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ELECTRONICALLY FILED

February 1, 2007

The Honorable Sue L. Robinson
United States District Court
844 King Street
Wilmington, DE 19801

**Re: AstraZeneca, et al. v. Dexcel, LTD, et al. C.A. No. 06-358 (SLR)**

Dear Chief Judge Robinson:

We write in response to Plaintiffs' letter (of January 31, 2007) proposing an agenda for today's hearing and to provide Defendants' own proposed agenda. We note that Plaintiffs did not consult Defendants before submitting their proposed agenda to the Court.

Contrary to what Plaintiffs state in their letter, Dexcel is in compliance with the Court's Order. On January 19, 2007, Defendants produced more than a thousand pages of documents relating to its various R&D programs, and also produced a list of the types of tests conducted during those programs. Plaintiffs' letter was written following a teleconference between the parties' Counsel yesterday afternoon, during which Defendants assured Plaintiffs that they would provide them, in the coming days, with additional documentation relating to research and development and analytical testing of product sold outside the US. This additional production is made following both the letter and spirit of the Court's directive and Plaintiff's request following the January 19 production, despite Defendants' continuing position that such documentation is not relevant to this case.

Plaintiff's misrepresentations in their letter and earlier during the last hearing on January 12, 2007 (see Item A below) are an attempt to deflect attention away from Plaintiffs' continuing failure to produce responsive documents to Defendants. Counsel for the parties conferred on discovery issues on January 25 and 31, 2007. Defendants initiated these conferences because Plaintiffs have failed to produce, using a plethora of excuses, virtually *any* relevant documentation and *no* samples. Defendants request the opportunity to address the Court at the outset of today's hearing, which will allow Defendants to have its complaints addressed in a meaningful manner, and, further, to put Plaintiffs' discovery complaints in context.

Defendants have been frustrated from the very *outset* of these proceedings by Plaintiffs' seeming ability to delay proceedings and forestall generic competition from the marketplace. Defendants remain hopeful of achieving a final court decision in this case by April 2007.

## Defendants' Proposed Agenda

### A. Correction of Misrepresentations During the January 12, 2007 Hearing

At the last hearing, Plaintiffs' Counsel made several factual assertions regarding the development of the accused product. Many of these assertions, upon which the Court relied in addressing Plaintiffs' discovery complaints, are false and potentially misleading. Defendants seek an opportunity to correct the record, to explain to the Court the true state of affairs and to have the related discovery issues amended accordingly.

### B. Plaintiffs' Failure to Produce Requested Documents

Defendants have diligently attempted to comply with all of Plaintiffs' requests and already have produced more than 30,000 pages of documents (with more to follow in the next few days as indicated above). In contrast, Plaintiffs have failed to produce almost *any* requested documents and *no* samples. Indeed, Plaintiffs' entire production to date is fewer than 4,000 pages.

Plaintiffs have failed to produce, inter alia, certain New Drug Applications ("NDAs") and Drug Master Files ("DMFs"). These types of documents are highly relevant to disputed issues in this litigation and are routinely produced in Hatch-Waxman litigation. Indeed, Plaintiffs admitted to producing at least portions of its NDAs in prior omeprazole litigation.

At the January 25 and 31 conferences, Counsel for Plaintiffs suggested that they had not yet produced such documents in this litigation because they did not know where the files were located. This excuse is simply not credible. It is not possible that AstraZeneca does not know where to locate a copy of its own NDAs. Plaintiffs' Counsel also refused to produce the requested NDAs and DMFs on the basis of relevance, which objections should be overruled.

### C. Plaintiffs' Failure to Produce Requested Samples

Plaintiffs also have failed to provide samples of (1) the product claimed in the '380 patent ("Form A"); (2) the product differentiated from the claimed product ("Form B"); and (3) any omeprazole products sold prior to the "critical date" of the '380 patent. Plaintiffs only excuse for their failure to produce the requested samples is that they are still "searching" for them. This excuse is also not credible. They should be compelled to produce such samples without further delay.

**D. AAIPharma Documents**

For more than three months, Defendants have sought documents exchanged between Plaintiffs and AAIPharma. Plaintiffs objected to these requests on the basis of third party confidentiality agreements. Despite numerous unequivocal representations that they were not withholding any documents on this basis, including at the last hearing, Plaintiffs' Counsel informed Defendants on January 30, 2007 that they had, in fact, withheld AAIPharma documents due to a confidentiality agreement. This stunning reversal came only days after Defendants served subpoenas on AAIPharma seeking the same information. Plaintiffs should be compelled to immediately produce all withheld documents.

**E. Merck Documents**

On behalf of Plaintiffs, Merck marketed and/or manufactured omeprazole for years before the "critical date" of one of the patents in suit. Merck unquestionably possesses material information to this lawsuit. Plaintiffs have produced agreements that obligate Merck to cooperate in producing documents in this litigation. Completely ignoring the Court's instruction of January 12, 2007, Plaintiffs have not provided Defendants with such information or formal correspondence relating thereto. Plaintiffs should be compelled to obtain from Merck all documents that Plaintiffs could obtain under its various agreements.

**Defendants' Response to Plaintiffs' Suggested Agenda**

**1. Dexcel's Compliance with the Court's Order**

On January 19, 2007, in compliance with the Court's order issued only one week earlier, Defendants produced more than a thousand pages of documents relating to its various R&D programs. On this same day, Defendants also produced the requested "list," which reflects the types of tests conducted during the R&D program.

At the January 25, 2007 conference, Plaintiffs' Counsel specifically requested classes of additional documents. In response to these requests, on January 31, 2007, Defendants produced to their Counsel additional documents. These documents, although considered not relevant by Defendants, will be produced to Plaintiffs on an expedited and rolling basis.

**2. Plaintiffs' Additional Discovery Issues**

As noted above, Defendants are in the process of producing additional documents, which process they expect to complete by early to mid next week. The scope of any remaining disputes between the parties is not presently known. Indeed, the parties have arranged for a follow-up discovery conference on February 6, 2007.

**3. Defendants' Discovery Issues**

This topic is addressed above.

**4. Participation in the Case by Cipla**

Counsel for Defendants have informed Counsel for Plaintiffs that Cipla has agreed in principle to be represented by current Counsel in this action. Cipla and prospective Counsel expect to finalize the terms of engagement in the coming days.

**5. Entry of a Protective Order**

Counsel for the parties have engaged in numerous discussions of this issue. The Court resolved one issue at the January 12, 2007 hearing. Defendants object to the number of proposed "insiders" as well as Merck's participation under the Protective Order because Merck holds several "Orange Book" patents that it may, at some point, choose to assert against the Defendants. Defendants cannot agree that Merck's inside counsel be allowed access to Defendants' confidential information.

**6. Location of Depositions**

Plaintiffs have not previously raised this proposed agenda item. Consequently, Defendants do not know what, if any, dispute exists. We therefore respectfully propose that this item be tabled until Counsel have an opportunity to confer with each other and with their respective clients.

Respectfully submitted,

Richard D. Kirk /ABS

Richard D. Kirk (#0922)

RDK:ABS
cc: Clerk of the Court
All counsel as shown on attached certificate

**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that, on February 1, 2007, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that, on February 1, 2007, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

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