibly, the AstraZeneca parties argue that the Dexcel parties will not be prejudiced in any way by a transfer and consolidation with MDL-1291. *See* Response at 15-18. They are wrong. A transfer to the Southern District of New York will immediately and irreparably injure the Dexcel parties because this procedure will effectively deny the Dexcel parties their right to a trial on the merits as to two of the three asserted patents expiring in April 2007.

1. The AstraZeneca Parties Are Attempting to Obtain Through Delay That Which They Cannot Obtain on the Merits

The AstraZeneca parties own several foreign counterpart patents to the '505 and '230 U.S. patents. *See* Exs. 18 and 19 (a schedule of all counterpart patents to the '505 and '230 patents, respectively). They also acknowledge that the Dexcel parties "have been selling generic omeprazole outside of the United States for some time." *See* Ex. 16 at 12-13. The AstraZeneca parties have been well aware of the Dexcel parties' product for nearly five years from its

inspections of Dexcel's similar, non-infringing product in Israel and the UK. Tellingly, the AstraZeneca parties have not pursued their charge of patent infringement against the Dexcel parties outside of the United States.

The reason for this is clear. The product that Dexcel Pharma Technologies Ltd. ("DPT Ltd.") seeks to introduce into the United States does not infringe the foreign counterpart patents, whose claims are highly similar in all material aspects to those of the asserted U.S. patents. The product that DPT Ltd. seeks to introduce to the U.S. market also does not infringe the U.S. patents.

Rather than simply conceding this issue, the AstraZeneca parties hope to use the MDL proceeding and the crowded U.S. court dockets as procedural obstacles to delay a trial on the merits until after the '505 and '230 patents expire in April 2007. If the '505 and '230 patents expire prior to a trial, the AstraZeneca parties will obtain, by default, an additional six-month exclusivity period. The reason for this relates to the AstraZeneca parties' claim of "pediatric exclusivity." During the term of a patent and for a potential six-month period thereafter, the Food and Drug Administration will not approve a generic drug manufacturer's application to make and sell a drug prior to the expiration of an automatic 30-month period or a judgment in the generic manufacturer's favor, whichever occurs first. *See* 21 U.S.C. § 355 and 35 U.S.C. § 271(e). In the event that a patent expires during litigation without a judgment, however, the district courts (under current case law) lose subject matter jurisdiction over the dispute. The additional six-month "pediatric exclusivity" period recognized by the FDA, therefore, effectively cannot be challenged. *Ranbaxy Labs. v. U.S. Food and Drug Administration*, 307 F.Supp.2d 15, 21 (D.D.C. 2004).

Dated: August 22, 2006

Respectfully submitted,

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EXHIBIT B

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

ASTRAZENECA AB, et al., Plaintiffs, -vs- DEXCEL, LTD., et al., Defendants.	Case No. 1:06-cv-634

HEARING ON MOTIONS

November 3, 2006

Before: Claude M. Hilton, Judge

APPEARANCES:

Robert J. Koch, Counsel for the Plaintiffs

Robert F. Green, Counsel for the Defendants

the meantime, there is an $800,000,000 product at stake here.

THE COURT: Well, I can understand all that, but I am not so sure that the Courts ought to have two suits going at the same time just to get around the Waxman legislation.

MR. GREEN: Your Honor, this was a very similar situation in the Aventis versus Lupin case where there was a suit here in the Eastern District of Virginia and there was a suit filed in Maryland. And the judge in that case said it was your choice, plaintiffs, to file the two suits. Indeed, it was their choice, they filed two suits. We didn't. And the judge ruled in the Aventis case that you are here, you filed the suit in Virginia--

THE COURT: Well, I am sure, I have done that myself before, but I don't know whether I am inclined to do it here or not.

MR. GREEN: Well, Your Honor, to be quite frank, they don't have an infringement case. And we have no opportunity to prove it in Delaware as to the two basic patents here because the Delaware Court, as they know, has a backlog. They have a backlog such that the earliest date, and we certainly asked for an earlier date when we went in front of the judge for a scheduling order, is November of 2007.

THE COURT: Well, by the time, if I lift the stay, you are not going to do a whole lot better than that here. I mean, you are talking about a very minor period of time.

MR. GREEN: Well, Your Honor, your original order would have allowed for a trial in this case before April of 2007.

We submit that from a discovery standpoint, they have what they need on those two patents. They have the samples. They have the NDA. They have people that can perform testing that have done it in two separate MDL waves in New York. And if they haven't done it by now, I certainly have no explanation.

But presumably they had a basis to file this suit in the first place. But under the rules in Delaware, with the judge that we have, we can't even file a summary judgment motion. She won't allow it.

Here, if you lift the stay, Your Honor, we are going to file a summary judgment motion. We are going to file it immediately because we don't believe they have any proof whatsoever that those two patents are infringed.

THE COURT: Well, of course, we couldn't have a summary judgment motion heard until after discovery was over.

MR. GREEN: Well, Your Honor, with respect to discovery on those two patents, we don't have anything else. We have given them the NDA, which defines the product.

THE COURT: Well, I know you are telling me that, but if I did open up this case, there would be depositions and there would be interrogatories, there would be a whole lot of

things. And we would take quite a period of time before I could ever get this case in front of me in a posture that I could rule on a summary judgment motion.

I am just not sure, I understand what you want is speed, but I don't think it's all that practical to think that we are going to have that much speed in the case.

He says there is one deposition-- Or has the last deposition been taken?

MR. GREEN: They have not taken the last deposition, which is of a third party.

THE COURT: When is that being taken?

MR. GREEN: It is currently scheduled for November 7. They have then agreed, I believe, within two weeks after that to file their brief in opposition to our motion filed in July to dismiss that action. And at some point thereafter the judge will rule, presumably, then on the issue of jurisdiction.

But in the meantime, Your Honor, discovery to the extent that we need it, we haven't obtained.

And again, this is a tactic to keep two patents which are not infringed at bay from going in front of a Court until it's too late for a Court to do anything.

And I again submit that filing an action required some evidence of infringement. If they had it, they should have given it to us. And we don't have it.

So, the strategy is working, Your Honor. The strategy is delay. And as long as they delay, they win because our client can't go to market, the public can't buy the product, the FDA can't approve it, and there is an $800,000,000 revenue stream falling to the plaintiffs.

THE COURT: Well, if it's what you say it is, your motion to dismiss will be granted over in Maryland and there won't be any problem.

MR. GREEN: Well, Your Honor, we do expect that to happen. But in the meantime, since this action is stayed and there is no scheduling order, and we are not getting meaningful discovery from the plaintiffs, the concern is how do we get this case back on track unless you lift the stay and at a minimum set a trial date.

And if they feel that we didn't provide discovery, they can tell you that we didn't provide discovery. But we have cooperated. When they moved--

THE COURT: Well, you know, I just can't start grabbing cases and doing that with them. I mean, there has got to be some orderly process to proceed. I can't just look to somebody over here and say, stand up here at the podium and tell me something.

This is a patent case. By the time we get around to doing something on a summary judgment, you are going to have a whole lot of technical information in front of me. And, you

know, I just simply can't do that.

MR. GREEN: And I appreciate the concern.

THE COURT: I just can't do it. I just don't think at this point in time, the situation we are here in, I have entered a stay to see about this Maryland litigation.

MR. GREEN: Delaware.

THE COURT: You tell me now it is about the time that we are going to get a ruling on it, and I think I am going to have to leave this stay in effect until at least the first of the year. That should be ample time to have a motion to dismiss filed and ruled on.

So, I will deny your motion at this time, but you can file it again if nothing is done by the first of year because there ought to be time to do it by then.

MR. GREEN: All right. Thank you, Judge.

THE COURT: All right. Thank you. And we will adjourn until Monday morning at 9:30.

HEARING CONCLUDED

I certify that the foregoing is a true and accurate transcription of my stenographic notes.

Norman B. Linnell, RPR, CM, VCE