IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Declaration of Exhibits by Saumil S. Mehta

I, Saumil S. Mehta, declare under the penalty of perjury that the following is true and correct:

1. I am an attorney with the law firm of Leydig, Voit & Mayer, Ltd. who is representing Dexcel Ltd., Dexxon Ltd., and Dexcel Pharma Technologies Ltd. (collectively "Defendants") in the above-captioned action.

2. This declaration is submitted in support of "DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO LIFT THE STAY ON FDA APPROVAL OF DEXCEL PHARMA TECHNOLOGIES, LTD.'S OMEPRAZOLE DELAYED-RELEASE TABLETS."

3. Attached to this Declaration are what I believe to be true and correct copies of the following documents:

Exh.No.	Description
1	*Prilosec P & G's Alone Until at Least 2008*, Cincinnati Business Courier, July 10, 2006
2	FDA approvable letter dated December 8, 2006
3	Letter From J. Frangella to R. Koch dated May 26, 2006
4	Letter from R. Green to R. Koch dated May 24, 2006
5	Letter from D. Airan to R. Koch dated August 3, 2006

Exh.No.	Description
6	Letter from C. Borg-Breen to R. Koch dated November 9, 2006
7	Letter from R. Koch to R. Green dated May 4, 2006
8	Letter from R. Koch to R. Green dated May 26, 2006
9	Letter from S. Mehta to R. Koch dated November 6, 2006
10	Letter from R. Koch to D. Airan dated November 9, 2006
11	Letter from R. Koch to R. Green dated January 29, 2007
12	Letter from D. Airan to R. Koch dated February 15, 2007
13	Letter from C. Borg-Breen to R. Koch dated March 6, 2007
14	Letter from R. Koch to D. Airan dated March 9, 2007
15	Letter from R. Koch to D. Airan dated March 15, 2007
16	Letter from C. Borg-Breen to R. Koch dated March 16, 2007
17	Hearing Transcript excerpts from December 6, 2006
18	Hearing Transcript excerpts from March 12, 2007
19	Letter from C. Borg-Breen to R. Koch dated March 15, 2007
20	Hearing Transcript excerpts from February 1, 2007
21	Letter from R. Koch to D. Airan dated March 15, 2007
22	Letter from R. Green to R. Koch dated January 26, 2007
23	Letter from J. Blumenfeld to Judge Robinson dated February 9, 2007
24	Letter from C. Borg-Breen to R. Koch dated March 13, 2007
25	Letter from R. Koch to C. Borg-Breen dated March 15, 2007
26	Email request for emergency relief
27	Letter from C. Borg-Breen to R. Koch dated March 20, 2007
28	Letter from R. Koch to R. Green dated March 23, 2007
29	Letter from C. Borg-Breen to R. Koch dated March 26, 2007
30	Letter from R. Green to R. Koch dated March 22, 2007
31	Letter from R. Koch to R. Green dated March 23, 2007
32	Physicians Desk Reference (1996) – entry for Prilosec®
33	Subpoena of Merck & Co., Inc. served January 26, 2007
34	Subpoena of Merck & Co., Inc. served February 21, 2007
35	Merck & Co., Inc.'s Objections to Subpoena
36	Letter from C. Borg-Breen to R. Koch dated February 23, 2007
37	Letter from R. Koch to D. Airan dated March 23, 2007
38	Letter from D. Airan to R. Koch dated December 21, 2006
39	Letter from R. Green to R. Koch dated January 8, 2007
40	Letter from R. Koch to R. Green dated January 11, 2007
41	Hearing Transcript excerpts from January 12, 2007
42	Subpoena of AAIpharma, LLC served January 25, 2007
43	Subpoena of AAIpharma, Inc. served January 25, 2007

Exh.No.	Description
44	Letter from R. Koch to R. Green dated January 30, 2007
45	Declaration of Caryn Borg-Breen dated March 29, 2007
46	Letter from J. Gumina to R. Green dated February 14, 2007
47	Letter from C. Borg-Breen to J. Gumina dated February 22, 2007
48	Letter from R. Green to J. Gumina dated March 19, 2007
49	Letter from J. Gumina to R. Green dated March 21, 2007
50	Declaration of Saumil S. Mehta dated March 29, 2007
51	*Glaxo, Inc. v. Torpharm, Inc.*, 1996 WL 288524, *2 (N.D. Ill. May 30, 1996)
52	In re Nifedipine Capsule Patent Litigation, 1989 WL 11111, *2 (S.D.N.Y September 20, 1989)
53	Letter from R. Koch to D. Airan dated March 22, 2007
54	*Dey L.P. v. Eon Labs., Inc.*, 2005 WL 3578120 (C.D. Cal. Dec. 22, 2005)

4. I hereby declare that all statements made herein of my own knowledge are true, that all statements of opinion or those made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18 of the United States Code.

DATE: March 29, 2007

Saumil S. Mehta

EXHIBIT 1

Cincinnati Business Courier - July 10, 2006
http://cincinnati.bizjournals.com/cincinnati/stories/2006/07/10/daily6.html

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Prilosec P&G's alone until at least 2008

Cincinnati Business Courier - July 10, 2006

A U.S. District Court decision has postponed private-label distribution of **Procter & Gamble Co.**'s over-the-counter heartburn drug, Prilosec OTC.

According to Ad Age magazine, a court-ordered stay will prevent manufacturer **Perrigo Co.** from rolling out store-brand versions of the drug. Cincinnati-based Procter (NYSE:PG) now will likely get until mid- to late 2008 to exclusively market Prilosec. This extends the period two years past the cutoff date initially set by the Food and Drug Administration

P&G has a licensing agreement with AstraZeneca Plc to sell Prilosec without a prescription. In May, AstraZeneca filed a patent-infringement lawsuit in U.S. District Court in Delaware and Eastern Virginia against Perrigo's partner, **Dexcel Pharma Technologies**, an Israeli company that has developed a generic version of Prilosec. The court in June issued a 30-month stay blocking Dexcel or Perrigo (NYSE: PRGO) from marketing their private-label version, according to Ad Age.

A representative from Perrigo told Ad Age that the company expects to begin shipping a private-label version no sooner than 2008.

Prilosec OTC has U.S. retail sales of more than $800 million.

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EXHIBIT 2

ATTORNEY CONFIDENTIAL PURSUANT TO COURT ORDER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-032

Dexcel Pharma Technologies Limited
Attention: John D. Franolic, Ph.D.
Manager, Lachman Consultant Services, Inc
US Agent
1600 Stewart Ave
Westbury, NY 11590

Dear Dr. Franolic:

Please refer to your new drug application (NDA) dated February 8, 2006, received February 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for omeprazole 20 mg delayed-release tablets.

We acknowledge receipt of your 2006 submissions dated March 7 and 23, June 20, July 21, August 25 (2), September 1 (2), October 23, and November 7, 15, 17, and 30.

We have completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to address the following:

1. During a recent inspection of one MDS Pharma Services Bioequivalence facility for this application, our field investigator issued a 483 Notice of Findings to the facility's representative. Satisfactory resolution of these deficiencies is required before this application may be approved.

2. During a recent inspection of one of the manufacturing facilities for this application, our field investigator verbally conveyed issues to the facility's representative requiring revision to specifications and analytical procedures. Our review of these revisions is required before this application may be approved.

In addition, it will be necessary for you to submit draft labeling revised as follows:

1. Add a phone number under the heading **"Questions?"** in *Drug Facts*, according to 21 CFR 201.66 (c)(9) - or remove **"Questions?"** from the *Drug Facts* section.

2. Delete the statement "Compare to the active ingredient in Prilosec OTC" from the label. FDA does not consider omeprazole base to be identical to omeprazole magnesium used in Prilosec OTC™. Additionally, your product is not a generic version of Prilosec OTC™, therefore, you cannot reference the Prilosec OTC™ name on the label of your product.

3. Delete the statement, "If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional," in the package insert, under the paragraph

heading "For Questions or Comments About Omeprazole Delayed Release Tablets 20 OTC." Questions about the product should be referred to the manufacturer, not to a health care professional. However, the FDA has no objections to the statement if it is placed in the package insert under an appropriate heading. In addition, remove "OTC" from the official trade name in all parts of the labeling.

4. Provide draft labeling including the carton label with *Drug Facts*, package insert, and blister card for all package sizes (SKUs).

These draft labels should include the agreed upon labeling revisions submitted in your November 30, 2006 submission.

New drug interaction warnings have been added to the prescription omeprazole products and are being considered for labeling of the omeprazole-containing nonprescription products. Any labeling changes to the OTC omeprazole products will affect the labeling for your product.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

When you respond to the above deficiencies, include a summary of worldwide experience, including all adverse events, on the safety of your formulation currently marketed outside the United States. Include an updated estimate of use for your drug marketed in other countries.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with the Division of Nonprescription Clinical Evaluation and the Division of Gastrointestinal Products to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center of Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center of Drug Evaluation and Research

ATTORNEY CONFIDENTIAL PURSUANT TO COURT ORDER

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
12/8/2006 03:22:30 PM

Andrea Segal
12/8/2006 03:26:16 PM

EXHIBIT 3

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May 26, 2006

Via Federal Express

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: Omeprazole Delayed Release Tablets, 20 mg; NDA No. 22-032

Dear Mr. Koch:

Enclosed please find a CD containing images of NDA 22-032 being provided pursuant to the letter agreement dated May 24, 2006. The entire content of this CD is designated as confidential information.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Jennifer J. Frangella

Jennifer J. Frangella
Litigation Paralegal

/jf
Enclosure

cc: Katarina Ageborg (with enclosure)

EXHIBIT 4

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May 24, 2006

Via Facsimile and Email Confirmation by Federal Express

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: Omeprazole Delayed Release Tablets, 20 mg; NDA No. 22-032

Dear Bob:

We understand that you are outside counsel for AstraZeneca AB. As you know, we are outside counsel for Dexcel Pharma Technologies Ltd. ("DPT"), on whose behalf we sent the April 17, 2006 Notice of Certification relating to NDA No. 22-032 (hereinafter referred to as the "DPT NDA"). That letter related specifically to U.S. Patent Nos. 6,150,380 ("the '380 patent"), 6,428,810 ("the '810 patent"), 5,690,960 ("the '960 patent"), 5,900,424 ("the '424 patent"), 6,403,616 ("the '616 patent"), 5,753,265 ("the '265 patent"), and 5,817,338 ("the '338 patent).

In your letter dated May 4, 2006, you requested certain documents and samples related to the DPT NDA. In response, DPT is willing to provide copies of NDA No. 22-032, as well as certain samples of finished tablets, omeprazole API and ingredients used in the manufacture of the tablets ("Confidential Information"). Also, DPT is willing to provide certain documents related to the March, 1997 sale of omeprazole by Cipla to Andrx.

AstraZeneca AB will limit access to the Confidential Information to the following:

(1) Milbank, Tweed, Hadley & McCloy LLP ("Milbank"), outside counsel for AstraZeneca;

(2) Marcus Heifetz, Senior Litigation Counsel for AstraZeneca Pharmaceuticals, LP;

(3) Katarina Ageborg, Assistant General Counsel for AstraZeneca AB;

(4) Kurt Lövgren, Ph.D., AstraZeneca AB employee: Scientific Advisor;

(5) David Noreland, Ph.D., AstraZeneca AB employee: Senior Scientist.

AstraZeneca AB and Milbank will keep the Confidential Information confidential and restrict its use to the terms in this agreement.

Each permitted recipient of the Confidential Information disclosed by DPT will receive a copy of this letter agreement and agree to be bound by its terms. DPT will mark the disclosed materials to indicate they are subject to this agreement.

Additionally, none of the DPT Confidential Information, nor any information derived through testing or otherwise, will be used for any purpose other than reaching a determination whether to institute an infringement action against DPT based upon one or more of the patents included in DPT's notice letter as identified in the first paragraph of this letter. Furthermore, if no such infringement action is filed by June 15, 2006, all Confidential Information is to be returned by that date and any information, including but not limited to testing, studies or analyses derived from the Confidential Information shall be destroyed by said date.

This agreement does not operate to restrict the use of any information that AstraZeneca AB may receive in discovery in the course of any future litigation between the parties. The restrictions of this agreement shall not apply to any information or materials that were (a) in the public domain before being disclosed by DPT to AstraZeneca AB, (b) in the public domain subsequent to its disclosure by DPT through no act, or failure to act, of AstraZeneca AB; (c) received from a third party not bound by confidentiality towards DPT, or (d) in AstraZeneca AB's legal possession before its disclosure by DPT.

If these terms are acceptable, please sign this letter where indicated and return it to me.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

By: _____
Robert F. Green

RFG/krs

ACCEPTED AND AGREED

_____
for AstraZeneca AB and
Milbank, Tweed, Hadley & McCloy LLP

EXHIBIT 5

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August 3, 2006

Via Federal Express

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al.
Civil Action No. 06-358 (SLR) (D. Del.)

Dear Bob:

We have enclosed nine boxes (identified as DPT009737-9745) of the 20 mg omeprazole tablets manufactured according to NDA 22-032. Each box contains fourteen tablets.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

David M. Airan

Enclosure

EXHIBIT 6

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ROBERT F. GREEN
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BRETT A. HESTERBERG
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ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
*RESIDENT IN WASHINGTON OFFICE ***RESIDENT IN SEATTLE OFFICE
**RESIDENT IN ROCKFORD OFFICE

November 9, 2006

Via Email
Confirmation by First Class Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: *AstraZeneca AB et al. v. Dexcel Ltd. et al.*
Civil Action No. 06-358 (SLR)

Dear Bob:

We write in partial response to your letter received today. For sake of clarification, we sent to you nine boxes of 20 mg omeprazole tablets manufactured according to NDA 22-032 on August 3, 2006. Those samples were produced without any restriction with respect to use or access whatsoever. In addition, we sent to you a CD containing images of NDA 22-032 on May 26, 2006, which material was designated as confidential information pursuant to your letter of May 26, 2006 forwarding the countersigned letter of May 24, 2006, which indicated that such confidential material could be accessed by two in-house counsel of AstraZeneca, as well as two AstraZeneca scientists.

We will respond further to your proposed protective order in due course.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn Borg-Breen

Caryn Borg-Breen, Ph.D.

cc: Errol B. Taylor, Esq.
Jay I. Alexander, Esq.

EXHIBIT 7

MILBANK, TWEED, HADLEY & McCLOY LLP

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ROBERT J. KOCH
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May 4, 2006

BY FACSIMILE & FIRST CLASS MAIL
(312)-616-5700

Robert F. Green
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

Re: Omeprazole Delayed Release Tablets, 20 mg; NDA No. 22-032

Dear Mr. Green:

I am outside counsel for AstraZeneca AB ("AstraZeneca"). AstraZeneca received Dexcel Pharma Technologies Ltd.'s ("Dexcel") April 17, 2006 Notice of Certification relating to NDA No. 22-032 (hereinafter referred to as the "Dexcel Notice Letter").

Dexcel's offer of access to confidential information appears to be limited to Dexcel's NDA No. 22-032. We request the following documents and samples (hereinafter referred to as the "Dexcel Product Information") by May 9, 2006 to further investigate Dexcel's Notice Letter:

(1) NDA No. 22-032, including all correspondence with the FDA relating to Dexcel's NDA product;

(2) The DMFs for the product, as well as the active ingredient of the product described in NDA No. 22-032;

(3) Specification sheets for each material in Dexcel's NDA products;

(4) All results or data, in electronic form, from any testing, studies or analysis of the structure, identity or solid-state properties of the omeprazole used in Dexcel's

NDA product and of Dexcel's omeprazole formulation, including, but not limited to, any testing, study, or analysis of: 1) the crystallinity, crystalline form or crystal structure; 2) chemical purity; and 3) any testing, study, or analysis using or relying on FT-IR, Raman Spectroscopy and x-ray powder diffraction (XRPD) and the like.

(5) 240 tablets (8 plastic bottles containing 30 tablets each) of Dexcel's NDA product and any package inserts or instructions to be included with the product when sold;

(6) 50 grams (10 samples, 5 grams each) of Dexcel's product at each stage of production, including the bulk omeprazole;

(7) 50 grams (10 samples, 5 grams each) of each of the ingredients used to make Dexcel's NDA product, packaged consistent with the way Dexcel maintains these ingredients.

(8) The "evidence related to a sale and shipment of omeprazole" in March 1997 referred to on page 5 of the Dexcel Notice Letter.

(9) The "evidence that the omeprazole sold in March 1997 was form A omeprazole" referred to on page 5 of the Dexcel Notice Letter.

(10) All results or data, in electronic form, from any testing, studies or analysis of the structure, identity or solid-state properties of the omeprazole referred to on page 5 of the Dexcel Notice Letter which was allegedly shipped and sold by its API supplier in March of 1997, including, but not limited to, any testing, study, or analysis of: 1) the crystallinity, crystalline form or crystal structure; 2) chemical purity; and 3) any testing, study, or analysis using or relying on FT-IR, Raman Spectroscopy and x-ray powder diffraction (XRPD) and the like.

(11) 50 grams (10 samples, 5 grams each) of the omeprazole allegedly shipped and sold by its API supplier in March 1997 and referred to on page 5 of the Dexcel Notice Letter.

AstraZeneca seeks to provide access to the Dexcel Product Information to employees of AstraZeneca and The Procter & Gamble Company (hereinafter "P&G") so that they may perform evaluation and testing. AstraZeneca and P&G will limit access to Dexcel Product Information to the following persons:

(1) Milbank, Tweed, Hadley & McCloy LLP, outside counsel for AstraZeneca;

(2) Marcus Heifetz, Senior Litigation Counsel for AstraZeneca Pharmaceuticals LP;

(3) Katarina Ageborg, Assistant General Counsel for AstraZeneca;

(4) Kurt Lövgren, Ph.D., AstraZeneca employee: Scientific Advisor;

(5) David Noreland, Ph.D., AstraZeneca employee: Senior Scientist;

(6) Karen Clark, Associate General Counsel for P&G

(7) Patrick Lane, Associate General Counsel for P&G

(8) Kelly McDow Dunham, Senior Counsel for P&G

(9) Richard Dansereau, Ph.D., Research Fellow for P&G

(10) Linda Jones, Ph.D., Senior Scientist for P&G

(11) Gary Thompson, Ph.D., Research Fellow for P&G

AstraZeneca and P&G also seek to use the Dexcel Product Information, including testing of the bulk material and evaluation of the Dexcel NDA and DMFs, for assessment of infringement of AstraZeneca patents and/or other patents. This agreement does not operate to restrict the use of any information that AstraZeneca and P&G may receive in discovery in the course of any future litigation between the parties. The restrictions of this agreement shall not apply to any information or materials that were (a) in the public domain before being disclosed by Dexcel to AstraZeneca and P&G; (b) in the public domain subsequent to its disclosure by Dexcel through no act, or failure to act, of AstraZeneca or P&G; or (c) received from a third party not bound by confidentiality towards Dexcel or (d) in AstraZeneca's or P&G's legal possession before its disclosure by Dexcel.

Each permitted recipient of the Dexcel Product Information disclosed by Dexcel will receive a copy of this letter agreement and agree to be bound by its terms. Dexcel will mark the disclosed materials to indicate they are subject to this agreement.

AstraZeneca and P&G will keep the Dexcel Product Information confidential and restrict its use to the terms in this agreement, with the exception that copies or samples of the Dexcel Product Information will not be returned to Dexcel Counsel should AstraZeneca or P&G decide to initiate a patent infringement suit relating to Dexcel's NDA products.

If these terms are acceptable, please sign this letter where indicated and return it to me. Our agreement to accept the Dexcel Product Information is not a concession that the Dexcel Product Information is sufficient to address the accuracy of the statements in Dexcel's Notice Letter. AstraZeneca requests that the documents and half the requested samples be shipped to me at the address below and that half the samples be shipped to Katarina Ageborg at the address below:

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street, N.W.
Suite 1100
Washington, DC 20006

Katarina Ageborg, Esq.
AstraZeneca AB
R&D Mölndal
SE-431 83 Mölndal
Sweden

We look forward to receiving the requested materials on or before May 9, 2006. If Dexcel is unable to provide all of the Dexcel Product Information, AstraZeneca requests that Dexcel send whatever portion of the requested Dexcel Product Information that it is able to send by that date. Please contact me in advance of mailing, so that I can assure that the materials are appropriately handled upon receipt.

Very truly yours,



Robert J. Koch

ACCEPTED AND AGREED

_____

for Dexcel Pharma Technologies Ltd.

EXHIBIT 8

ミルバンク・ツィード・ハドリ & マックロイ外国法事務弁護士事務所
MILBANK, TWEED, HADLEY & McCLOY LLP

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May 26, 2006

By Facsimile and Email
Confirmation by Federal Express

Robert F. Green, Esq.
Leydig, Voit & Mayer, Ltd.
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Chicago, Illinois 60601-6780
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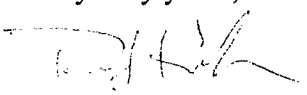
Re: Omeprazole Delayed Release Tablets, 20mg; NDA No. 22-032

Dear Bob,

Thank you for your letter of 24 May 2006, setting forth your limited offer of information for our review. We have countersigned it, enclosed it herewith and ask that you provide the information to us as soon as possible.

We believe the information requested in our letter of 4 May 2006, would enable us to properly evaluate whether or not to institute litigation. We appreciate the fact that you needed to take up our requests with your client. However, we are most disappointed that you did not provide us, during the 20 days of your deliberation, at least the DPT NDA and tablet-samples you originally offered to us. Once we receive the DPT NDA, finished tablets, omeprazole API and ingredients used in the manufacture of the tablets, we will promptly begin our evaluation of the information. We look forward to receiving the promised information and samples.

Very truly yours,



Robert J. Koch

Enc.: Countersigned 24 May 2006 letter

EXHIBIT 9

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**RESIDENT IN ROCKFORD OFFICE

November 6, 2006

Via Email
Confirmation by First Class Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: *AstraZeneca AB et al. v. Dexcel Ltd. et al.*
Civil Action No. 06-358 (SLR)

Dear Bob:

We write to address outstanding discovery matters in the above-captioned case. First, we are still awaiting your instructions to arrange transfer of the requested API and excipients. As indicated by our email of October 24, 2006 (attached hereto), we have been prepared to convey these materials to you for some time now, but have received no response to our message. Please inform us of and make ready immediately your arrangements to transfer the requested materials so as to proceed with discovery.

Second, Plaintiffs responses to Defendants' First Set of Interrogatories Relating to the Merits, state that it will produce all documents responsive to the interrogatories. Plaintiffs answered the interrogatories on September 7, 2006 and to date have failed to produce any responsive documents. Accordingly, we expect Plaintiffs' immediate production of documents responsive to DPT Ltd.'s interrogatories on the merits.

We find any further delay in addressing the above-mentioned issues to be intentional and calculated to hinder the progress of this action.

As previously discussed with members of your firm, please produce any electronic documents as single-page TIFF images along with a ".dat" file and an ".opt" or ".log" file. Please contact us with any questions to this regard.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Saumil S. Mehta

SSM/knr

cc: Errol B. Taylor, Esq.
Jay I. Alexander, Esq.

Borg-Breen, Caryn

From: Mehta, Saumil
Sent: Tuesday, October 24, 2006 1:24 PM
To: Koch, Robert
Cc: Airan, David; Green, Robert; Borg-Breen, Caryn; Mehta, Saumil; Taylor, Errol; Alexander, Jay I.
Subject: RE: Dexcel's Discovery Responses

Dear Bob,

As a preliminary reply to your letter regarding Dexcel's discovery responses, we are prepared to provide you with samples of Dexcel's bulk omeprazole (Request No. 29), and requested excipients (Request No. 31). We received these samples directly from Dexcel, as verified by accompanying documentation, and have securely stored the samples under the appropriate conditions. Please indicate how you would like to arrange transfer of the requested API and excipient samples.

Best Regards,

Saumil

Saumil Mehta
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From: Koch, Robert [mailto:RKoch@milbank.com]
Sent: Tuesday, October 24, 2006 10:42 AM
To: Airan, David; Green, Robert; Mehta, Saumil
Cc: Taylor, Errol; Alexander, Jay I.
Subject: Dexcel's Discovery Responses

Gentlemen,
I am attaching a letter addressing certain inadequacies in Dexcel's responses and objections to Astra's discovery requests. Please let us know if you foresee problems with our requested response period in the last line of the letter.

Regards,
Bob

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<<2006-10-24 Inadequate Dexcel Responses.PDF>>

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EXHIBIT 10

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ROBERT J. KOCH
PARTNER
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November 9, 2006

VIA ELECTRONIC MAIL

David M. Airan
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

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

Dear David:

This letter is to follow up on our previous correspondence, to which we have received no response, and to respond to Saumil Mehta's November 6, 2006 letter.

Our October 24, 2006 letter noted in detail various items for which Dexcel has produced inadequate information, and requested production of additional information by November 8. To date, we have received no response to our letter and no additional documents or information. As you know, the Delaware court's scheduling order requires the parties to complete document production by December 15, 2006 in order to allow discovery to efficiently proceed thereafter. In order to expedite matters, we would like to propose a telephonic discovery conference with you on November 10, 2006 at 11:00 A.M. EST. Please let us know if you will be available at that time.

In addition, on November 1, 2006, Jay Alexander forwarded to you a proposed form of stipulated protective order regarding confidential information. We have yet to receive your response. As you know, the Local Rules provide that, in the absence of a protective order, confidential information may be shown only to outside counsel. Experts and client representatives may have access to the other party's confidential information only under the terms of an order entered by the Court. Please let us have your comments on our proposed order

so that we may determine whether the parties can submit an agreed order to the Court, or at least narrow the scope of any disputes.

Finally, in response to Mr. Mehta's November 6 letter: We are in the process of reviewing documents collected from our client and expect to begin production on a rolling basis of the documents relevant to AstraZeneca's response to Dexcel's interrogatories.

Our response to your offer to produce samples of bulk omeprazole and other excipients depends, however, on clarification of your position regarding infringement of the '380 patent. As you know, testing of this material is complex and expensive. To date, however, Dexcel has not stated whether it contends that its NDA product does not infringe claims 1-4 of the '380 patent, the issue to which such testing would be directed. We note the absence of any statement regarding infringement of these claims in Dexcel's Paragraph IV Certification as well as Dexcel's refusal to take a position in response to AstraZeneca's Interrogatory No. 2 on the Merits. That response alleges that Dexcel lacks "sufficient information" to respond because AstraZeneca has not provided a claim construction. This position is completely opposite what Dexcel argued to the Court during implementation of the Scheduling Order. In those discussions, Dexcel urged that no claim construction issues existed with respect to any of the patents-in-suit. Dexcel clearly must have had a claim construction in mind when it made that representation to the Court and thus is able to take a position on infringement. The absence of discussion of the issue in Dexcel's Paragraph IV Certification suggests that Dexcel does not challenge infringement. If that were the case, testing of the bulk API may be unnecessary. Before AstraZeneca can make this determination, however, we must know with more clarity what Dexcel's infringement position actually is. Please respond.

Very truly yours,



Robert J. Koch

cc: Robert F. Green, Esq.
Saumil S. Mehta, Esq.
Richard D. Kirk, Esq.
Errol B. Taylor, Esq.
Jack B. Blumenfeld, Esq.

MILBANK, TWEED, HADLEY & McCLOY LLP

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January 29, 2007

VIA ELECTRONIC MAIL

Robert F. Green, Esq.
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

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

Dear Bob:

We have reviewed Dexcel's recent document productions in light of Dexcel's responses to Plaintiffs' document requests and the parties' subsequent communications on these issues. We note that Dexcel's production and its responses are still deficient in a number of respects as discussed below and do not comply with the Court Order to "either provide a list, a 30(b)(6) witness or actual documents that relate to the research and development surrounding the reformulated commercial product being sold outside the United States."

As an initial matter, we note that we have not had the courtesy of a response to my letter of January 25, which pointed out that we have not been able to locate the list of testing you stated had been included in Dexcel's most recent production.

You have also failed to inform us whether you will be representing Cipla in this action even though you promised to do this long ago and the Court advised you to do so immediately.

Also, we continue to await your formal response to our proposed stipulated protective order, which we sent to you on December 12. Your failure to address these issues for so long is unacceptable and has hindered our ability to move forward in this lawsuit.

The following list details the deficiencies we continue to observe in Dexcel's discovery responses:

1. Development of Dexcel's Tablet Formulation (Requests Nos. 57, 92-94): Dexcel still has not provided full discovery regarding the development of its omeprazole tablet formulation even though the Court has ordered it to do so. We received Dexcel's most recent document production on January 22. While that production contains many documents in Hebrew that will be translated, there appear to be very few documents that date back to the 1999-2000 time period and no documents that appear to date back any earlier. Moreover, the documents appear to be limited to routine test results. While these types of test results from this time period are responsive, the full scope of these requests seek all materials relating to the Dexcel formulations at issue, including the products described or claimed in Dexcel's patent application[1] as well as in any related applications. Inasmuch as the research and development project that led to this patent application apparently represented a departure from Dexcel's previous capsule formulation, it is difficult to conceive why Dexcel continues to withhold production of all of the documents relating to this project. We again request production of all of the documents sought in our document requests.

2. Documents Relating to Omeprazole Patents/Applications (Request No. 59): Dexcel has also not produced any omeprazole patents, patent applications or all the documents referring or relating thereto as requested, even though it is clear that Dexcel has such patents or applications. We request that Dexcel produce all documents relating to the WO 2000/78284 application, including drafts, correspondence, invention disclosures, inventor files and prosecution histories, as well as similar documents for any other patent or patent application that discloses a similar omeprazole formulation, including the Israeli priority application.

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on-sale activity by Cipla.

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11. Chain of Custody/Certification Regarding Produced Tablets (Request No. 32): Although Dexcel has produced sample tablets, it has not produced the requested certifications as to chain of custody and storage conditions. Please provide those certifications immediately. If Dexcel is unable to provide certifications for the previously produced samples, please produce additional samples with the requested certifications.

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We look forward to your response to the points raised above and we intend to address these issues at our meet and confer on January 31.

Very truly yours,



Robert J. Koch

cc: Edgar H. Haug, Esq.
David M. Airan, Esq.
Richard D. Kirk, Esq.
Jack B. Blumenfeld, Esq.

EXHIBIT 11

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January 29, 2007

VIA ELECTRONIC MAIL

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Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

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

Dear Bob:

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Very truly yours,



Robert J. Koch

cc: Edgar H. Haug, Esq.
David M. Airan, Esq.
Richard D. Kirk, Esq.
Jack B. Blumenfeld, Esq.

EXHIBIT 12

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ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
*RESIDENT IN WASHINGTON OFFICE ***RESIDENT IN SEATTLE OFFICE
**RESIDENT IN ROCKFORD OFFICE

February 15, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

This will confirm our conversation from yesterday and address a few additional issues.

First, as noted yesterday, we agree to accept Plaintiffs' discovery requests directed to Cipla and to try to expedite such discovery. Please note that this willingness to work with Plaintiffs on discovery is not, and should not be construed as, a waiver of any objections or defenses by Cipla to the lawsuit, including any Rule 12(b) defenses relating to the Amended Complaint.

Also, we accept your proposal and vendor (Quick Int'l) for handling samples. We will contact the Quick representative you noted yesterday to arrange pick up and delivery of the API and excipient samples. The samples of bulk omeprazole will be picked up directly from Cipla in India. Please let us know where you would like Plaintiffs' samples to be delivered.

As to the Protective Order, you indicated that Plaintiffs would not object to those individuals Defendants identified in Paragraph 4(c) if Defendants would agree to the individuals Plaintiffs identified in Paragraph 4(b), except for the Merck employees, whom we understand to be William Krovatin and Paul Matukaitis. We both agreed to let Chief Judge Robinson decide

the issue as it relates to Merck employees. In the interests of advancing our discussions on the Protective Order, we will agree with your proposal on paragraphs 4(b) and 4(c).

We note, however, that Cipla is not yet a party to the litigation and has not accepted this Protective Order. In particular, we understand that Cipla does not want its DMFs and related manufacturing information to be accessed by any in-house Dexcel, Astra or Merck personnel. We therefore propose that this category of Cipla documents be available only to those persons authorized under paragraphs 4(a) and 4(d)-(h). Please let us know if you agree with this proposal.

Finally, please let us know what dates you may be available during the week of March 5, 2007 for a status conference with the Court. During our call yesterday, you indicated that you were free on March 1 and 2, but we are running into scheduling problems on our side on those days.

Thanks for your continuing cooperation.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

David M. Airan /ccb

David M. Airan

DMA/CCB

EXHIBIT 13

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JASON A. MILLER
ELIZABETH A. LITZINGER

ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
*RESIDENT IN WASHINGTON OFFICE ***RESIDENT IN SEATTLE OFFICE
**RESIDENT IN ROCKFORD OFFICE

March 6, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

You have not responded to our letter of February 15, 2007 asking you to identify the delivery location for your requested samples. If we do not hear from you by the close of business today, we will instruct our client to ship the samples to Milbank for your attention. Information concerning the environmental conditions under which the samples should be maintained upon arrival in your offices will be sent to you under separate cover prior to the delivery of the samples.

Please arrange to deliver Defendants' requested samples to our offices no later than Friday, March 9, 2007. Prior to the delivery of the samples, please provide us with information concerning the environmental conditions under which the samples should be maintained.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn C. Borg-Breen

EXHIBIT 14

MILBANK, TWEED, HADLEY & McCLOY LLP

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FAX: 44-207-448-3029

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FRANKFURT
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ROBERT J. KOCH
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March 9, 2007

VIA ELECTRONIC MAIL

David A. Airan, Esq.
Leydig, Voit & Mayer Ltd.
Two Prudential Plaza
180 N. Stetson Ave.
Chicago, IL 60601

RE: *AstraZeneca AB, et. Al v. Dexcel, Ltd. et. al*, C.A. No. 06-358 (SLR)
Deficiencies in Dexcel's Discovery Responses

Dear David:

We were disappointed not to have been able to meet and confer with you today on a number of issues in an effort to narrow or eliminate the parties' disputes before the conference with the Court scheduled for March 12. We would still like to meet with you prior to the conference and believe that your suggestion for an in-person conference prior to the hearing with the Court is a good one. Accordingly, we are happy to host a meeting with you at 12:00 noon on Monday, March 12 at Morris, Nichols' offices located at 1201 North Market Street.

At that meeting, we intend to raise the following items with you:

1. Extension of the Discovery Schedule

It is apparent that the close of fact discovery should be extended in this case. Although the Court's Scheduling Order had set a deadline of December 15, 2006 for completion of document production, and although AstraZeneca as early as October 2006 identified to Dexcel its critical need for discovery as to the development of Dexcel's omeprazole tablet formulation in the mid to late 1990s, we did not receive *any* documents related to that development until early February. Then, we received approximately

100,000 pages of documents, many in Hebrew. This has seriously prejudiced our ability to complete discovery as to the '505 and '230 patents within the time set by the Court.

In addition, once it became apparent that Dexcel could not, or would not, make complete discovery as to the production of bulk omeprazole to be used in Dexcel's NDA formulation, AstraZeneca amended its complaint—as of right—in January to add Cipla as a defendant. AstraZeneca also served the complaint on Cipla's U.S. agent, Byron Chemical. Cipla's answer was due on February 23, 2007, but Cipla has yet to respond. AstraZeneca also served initial discovery to Cipla on February 23, 2007. Cipla's responses are due Monday, March 26, only one week before the April 2 deadline for the close of fact discovery.

In addition, the parties have only just in the past week come to an agreement on the protective order, which awaits entry by the Court. Until that Order is entered, AstraZeneca will not be able to consult with its technical resources both inside and outside the company.

Given all of this, we will seek to have the Court amend the Scheduling Order to extend the discovery period by a reasonable amount of time. We seek your agreement as to a suitable set of new deadlines.

2. Dexcel's Response to AstraZeneca's Interrogatory No. 1

Dexcel has not stated, either in its initial response or supplemental response to Interrogatory No. 1, which claims of the '380 patent are allegedly are invalid. Nor has Dexcel shown how the alleged prior art omeprazole meets each limitation of any claim. Further, the identification of documents in response to Interrogatory No. 1 does not comply with the Federal Rules and is not sufficiently specific with respect to particular sales alleged to meet 35 U.S.C. §102(b). We wish to discuss these deficiencies with you.

3. Production of the Agreements between Dexcel and Cipla

Dexcel continues to refuse to produce its agreements with Cipla relating to omeprazole and specifically relating to bulk omeprazole used in Dexcel's NDA 22-032. Those agreements likely contain, at a minimum, provisions directed to the parties' cooperation in the event of litigation.

4. Reclassification of Confidential Documents

Once the Protective Order is entered, the parties will have to clarify which documents are to receive which level of confidential protection before they can be shared with qualified in-house technical experts. Toward that end, we ask that you identify which documents, by production numbers, that Dexcel contends should be designated as

"Confidential- Attorneys' Eyes Only" pursuant to 4(b)(1) of the agreed Protective Order. AstraZeneca will do the same.

Documents not so designated will be assumed to be designated as "Confidential" and may be shared with the persons listed in 4(b)(2) of the Protective Order.

5. Cipla's Answer to the Amended Complaint and Response to Discovery

We served Cipla's U.S. agent with the amended complaint on January 24, 2007. Although you have now indicated that you will represent Cipla in this action, you have not stated whether Cipla will contest this manner of service or whether, alternatively, you are authorized to accept service of the amended complaint on Cipla's behalf.

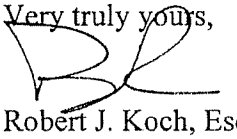
In addition, you have previously indicated that you would accept service of discovery on Cipla's behalf and we have served discovery to Cipla on your office. Please confirm that Cipla intends to answer discovery fully and completely on or before the end of the 30-day response period on March 26, 2007.

6. Sample Handling

Ms. Borg-Breen's March 6, 2007 letter indicated that you intend to ship the samples that AstraZeneca has requested to my attention. Before doing so, however, we need to receive your instructions as to how such samples must be handled to preserve their integrity in order to be able to ensure that we have the proper equipment and facilities to do so. If you ship samples to us before we are able to ensure their proper storage, a risk may exist as to their integrity and thus the validity of any tests that are performed on such samples. We therefore ask that you provide storage instructions and conditions in advance of any shipment.

We look forward to our meeting. In addition, if you are able to provide us with a list of the items you would like to raise we would appreciate it.

Very truly yours,



Robert J. Koch, Esq.

cc: Robert F. Green, Esq.
Richard D. Kirk, Esq.

EXHIBIT 15

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March 15, 2007

VIA ELECTRONIC MAIL
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Leydig, Voit & Mayer Ltd.
Two Prudential Plaza
180 N. Stetson Ave.
Chicago, IL 60601

RE: ***AstraZeneca AB, et al. v. Dexcel, Ltd. et al.*, C.A. No. 06-358 (SLR)**

Dear David:

Further to our letter of March 9, 2007, we provide below storage conditions for the omeprazole samples we will be shipping to you. Once you have made appropriate arrangements for receiving the samples, please provide us with the shipping address and name of a contact person to whom you would like us to ship the samples.

The omeprazole samples we will produce should be stored in closed, light-resistant containers under dry conditions at a temperature between 2° C and 8° C. The samples should be stored away from heaters, flame, sparks and sunlight. Due to the age of the samples, we are unable to confirm or verify that the samples have been maintained under these conditions from the date of manufacture up to the date of production. Consequently, we are unable to confirm or verify that the samples are representative of any omeprazole sold or offered for sale in the United States or abroad.

With respect to your letter of March 13, 2007 detailing the various storage conditions for the chemicals you will produce to us, we are working to confirm whether we can store these samples in our offices or will need to send them elsewhere in light of the various conditions applicable to the different samples. We will let you know where to send the materials shortly.

Very truly yours,

Robert J. Koch, Esq.

cc: Robert F. Green, Esq.
Richard D. Kirk, Esq.

EXHIBIT 16

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**RESIDENT IN ROCKFORD OFFICE

March 16, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

Further to our discussion moments ago, the shipment from Israel contains only excipients and tablets. As you know from our letter dated March 13, 2007, you can store all of these samples "in well-closed containers at a temperature between 15°C [59°F] and 25°C [84°F] in a dry, well-ventilated location." The only exception is lactose monohydrate (storage at less than 23°C/73°F), which can be stored in a refrigerator. Your office is a suitable environment for these conditions as there are no special safety concerns. As noted during our call, we recommend keeping the samples in the original shipping containers until you are ready for your testing or expert analysis.

Please let us know promptly if you will not accept the samples from Israel. We also urgently need to know your preferred location for delivery of the API. We do not want to get into the same situation with the API as with this shipment.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.



Caryn C. Borg-Breen

EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ASTRAZENECA AB, AKTIEBOLAGET HASSLE, KBI-E, INC., KBI INC., and ASTRAZENECA LP, Plaintiffs vs. DEXCEL, LTD., DEXXON, LTD., DEXCEL PHARMA TECHNOLOGIES LTD., and DEXCEL PHARMA TECHNOLOGIES, Defendants	:	CIVIL ACTION NO. 06-358 (SLR)

- - -

Wilmington, Delaware
Wednesday, December 6, 2006
4:30 o'clock, p.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

- - -

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: JACK B. BLUMENFELD, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

Because the claims of the '380 patent, with respect to the process of making it, have been contended to be noninfringed by Dexcel, but because the Claims 1 through 4 haven't been contended, we wanted to know Dexcel's contentions with respect to that. They've refused to give us those because we have not provided our assertions as to infringement of those claims.

What we want to have is all the written discovery with respect to how the product is made, how bulk Omeprazole the made. We want to have all of the testing information that Dexcel has. And in that regard, we believe there's probably a fairly large amount of that, because Dexcel has had this product on the market for four or five years in Europe, in Israel.

In Israel, there was a first litigation, Astra against Dexcel, and there was an injunction issued. Dexcel made some changes to the product and then the litigation was pursued, but it ended up Dexcel is selling product there. Dexcel indicates that the product they're intending to sell in the United States is the same as the product, is virtually the same as the product they are selling in Israel.

So we want to see what testing they've done anywhere in the world to that product, what changes they've made to that product, what research and development they've done to that product, which is alleged to be the

product that will be sold in the United States, what -- if they have done a design-around, if they've done any bio-equivalency studies to determine what we need to give to our experts to provide our own testing to determine whether they, indeed, infringe Claims 1 through 4 or not or 5 and 6 for that matter.

So basically our requests are pretty standard requests: For all the testing you've done on your product, all of the drug master file, which would be a normal thing that would be produced in a Hatch-Waxman case, the research and development. And we need to find out what the product is from written discovery before we start our depositions and before we start our expert discovery, and all we have received so far is our documents that were filed with the Food & Drug Administration for the NDA, and documents pertinent to that.

Our first meet and confer was -- we were asking for any amendments, any correspondence with the FDA and any amendments and things like that. I believe they've started producing that sort of thing to us, but so far we don't have any indication in their answers or in their actions that would indicate that we're getting any of the other information, such as testing and the drug master file.

THE COURT: All right. Thank you very much.

And Request 33 and 34, again, we've asked them

for all documents relating to isomeric forms of Omeprazole sold or offered for sale in the United States prior to the critical date of the '380 patent. AstraZeneca and its scientists have written papers on this topic, isomeric forms. They know exactly what we're talking about, but they are basically saying these are undefined terms, so we're not going to give you any documents there.

We think they know what they're talking about and they ought to give us documents responsive to those requests.

So those are our issues, your Honor.

THE COURT: All right.

MR. AIRAN: Thank you.

THE COURT: Thank you.

MR. KOCH: Well, I have a very simple response to all of those. This is the first time I've heard of any of those problems. We did not discuss those during our meet and confer. The meet and confer was strictly at our request and I don't remember any of them being raised by Dexcel.

I don't think we have a problem with them. We are in -- our rolling production is giving them a lot of documents and the other issues we can discuss with them, but that hasn't been raised before, so this is the first time

EXHIBIT 18

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ASTRAZENECA AB, AKTIEBOLAGET HASSLE, KBI-E, INC., KBI INC., and ASTRAZENECA LP,

Plaintiffs

vs.

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

Defendants

: CIVIL ACTION

: NO. 06-358 (SLR)

- - -

Wilmington, Delaware
Monday, March 12, 2007
2:03 o'clock, p.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

- - -

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: KAREN JACOBS LOUDEN, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

APPEARANCES (Continued):

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BY: ROBERT J. KOCH, ESQ.
JAY J. ALEXANDER, ESQ. and
JACK GREEN, ESQ.
(Washington, D.C.)

Counsel for Plaintiffs

THE BAYARD FIRM
BY: RICHARD D. KIRK, ESQ.

-and-

LEYDIG, VOIT & MAYER
BY: ROBERT F. GREEN, ESQ. and
DAVID M. AIRAN, ESQ.
(Chicago, Illinois)

-and-

FROMMER, LAWRENCE & HAUG
BY: MICHAEL F. BROCKMEYER, ESQ. and
(Washington, D.C.)

-and-

FROMMER, LAWRENCE & HAUG
BY: DILLON KIM, ESQ.
(New York, New York)

Counsel for Defendants

- - -

PROCEEDINGS

(Proceedings commenced in the courtroom, beginning at 2:03 p.m.)

THE COURT: Good afternoon, everyone.

I will let you fill me in on what topics we need to discuss this afternoon.

MR. KOCH: Well, I'm pleased to say we had a meet and confer before we came here this morning and I think we have it down to a number, a couple of issues I think on each side.

THE COURT: All right.

MR. KOCH: Since the last time we were here, there has been a substantial production of documents from Dexcel to us, over 100,000 pages of documents, which we are going through. A lot of them are in Hebrew, so we've had to have a lot of translations done, so we are not exactly sure we've digested all of them yet, but we're getting there.

Our main issue today is Cipla. Number one, we don't know whether Cipla is going to be a party or not.

Counsel informed us that they believed that the service we did on Cipla's U.S. agent, they consider it to be

ineffective. However, counsel said they intend to respond to discovery and have suggested that we treat that -- treat it like a response to a subpoena, and that -- while I'm not saying it's impossible, it does note -- we wanted to know whether they're going to be a party or not and how we handle them, because we want them to respond to discovery as if they were or as a party, because we're quite certain that we will have a lot of discovery we need.

We've got discovery issues out there, but the -- discovery requests out there, but nothing has been produced yet. It's due on the 26th and I understand counsel is going to be producing. Whether it will be everything we've asked for, I don't know yet.

So we would like to know, number one, whether -- I mean, we have learned that the Leydig firm is representing Cipla. We've learned that Cipla intends to respond to some discovery, and what we don't -- and we've learned that Cipla considers our service of process to be ineffective.

So if we have to do letters rogatory and have a -- and have them served directly in India, our research has led us to, has informed us that it takes six to twelve months to do that. So obviously, that's a terrible delay.

So that's our number one issue.

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The second issue we have is the current close of fact discovery we believe cannot be met and that should be moved. Exactly how much it should be moved is dependent upon the Cipla issue, our first issue. However, let me make an assumption, and that if Cipla is willing to accept service and be a party and respond to discovery in full as a party, then what we would propose is extending a couple of the deadlines that are pretty much internal deadlines, not important deadlines from the Court's scheduling perspective, because there's some flexibility in the schedule.

Namely, the -- what we would like to suggest is the close of fact discovery to be end of May, May 31, and then the opening of expert reports June 15th, rebuttal reports July 15th, and the close of expert discovery August 30th, which is just at the end of the month of August, where it's currently set for the beginning of August. And we don't have to make any changes to the Markman schedule or the trial schedule but I don't think we can complete the fact discovery primarily because of the Cipla issue.

Now, those are our two issues. As I understand, Dexcel has two issues and I will just address them so I can have all four put down.

Dexcel indicates that they are unhappy with the subpoena to Merck. I mean, I should say the response to the subpoena to Merck. We have -- there have not been any

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documents or response to discovery yet other than our objections to the breadth of the subpoena. We offered today to provide summary information directly on the issue that Dexcel has indicated they need information from Merck, and that is the issues having to do with 103 sale, on sale or invalidity issues with respect to the sale of -- with respect to the '380 patent.

We will provide that summary information. Dexcel has said that they don't want to accept that and that's basically as far as we've gotten on the -- on the -- on our offer to compromise. We have not heard anything from Dexcel as to what they want specifically instead of that.

And the fourth issue is a similar one with respect to AAI, the subpoena on AAI, the response to the subpoena on AAI. Namely, we have produced the documents that we said we would produce in response to the AAI subpoena. We had thought that issue was over with because it wasn't raised at the last discovery conference. It was raised at the one before the last, where -- in which we agreed to produce any documents that had to do with the technical -- the technology, the testing that was done from a technical standpoint so that they could determine, again, the invalidity issues. And we've done all of that, so I don't know what further information Dexcel wants.

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And I believe those are the only four outstanding issues. We've resolved the issue of the NDA EMF, I think, and so our issues are basically Cipla and timing.

THE COURT: All right. Thank you very much.

MR. GREEN: Good afternoon, your Honor.

THE COURT: Good afternoon.

MR. GREEN: Again, we appreciate taking time out of your busy schedule to accommodate us.

Let me dispose of Cipla I think reasonably quickly. I think this is a red herring.

Before Cipla was brought into this case, the reason why Cipla was even mentioned was because Cipla makes the drug product, the actual active Omeprazole that's used by Dexcel to make the tablets. And after Cipla was brought into this case by the plaintiffs, the alleged reason was so they could have access to the drug master file.

The drug master file is the document that identifies exactly how the Omeprazole is manufactured that is then sold to Dexcel for use in making the tablets. This issue relates solely to the '380 patent. This is a patent on the polymorph.

As we have said multiple times, the drug master file will be produced. Indeed, I actually met with Cipla personnel a few weeks ago in India, encouraged them to produce that document to us as soon as possible. It's my

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understanding that it's actually being received in our offices today. We expect to turn that document over later this week. And, again, that was the reason why Cipla was allegedly brought into this case.

We did receive document requests. I think it totals about 80. Obviously, we're going to have issues with that.

Whether Cipla is a party or not I think is beside the point at the moment, your Honor. Cipla has agreed to produce a drug master file and we've indicated that reasonable discovery requests will result in the production of documents.

To the extent that Cipla is in this case as an inducer of infringement, that is a secondary issue. There's no issue of inducement unless there's a finding that there's actually infringement here. I think we suggested before that those issues should simply be bifurcated because they are secondary to the issues of actual infringement.

Now, what is happening here, and this comes out with this proposal for an extension of discovery, is exactly what the plaintiffs want.

The main issue in this case focuses on the subcoating patents. The subcoating patents expire on April 20th. There is little need to be concerned about discovery going into May and June from a pure infringement standpoint

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agree on what's relevant discovery that needs to be completed yet, and we tried to discuss that and I think Dexcel is willing to give us what we want and we're willing to take what we have and we're willing to do the depositions and so on, but we can't see any particularly hopeful process that would get us to early expert reports or anything of that nature.

We think the -- again, perhaps if we had received the documents in December like we originally expected to, we would be here in a better position today, but we're both still going through them. We've got to finish the translations.

We would like to prepare for depositions. We know we want to take at least two people's depositions, maybe more, and then we would like to submit stuff to our experts.

We still have, for example, on the -- we have to qualify experts under the protective order that just has gone into effect and that's a ten-day period, I think, itself, and assuming there are no objections.

And so we have a lot of work to do and we're willing to do it, but as far as any process, we have no proposal, your Honor.

THE COURT: All right. Well, I think that I will still like to meet with you on April 2nd in the afternoon, if

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you all are available, at 3:00 o'clock.

I am certainly willing to entertain -- depending on what happens on the 2nd, I am still willing to entertain the thought of an accelerated portion of this case, but it has got to be based on something more than what I have before me now, and it might not be done by April 2nd, or April 20th, but, on the other hand, it could be done before next fall. So I think that's the best I can do for you right now.

I want you all to be prepared on April 2nd to tell me exactly what discovery is needed and why given the discovery that has already been produced and given the relatively narrow issues in this case. This case is not complex compared to to many other cases I have. I think the issues are fairly well defined at this point, and that is what we will do. All right?

Nothing foreclosed, but nothing decided yet today.

All right. Thank you very much, counsel.

(Counsel respond, "Thank you, your Honor.")

(Court recessed at 3:10 p.m.)

- - -

EXHIBIT 19

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March 15, 2007

Via Electronic Mail

Robert J. Koch, Esq.
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1850 K Street N.W.
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Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

At the March 12, 2007 conference with the Court, you indicated that Plaintiffs sought depositions of only the two inventors listed on WO 00/78284 A1, Raffael Lahav and Valerie Azoulay. Please note that Raffael Lahav is deceased. As for Valerie Azoulay, she is available for deposition any day before March 30, 2007. As previously agreed, we will present Ms. Azoulay at the Frommer Lawrence firm in New York. She must travel to the United States, however, so we ask that you promptly identify your preferred date for this deposition. Also, please be advised that Ms. Azoulay's first language is French. Accordingly, you will need to arrange for a French-English interpreter to be present at the deposition.

We look forward to your timely response.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn C. Borg-Breen

EXHIBIT 20

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ASTRAZENECA AB, AKTIEBOLAGET HASSLE, KBI-E, INC., KBI INC., and ASTRAZENECA LP, Plaintiffs	:	CIVIL ACTION
vs.	:	
DEXCEL, LTD., DEXXON, LTD., DEXCEL PHARMA TECHNOLOGIES LTD., and DEXCEL PHARMA TECHNOLOGIES, Defendants	:	NO. 06-358 (SLR)

- - -

Wilmington, Delaware
Thursday, February 1, 2007
4:38 o'clock, p.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

- - -

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: JACK B. BLUMENFELD, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

APPEARANCES (Continued):

MILBANK, TWEED, HADLEY & McCLOY LLP
BY: ROBERT J. KOCH, ESQ.
JAY I. ALEXANDER, ESQ.
(Washington, D.C.)

Counsel for Plaintiffs

THE BAYARD FIRM
BY: RICHARD D. KIRK, ESQ.

-and-

LEYDIG, VOIT & MAYER
BY: ROBERT GREEN, ESQ.

Counsel for Defendants

- - -

PROCEEDINGS

(Proceedings commenced in the courtroom, beginning at 4:38 p.m.)

THE COURT: All right. I've reviewed all of your letters. Quite frankly, given the week I've had, I really, truly, am not interested in hearing your versions of what the other party has done over the past month. All I want is an efficient, clear articulation of what you need to get us to trial, period. No other elaboration.

I'm going to start with defendant tonight, and although you've sent me a long letter, which, you know, how many times have I said I don't want long letters, all I want is the list of things we need to resolve tonight so that we can bring this case to trial.

So counsel for defendant, I believe.

MR. GREEN: Good afternoon, your Honor. Robert Green, from Leydig Voit & Mayer, in Chicago, representing the defendants in this case.

Again, we appreciate you taking the time out of your busy schedule for this. I will try to be succinct.

Let me first start with probably the most important set of documents that we do not have from the

plaintiffs, and we have had a meet and confer on this. That would be the new drug application, the NDA filed by the plaintiffs covering Omeprazole. We've asked for that. They've objected based on the relevance and we don't have it.

It's important. The Omeprazole product formulation contains the subcoating, that's the subcoating they must allege to be present in the defendants' product here, Dexcel's product, that NDA deals with. A formulation having a subcoating information in there with respect to the characterization of that subcoating, for example, is going to be extremely relevant from the standpoint of determination of infringement in this case.

I, frankly, have never been in a Paragraph 4 case where the NDA has not been produced.

There is a second NDA in issue as well. It covers the related product Nexium. They've objected to producing that document as well based on relevance.

The Nexium NDA is relevant, however, your Honor. Without going into the chemistry, the active agent in Omeprazole is essentially two molecules. One molecule is the molecule which is present in the Omeprazole product and in Nexium.

Nexium is made with the same subcoating. The same patents in suit in this litigation are also listed in

of custody.

Yes, they did turn over tablets to us some time ago. We have asked for the chain of custody of those tablets to see where they've been and how they've been kept and so on. It's not a major point, but it shouldn't be a difficult one to produce.

The next number is any X-ray powder diffraction tests that they've done on their product, on either the bulk Omeprazole or any other -- any other Omeprazole that they have in developing their product.

So far we have seen none of that. I don't know how they could take -- make an assertion of noninfringement of a claim that has the X-ray powder diffraction as Claim 1 without actually doing an X-ray powder diffraction of their product or of the bulk Omeprazole.

So I assume they've done that or somebody else. Otherwise, they couldn't make the assertion.

The next item is the bioequivalents data. We have some of that from the NDA. They have to produce the bioequivalents information in the NDA, but we've seen so little comparisons to Prilosec or Prilosec OTC that we're -- we wonder whether we have it all. I mean, I would be happy if they simply said we have it all. I don't think they're going to say that.

Similarly, the -- we don't know and we have

asked them specifically if they have any data on multiple dosages of their product. What we've seen so far is single dosage or two doses, I guess, not multiple doses. And we suspect there may be some multiple dosing data that we would like to have.

The next thing is the, next-to-last item is the -- any subcoating analysis. If they've done any analysis of whether -- on their own product of whether they have a subcoat or not.

THE COURT: In other words, whether they've done testing for noninfringement --

MR. KOCH: Yes.

THE COURT: -- is basically what you are asking.

MR. KOCH: Yes. They could say they have not done any and that's fine.

THE COURT: It seems to me that there has to be some kind of exchange here. It's a little unfair for you to ask, have you done any testing for noninfringement when you have not given them any testing for infringement when it's your burden of proof.

MR. KOCH: Oh, no. We've given them a whole list of testing that we've done in response to their interrogatories.

Remember, as counsel indicated, this case has been through two waves of trials already. We tested at least

ten different defendants' product and we don't test them all the same way. So it depends on the product.

THE COURT: Okay.

MR. KOCH: Some of the defendants claim not to have a subcoating, so we test them for the subcoating. Some claim not to have an ACR in the core and we test for that. It depends on what the defendant is claiming. But we've given them a list of all the testing we've done. We haven't said that's the end of the world on testing. I mean, if they come up with a new tablet, maybe we need a new test to show that it infringes.

THE COURT: So you've tested their product?

MR. KOCH: We haven't tested their product because we haven't -- we have not finished the protective order and we don't test the products until we can tell our testing people what to test for.

THE COURT: All right. 11, then.

MR. KOCH: Okay. The last item, your Honor, is just very simple: An organizational chart we asked them so we could have some direction when we start wanting to take depositions.

THE COURT: Now, how about their requests? Forget the master files and NDA for the moment. How about their requests, the question about whether your product is covered by, I don't know which of the patents, and the

samples of form of the active agent.

MR. KOCH: Samples I didn't include because I was just talking about documents. Samples is another issue and I don't think we have -- we need -- I don't think we need the Court's assistance on samples.

We discussed with counsel yesterday that we need to agree upon a protocol for delivering samples to each other. We have located samples. We're -- we do not know how many samples we have or what samples we have. The pre-critical critical date samples they're asking for are at least ten years old, so I don't know how much of those batches will be available. But we have not refused to produce them, and what we're talking now is we're at the stage of just simply agreeing to a protocol. And what I would like to suggest on that, and I think we could put it to bed, is that each side should deliver the samples that they're going to deliver to the other side in whatever form and under whatever conditions that that side believes need to be present to preserve the integrity and effectiveness of the sample.

THE COURT: And what are the issues with the protective order? Why, after all these months, hasn't there been one entered?

MR. KOCH: As we spoke last time, the protective order has been in their court. Their objection has been to

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withholding under a confidentiality obligation.
That's the first we've heard of that. It's contrary to what we were told before.
THE COURT: So you've gotten some documents, but you think there are just more documents and you are not sure whether there's an agreement to produce them or not?
MR. KOCH: Well, we know there are more documents because they've told us that and they told us they're withholding it right now because of the confidentiality obligation to AAI Pharma.
THE COURT: Generally, the way we resolve that is I order them to be produced, and if AAI Pharma has a problem, they come in, or wherever they want to go and fight it.
MR. GREEN: And that's what we'd like you to do on that issue, Judge.
THE COURT: So ordered.
MR. GREEN: And then with respect to Merck, they claim there's no control. We have agreements from us, a specific contractual provision that says, with respect to documents from parties that are in the license agreement, that if there's litigation on Omeprazole patent, that there's supposed to be cooperation.
They claim cooperation means that I guess they

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asked if Merck doesn't want to produce the documents, then they don't have to.
We've asked if there has been any written correspondence back and forth with Merck on this issue. They say no, there has been some verbal communications.
Our reading of the agreement is Merck should clearly be obligated under the contract to produce the documents. We've also filed a subpoena on Merck. They say, Well, you have subpoenaed them from Merck, go get them from them. If they have them, Judge, then we want them.
Can I take the opportunity to correct one factual representation on the record from Astra's counsel?
I know you have to run, Judge. Our client insists that I do this and I understand why.
There was a statement on the record that the original Israeli product that was in litigation with Astra was found to be infringing. In fact, there's no such holding any place that that product was ever found to be infringing. This was the capsule product that they were selling. It's a capsule product that was actually sold by Dexcel but was under a license agreement from another party. That's the same product that they allege was used as a spring board to make the tablets in this case. But that was -- that was

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another party's product, this capsule.
The Dexcel product in this case is a product of their own making. It's a product that Dexcel themselves developed. They developed it independently. There's no subcoating on it.
And if I could have a moment, your Honor, to consult with counsel to see if there are any other issues.
(Pause.)
MR. GREEN: I think the only other issue that was raised, your Honor, was the issue of depositions. We've not had a meet an confer on that and I've not had an opportunity since this was raised just late last night to consult with my client about that. But I'd suggest that I will get back to my client.
They, of course, do not work on Fridays, so by, you know, by Monday I'd expect to have an answer back from them.
THE COURT: All right. Thank you.
All right. Mr. Koch, let's go through this again. Let's kind of start at the end. And that is the AAI Pharma and the Merck documents.
I take it you're going to represent on the record that you've -- well, I guess you can tell me what you want to represent.
MR. KOCH: Well, we're not withholding

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documents. What we have done with respect to AAI is we just reached agreement with counsel yesterday on, or last week culminating yesterday on what the scope of their request is. And due to that agreement, we now know what documents are responsive. And we have identified documents, certain documents to AAI under the confidentiality and we expect they will get back to us and see whether they have a problem with it or not.
I think the whole AAI thing is a non-issue at this point because they've also accepted AAI and AAI will respond to the subpoena however it responds to it. So whether this Court has that or whether the Court where AAI is located has that, I don't know. But I don't think it's an issue yet for any ordering.
With respect to Merck, counsel is correct: We certainly don't read the term "cooperation" to mean that we can't effectively get any document we want from Merck having to do with Omeprazole. Cooperation means cooperation.
I can tell you historically, there has been, what, 24 litigations on Omeprazole. Historically, Astra has never demanded a document from Merck and Merck has never given a document on Astra's demand to Merck.
As far as I understand, Merck has responded to one third-party subpoena and produced some documents after

EXHIBIT 21

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March 15, 2007

VIA ELECTRONIC MAIL
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RE: *AstraZeneca AB, et al. v. Dexcel, Ltd. et al.*, C.A. No. 06-358 (SLR)

Dear David:

Further to our letter of March 9, 2007, we provide below storage conditions for the omeprazole samples we will be shipping to you. Once you have made appropriate arrangements for receiving the samples, please provide us with the shipping address and name of a contact person to whom you would like us to ship the samples.

The omeprazole samples we will produce should be stored in closed, light-resistant containers under dry conditions at a temperature between 2° C and 8° C. The samples should be stored away from heaters, flame, sparks and sunlight. Due to the age of the samples, we are unable to confirm or verify that the samples have been maintained under these conditions from the date of manufacture up to the date of production. Consequently, we are unable to confirm or verify that the samples are representative of any omeprazole sold or offered for sale in the United States or abroad.

With respect to your letter of March 13, 2007 detailing the various storage conditions for the chemicals you will produce to us, we are working to confirm whether we can store these samples in our offices or will need to send them elsewhere in light of the various conditions applicable to the different samples. We will let you know where to send the materials shortly.

Very truly yours,

Robert J. Koch, Esq.

cc: Robert F. Green, Esq.
Richard D. Kirk, Esq.

EXHIBIT 22

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January 26, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

This letter sets forth our understanding of your positions regarding the numerous outstanding discovery issues we discussed yesterday. Please let us know if our understandings are incorrect or incomplete in any way.

- Regarding Requests 38 and 39, you maintain that the requested NDAs are irrelevant and that production would be burdensome. Plaintiffs nonetheless agree to produce an index for the NDA(s) relating to Prilosec™ and to thereafter produce sections of those NDAs upon Defendants request. However Plaintiffs will not produce NDAs relating to Nexium™ because Mr. Alexander stated his belief that the Nexium product manufacture does not involve the neutral omeprazole base. We ask that you at least confirm this statement. We further understand from our conference that Plaintiffs have previously produced the requested NDAs in the first and/or second wave omeprazole litigations involving the patents in suit.
- Regarding Request 40, you maintain that the requested DMFs are irrelevant and that production would be burdensome, despite our several explanations as to why these requested documents are indeed relevant. You do not know if any of the requested DMFs were produced in the first and/or second wave omeprazole litigations involving the patents in suit, but agree to inquire and let us know.

- Regarding Requests 3, 4, 5, 6, 9, and 10, you have not yet been able to determine if Plaintiffs have possession of any responsive samples. Regarding Requests 31 and 32, you do not know if Plaintiffs have any responsive samples in their possession, despite the fact that the requested samples are for materials claimed by Plaintiffs in the '380 patent. As you know, Defendants requested these samples many months ago. During our conference, we specifically asked that you produce responsive samples such as those identified in the spreadsheet attached as Exhibit A. Mr. Alexander suggested in the conference that Plaintiffs' counsel were attempting to determine the dates of these samples prior to producing them to us. This is unacceptable for the reasons we explained. Although the samples identified in the attached spreadsheet should be produced without delay, Plaintiffs also should be produce without further delay ***all*** other requested samples regardless of whether Plaintiffs or their counsel have doubts about the dates of the samples.
- Regarding responsive documents and things in the possession of Merck, you have not yet reviewed the specific sections of the agreements that we raised in our January 23, 2007 letter. You maintain that Plaintiffs do not have control over such documents and things but have nonetheless orally requested Merck to produce responsive documents. You are relying on Merck to indicate whether or not they will produce documents.
- Regarding Request 27, you will produce all responsive communications between Plaintiffs and any AAIPharma entity that relate to:
    - the '380 patent,
    - omeprazole Form A,
    - omeprazole Form B,
    - omeprazole tautomerization,
    - alleged infringement of patents or patent applications that relate to omeprazole and are owned by AAIPharma including but not limited to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225.
    - alleged prior art to the '380 patent including but not limited to possible prior invention or sale of omeprazole products containing omeprazole Form A, and
    - license agreements with AAIPharma relating to omeprazole.

  You agree to also request such documents from Merck.

- You are not withholding any documents solely on the basis of a third party protective order or confidentiality agreement.
- You will produce color stacked spectra to the extent that you have originals in color. For those originals that are not in color, we understand that you will produce electronic spectra to the extent such spectra are available electronically.

As we discussed, we will confer further regarding the outstanding discovery issues on January 31, 2007 at 2:00 p.m. CST.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Robert F. Green

	all spectra resolution 2 cm-1							FT-Raman intensity					5-isomer ratio			5-iso	5-iso
										1364/	1364/		type AAI			Rama	NMR
no	file	origin	article no	batch	nature	comment		1364	1355	1355	1364+1355	6-iso	5-iso	A-form	B-form	scaled	
1	BKCL3B8	AH			A	unmicr	1997	0	1	0.00	0.00	1.00	0.000	1.00	0.00	0	
2	BKCL3I6	AH			A	unmicr	1997	0	1	0.00	0.00	1.00	0.000	1.00	0.00	0	
3	B1501C4			1501/97		KCL slurry to produce opH 86		12	140	0.09	0.08	0.92	0.079	0.66	0.34	0.051	
4	BOPH86D4	AH		opH86/97	A	after KCL slurry. Dried omald		0	134	0.00	0.00	1.00	0.000	1.00	0.00	0	0
5	B60996C2	APH		609/96	B	unmicr		30	134	0.22	0.18	0.82	0.183	0.12	0.88	0.117	
6	B61096C3	APH		610/96	B	unmicr		34	134	0.25	0.20	0.80	0.202	0.00	1.00	0.13	0.14
7	B30297D8			302/97	B			32	128	0.25	0.20	0.80	0.200	0.02	0.98	0.128	0.14
8	KCL5ISG8	AH			C		2000	97	123	0.79	0.44	0.56	0.441	0.00	2.00	0.282	0.28
9	B12480F1			124/80	B	referensprov. Mald 801119		32	128	0.25	0.20	0.80	0.200	0.02	0.98	0.128	
10	RFOMESC3			128/81		CRS(1)		9	140	0.06	0.06	0.94	0.060	0.75	0.25	0.039	
11	RFOMESC			135			1987										
12	RFOMESC0		25-542-36	137		plv II	1992	9.5	140	0.07	0.06	0.94	0.064	0.73	0.27	0.041	
13	B30482F4			304/82		referensprov. Mald		22	128	0.17	0.15	0.85	0.147	0.32	0.68	0.094	
14	B20083F3			200/83		referensprov. Micron		17	128	0.13	0.12	0.88	0.117	0.48	0.52	0.075	
15	RFOMESA0	AH		122/91		CRS(2). Micron. MeCl		9	140	0.06	0.06	0.94	0.060	0.75	0.25	0.039	
16	RFOMESB1	AH		158/92		plv III. Unmicr. EtOH		12	140	0.09	0.08	0.92	0.079	0.66	0.34	0.051	
17	RFOMESD1			122/91		CRS(2)		10	146	0.07	0.06	0.94	0.064	0.73	0.27	0.041	
18	RFOMESD2			158/92		plv III		12	146	0.08	0.08	0.92	0.076	0.68	0.32	0.049	
19	RFOMESD3			159/92		plv III		13	146	0.09	0.08	0.92	0.082	0.65	0.35	0.052	
20	B14A4	APC	25-802-98	14/95		plv III. Micron. Toluene		12	139	0.09	0.08	0.92	0.079	0.66	0.34	0.051	
21	B14OMIB9			14/95		ome III. Unmicr		12	139	0.09	0.08	0.92	0.079	0.66	0.34	0.051	
22	B14MICC1			14		micron		13	139	0.09	0.09	0.91	0.086	0.63	0.37	0.055	

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	all spectra resolution 2 cm-1								FT-Raman intensity					5-isomer ratio			5-iso	5-iso
											1364/	1364/		type AAI			Rama	NMR
no	file	origin	article no	batch	nature	comment			1364	1355	1355	1364+1355	6-iso	5-iso	A-form	B-form	scaled	
23	B10000I2	Patric		100/00	A				3	134	0.02	0.02	0.98	0.022	0.91	0.09	0.014	
24	B10100I3	Fransson		101/00	45%A 55%B				19	134	0.14	0.12	0.88	0.124	0.44	0.56	0.079	
25	B10200I4	PR&D		102/00	B				30	134	0.22	0.18	0.82	0.183	0.12	0.88	0.117	
26	B10000J3			100/00	3m	25/50			1	152	0.01	0.01	0.99	0.007	0.97	0.03	0.004	
27	B10100J4			101/00	3m	25/50			18	158	0.11	0.10	0.90	0.103	0.55	0.45	0.066	
28	B10200J5			102/00	3m	25/50			31.5	152	0.21	0.17	0.83	0.172	0.18	0.82	0.11	
29	B10000J6			100/00	3m	40/75			0	152	0.00	0.00	1.00	0.000	1.00	0.00	0	
30	B10100J7			101/00	3m	40/75	degraded											
31	B10200J8			102/00	3m	40/75	degraded some		32	152	0.21	0.17	0.83	0.174	0.17	0.83	0.111	
32	BUSPF2	USP		47850, lot G					10	140	0.07	0.07	0.93	0.067	0.72	0.28	0.043	0.05
33	B347OMB1		25-556-88	347-01		unmicr		1997	12	140	0.086	0.078947	0.92	0.079	0.663	0.337	0.051	
34	B347MIB2		25-556-88	347-01		micron		1997	15	140	0.107	0.096774	0.9	0.097	0.578	0.422	0.062	
35	B347OMB3		25-556-88	347-01		unmicr		1997	12	140	0.086	0.078947	0.92	0.079	0.663	0.337	0.051	
36	B347MIB4		25-556-88	347-01		micron		1997	15	140	0.107	0.096774	0.9	0.097	0.578	0.422	0.062	
37	B13MerN2	BPS	25-815-10	13-01		Stälje		2000?	13	158	0.08	0.08	0.92	0.076	0.68	0.32	0.049	
38	B16MerN3	BPS	25-815-10	16-01		Stälje		2000?	13	158	0.08	0.08	0.92	0.076	0.68	0.32	0.049	
39	B20MerN4	BPS	25-815-10	20-01		Stälje		2000?	12	158	0.08	0.07	0.93	0.071	0.70	0.30	0.045	
40	B21MerN5	BPS	25-815-10	21-01		Stälje		2000?	12.5	158	0.08	0.07	0.93	0.074	0.69	0.31	0.047	
41	B23MerN6	BPS	25-815-10	23-01		Stälje		2000?	12	158	0.08	0.07	0.93	0.071	0.70	0.30	0.045	
42	AAI0G4	AAI			0% 5-iso	from Merck: HAZ3170			11	123	0.09	0.08	0.92	0.082	0.65	0.35	0.053	
43	AAI7G3	AAI			7% 5-iso	from Merck: HAZ3170			10	123	0.08	0.08	0.92	0.075	0.68	0.32	0.048	
44	AAI12F9	AAI			12% 5-iso	from Merck: HAZ3170			27	123	0.22	0.18	0.82	0.180	0.14	0.86	0.115	0.11
45	AAI20G2	AAI			20% 5-iso	from Merck: HAZ3170			33	123	0.27	0.21	0.79	0.212	0.00	1.00	0.135	

12.5 22.5 42 25

0 9 3: 46.856 88 160

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	all spectra resolution 2 cm-1							FT-Raman intensity					5-isomer ratio			5-iso	5-iso
										1364/	1364/		type AAI			Rama	NMR
no	file	origin	article no	batch	nature	comment		1364	1355	1355	1364+1355	6-iso	5-iso	A-form	B-form	scaled	
46	B16195A8	ASP	25-800-17	161/95		MeCl		14	139	0.101	0.091503	0.91	0.092	0.603	0.397	0.059	
47	RFOMESB3	ASP	25-800-17	11			ca 1992	10	123	0.081	0.075188	0.92	0.075	0.68	0.32	0.048	
48	RFOMESB5	ASP	25-800-17	17			ca 1992	10.5	123	0.085	0.078652	0.92	0.079	0.664	0.336	0.05	
49	RFOMESB7	ASP	25-800-17	18			ca 1992	12.5	123	0.102	0.092251	0.91	0.092	0.6	0.4	0.059	
50	RFOMESB9	ASP	25-800-17	19			ca 1992	11	123	0.089	0.08209	0.92	0.082	0.648	0.352	0.053	
51	B11PFRC5	ASP		11-01		ome III	1997	15	123	0.122	0.108696	0.89	0.109	0.52	0.48	0.07	
52	B12PFRC6	ASP		12-01			1997	13	123	0.106	0.095588	0.9	0.096	0.584	0.416	0.061	
53	B13PFRC7	ASP		13-01			1997	14	123	0.114	0.10219	0.9	0.102	0.552	0.448	0.065	
54	B13699J9	ASP	25-804-70		18m 5C	ome powder III ASP	1999	16	152	0.105	0.095238	0.9	0.095	0.586	0.414	0.061	
55	B13799K1	ASP	25-804-70		18m 5C	ome powder III ASP	1999	17	152	0.112	0.100592	0.9	0.101	0.56	0.44	0.064	
56	B13899K2	ASP	25-804-70		18m 5C	ome powder III ASP	1999	15	157	0.096	0.087209	0.91	0.087	0.624	0.376	0.056	
57	ASP252I7	ASP	25-804-70	252-01		ome powder III ASP	2000	16	135	0.119	0.106312	0.89	0.106	0.532	0.468	0.068	
58	ASP254I8	ASP	25-804-70	254-01		ome powder III ASP	2000	14.5	135	0.108	0.097315	0.9	0.097	0.576	0.424	0.062	
59	ASP255I9	ASP	25-804-70	255-01		ome powder III ASP	2000	16	135	0.119	0.106312	0.89	0.106	0.532	0.468	0.068	
60	ASP256J1	ASP	25-804-70	256-01		ome powder III ASP	2000	16	135	0.119	0.106312	0.89	0.106	0.532	0.468	0.068	
61	ASP257J2	ASP	25-804-70	257-01		ome powder III ASP	2000	14.5	135	0.108	0.097315	0.9	0.097	0.576	0.424	0.062	
62	RFOMESC4	Merck		AAZ-019			1994	6	128	0.047	0.044776	0.96	0.045	0.815	0.185	0.029	
63	RFOMESC5	Merck		AAZ-021			1994	5.5	128	0.043	0.041199	0.96	0.041	0.831	0.169	0.026	
64	RFOMESC6	Merck		AAZ-028			1994	5	128	0.039	0.037594	0.96	0.038	0.846	0.154	0.024	
65	RFOMESC7	Merck		AAZ-029			1994	5.5	128	0.043	0.041199	0.96	0.041	0.831	0.169	0.026	
66	RFOMESC8	Merck		AAZ-030			1994	5.5	128	0.043	0.041199	0.96	0.041	0.831	0.169	0.026	
67	VAZ012A7	Merck		VAZ-012		toluene		11	128	0.086	0.079137	0.92	0.079	0.662	0.338	0.051	

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	all spectra resolution 2 cm-1								FT-Raman intensity					5-isomer ratio			5-iso	5-iso
											1364/	1364/		type AAI			Rama	NMR
no	file	origin	article no	batch	nature	comment			1364	1355	1355	1364+1355	6-iso	5-iso	A-form	B-form	scaled	
68	WAZ020K3	Merck		WAZ 020		CH2Cl2		1993	7	152	0.046	0.044025	0.96	0.044	0.819	0.181	0.028	
69	WAZ039K4	Merck		WAZ 039		CH2Cl2		1993	6.5	152	0.043	0.041009	0.96	0.041	0.832	0.168	0.026	
70	AAZ005K5	Merck		AAZ 005		CH2Cl2		1994	5	146	0.034	0.033113	0.97	0.033	0.865	0.135	0.021	
71	AAZ020M4	Merck		AAZ 020		CH2Cl2		1994	5	158	0.032	0.030675	0.97	0.031	0.875	0.125	0.02	
72	BAZ005K6	Merck		BAZ 005		CH2Cl2		1995	5	146	0.034	0.033113	0.97	0.033	0.865	0.135	0.021	
73	BAZ050K7	Merck		BAZ 050		CH2Cl2		1995	5	146	0.034	0.033113	0.97	0.033	0.865	0.135	0.021	
74	CAZ050K8	Merck		CAZ 050		toluene		1996	8	140	0.057	0.054054	0.95	0.054	0.775	0.225	0.035	
75	CAZ100K9	Merck		CAZ 100		toluene		1996	8	140	0.057	0.054054	0.95	0.054	0.775	0.225	0.035	
76	DAZ238L1	Merck		DAZ 238		toluene		1997	8	140	0.057	0.054054	0.95	0.054	0.775	0.225	0.035	
77	DAZ250L2	Merck		DAZ 250		toluene		1997	7	140	0.05	0.047619	0.95	0.048	0.803	0.197	0.03	
78	EAZ238L3	Merck		EAZ 2380		toluene		1998	9	140	0.064	0.060403	0.94	0.060	0.747	0.253	0.039	
79	EAZ245L4	Merck		EAZ 2450		toluene		1998	9	140	0.064	0.060403	0.94	0.060	0.747	0.253	0.039	
80	HAZ230L5	Merck		HAZ 2300		toluene		1999	8.5	140	0.061	0.057239	0.94	0.057	0.761	0.239	0.037	
81	HAZ325L6	Merck		HAZ 3250		toluene		1999	9	140	0.064	0.060403	0.94	0.060	0.747	0.253	0.039	
82	B10200L7-M3	PR&D		102/00	B	FWL val			28.5	129	0.22	0.18	0.82	0.182	0.13	0.87	0.116	
83	B10200M5-N1	PR&D		102/00	B	RL val			28.5	129	0.22	0.18	0.82	0.182	0.13	0.87	0.116	
84	BMO005B5	Orex Pharma, Indi		MO-005					33.5	140	0.239	0.193084	0.81	0.193	0.058	0.942	0.124	
85	PLAMAE6	Plama, India		577	bottom of tube				9.5	140	0.068	0.063545	0.94	0.064	0.733	0.267	0.041	
86	PILAMAE7	Plama, India		577	top of tube				7	140	0.05	0.047619	0.95	0.048	0.803	0.197	0.03	
87	PIR572E8	pirate		572					15	146	0.103	0.093168	0.91	0.093	0.596	0.404	0.06	
88	PIR573E9	pirate		573					22	146	0.151	0.130952	0.87	0.131	0.407	0.593	0.084	
89	PIR588F5	pirate		588					19	146	0.13	0.115152	0.88	0.115	0.488	0.512	0.074	
90	PIR589F6	pirate		589					19	146	0.13	0.115152	0.88	0.115	0.488	0.512	0.074	
91	PIR590F7	pirate		590					20	146	0.137	0.120482	0.88	0.120	0.461	0.539	0.077	
92	PIR591F8	pirate		591					21.5	146	0.147	0.128358	0.87	0.128	0.42	0.58	0.082	
93	PIR608G1	pirate		608					11	140	0.079	0.072848	0.93	0.073	0.691	0.309	0.047	
94	PIR604G5	pirate		604					14	140	0.1	0.090909	0.91	0.091	0.606	0.394	0.058	
95	PIR611G6	pirate		611					16	140	0.114	0.102564	0.9	0.103	0.55	0.45	0.066	

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	all spectra resolution 2 cm-1								FT-Raman intensity					5-isomer ratio			5-iso	5-iso
											1364/	1364/		type AAI			Rama	NMR
no	file	origin	article no	batch	nature	comment			1364	1355	1355	1364+1355	6-iso	5-iso	A-form	B-form	scaled	
96	PIR625H1	pirate		625					28	140	0.2	0.166667	0.83	0.167	0.213	0.787	0.107	
97	PIR618H2	pirate		618					9	140	0.064	0.060403	0.94	0.060	0.747	0.253	0.039	
98	PIR629H3	pirate		629					22	140	0.157	0.135802	0.86	0.136	0.381	0.619	0.087	
99	PIR631H4	pirate		631					15	140	0.107	0.096774	0.9	0.097	0.578	0.422	0.062	
100	PIR637I5	pirate		637					10	140	0.071	0.066667	0.93	0.067	0.719	0.281	0.043	
	pir618w6			618					10	158	0.063	0.059701	0.94	0.060	0.75	0.25	0.038	
	pir619w7			619					16.5	158	0.105	0.094719	0.91	0.095	0.588	0.412	0.061	
	pir620w8			620					7	158	0.044	0.042553	0.96	0.043	0.825	0.175	0.027	
	BKCL3B8		1355.86	86		A												
	BKCL3I6			64		A												
	BOPH86C8			40		A												
	BOPH86C9			36		A												
	BOPH86D1			45		pure A												
	BOPH86D2			42		pure A												
	BOPH86D3			42		pure A												
	BOPH86D4			41		pure A												
	BOPH86D5			40		A												
	BOPH86D6			37		A												
	BOPH86D7			44		A												
	BOPH86D9			88		A												
	BOPH86E1			88		A												
	BOPH86E2			88		A												
	B60996A5			28		B												
	B60996C2			44		B												
	B61096A6			19		pure B												
	B61096C3			42		pure B												
	WAZ020K3		1355.72	72														
	WAZ039K4			68														
	AAZ005K5			72														
	AAZ020M4			61														

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Case 1:06-cv-00358-JJF Document 119-3 Filed 03/30/2007 Page 11 of 27

| | | |

EXHIBIT 23

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February 9, 2007

BY E-FILING

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

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

Dear Chief Judge Robinson:

In response to the Court's direction during the February 1, 2007 discovery conference (Tr. at 55:5-56:17), counsel for AstraZeneca has reviewed the NDAs and DMFs that Dexcel has requested be produced with the exception of the NDA for Nexium, which the Court recognized was not at issue in this case (Tr. at 17:9-12). That review has shown that there are no protocols in the NDA or DMFs at issue that describe tests for the presence of a subcoating or the presence of Form A.

However, to finally end this issue, AstraZeneca will produce sections of the NDA and DMFs that contain analytical data relating to the characterization of the neutral form of omeprazole used in Prilosec.

Respectfully,

Jack B. Blumenfeld (#1014)

cc: Peter T. Dalleo, Clerk (By hand)
Richard D. Kirk, Esquire (By hand and email)
David Airan, Esquire (By email)
Robert F. Green, Esquire (By email)
Edgar Haug, Esquire (By email)
Robert Koch, Esquire (By email)

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March 13, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

Minutes before the conference with Chief Judge Robinson yesterday, you agreed to produce the Prilosec NDA and DMF No. 4863. As you know, we will need to take depositions of AstraZeneca and Merck personnel prior to the close of fact discovery on April 2, 2007. Obviously we will need to review the NDA and DMF prior to any such depositions. Accordingly, we request that you send these documents out on Thursday for our receipt on Friday. We expect that you will produce the NDA and DMF in the form in which they exist in the normal course of business. In addition, we expect that you will segregate the production of the NDA and DMF onto different disks. If you are not able to produce the NDA and DMF simultaneously, we request that you produce the DMF prior to the NDA.

If we do not receive a communication from you by close of business on Thursday confirming that you have sent the NDA and DMF as requested above, we will be forced to seek the assistance of the court in this matter.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn C. Borg-Breen

Caryn C. Borg-Breen

EXHIBIT 25

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March 15, 2007

VIA ELECTRONIC MAIL
Caryn C. Borg-Breen
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

Re: Prilosec and DMF 4862

Dear Caryn:

We have your letter of March 13, 2007, requesting production of the Prilosec and DMF 4863.

As I indicated to Judge Robinson at the hearing on Monday, we believe that we will be able to produce these documents within a couple of weeks. The court indicated that both the CIPLA and Astra DMF's should be exchanged by April 2, 2007. We are promptly collecting and processing the documents so they may be produced before the April 2 deadline. Are we to assume from your March 13 letter that you are ready to exchange DMF's now? If so, we will let you know as soon as we can physically do so.

Very truly yours,

Robert J. Koch

cc: Richard D. Kirk, Esq.
Robert F. Green, Esq.
David M. Airan, Esq.
Edgar H. Haug, Esq.
Jack B. Blumenfeld, Esq.

EXHIBIT 26

E-Mail Request for Emergency Relief

1. Case Number: 06 -cv- 358 -SLR

2. Check the box that applies:

- [x] Requesting a teleconference with the parties and the court
- [ ] Requesting an in-person conference with the parties and the court
- [ ] Requesting either of the above listed options at the court's determination

3. BRIEFLY describe the reason for this **emergency** request:

Defendants reluctantly request the Court's intervention to obtain the NDA and DMF that Plaintiffs agreed to produce 3/12. As Plaintiffs well know, Dexcel needs the NDA and DMF as soon as possible for depositions on 3/29 and 3/30 which are necessarily taking place before fact discovery ends 4/2. Plaintiffs insist that they are not required to produce these documents until 4/2. Defendants believe that the NDA and DMF are kept electronically and that there is no reason such documents cannot be produced at once. As the DMF is particularly relevant to the noticed depositions, and should be by far the smaller document, Defendants requested that Plaintiffs produce at least the DMF now. Plaintiffs have not responded to Defendants' request for a meet-and-confer. Defendants request the Court to order Plaintiffs to produce to Defendants, at a minimum, the DMF no later than 3/23.

*Any text added beyond the limits of this space will be disregarded by the court.

4. Name of opposing counsel contacted about this request:

5. Response of opposing counsel to this request:

6. Name of local counsel making this request:

7. Today's Date:

****

For court use only:

- [ ] A teleconference will be held on to be coordinated and initiated by
- [ ] An in-person discovery conference will be held on:
- [ ] Other:

EXHIBIT 27

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March 20, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

We received today what appears to be the Drug Master File for omeprazole as originally filed. As you know, a Drug Master File includes the originally filed document as well as later communications with the FDA related to the original document including amendments to the original document. Please (1) confirm that there are no further communications with the FDA concerning the originally filed DMF document or amendments thereto, which you have not already produced to us or; (2), if such documents do exist, produce these documents promptly. Please respond by return email as to whether such additional documents exist and if so when you will be producing the same.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn C. Borg-Breen

EXHIBIT 28

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March 23, 2007

VIA ELECTRONIC MAIL

Robert F. Green, Esq.
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

Re: *AstraZeneca AB et al. v. Dexcel Ltd., et al.*, No. 06-358 (SLR) (D. Del.)

Dear Bob:

This letter is in receipt of Dexcel's deposition Notices directed to AstraZeneca LP, AstraZeneca AB, Karin Lovquist, and Frans Langkilde. The Notices do not provide adequate notice in advance of the proposed dates of deposition, and so are objectionable. The Rule 30(b)(6) notices include many objectionable categories. AstraZeneca will provide its objections to the Rule 30(b)(6) Notices in due course. Once these objections are resolved, we can schedule the depositions at a mutually agreeable time. It is unrealistic to hold the depositions on the dates proposed by Dexcel.

AstraZeneca intends to take a number of depositions as well of Dexcel and Cipla. At this point, we have not received the complete production of documents necessary before AstraZeneca can proceed with these depositions. AstraZeneca intends to take the deposition of Valerie Azoulay and Avi Avramoff, as well as witnesses on behalf of Cipla. We cannot identify the Cipla witnesses until AstraZeneca receives a complete response to its discovery requests served on Cipla. This discovery includes Cipla's interrogatory responses, which ask Cipla to identify witnesses with knowledge regarding the infringement and validity issues in this matter.

AstraZeneca proposes that the parties have a meet and confer to schedule the necessary depositions at a mutually convenient time, to proceed after all of the above issues have been resolved.

Sincerely,

Robert J. Koch

cc: David M. Airan, Esq.
Saumil Mehta, Esq.
Caryn Borg-Breen, Esq.
Edgar H. Haug, Esq.
Richard D. Kirk, Esq.
Jack Blumenfeld, Esq.

EXHIBIT 29

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March 26, 2007

Via Electronic Mail

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Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

We write in response to your letter dated March 23, 2007. Your assertion that the notices for deposition of AZ, Karin Lovquist and Frans Langkilde, all of which notices you received at least 10 days in advance of the proposed date of deposition, were not "adequate" is spurious in view of Delaware Local Rule 30.1 which defines "reasonable notice" as "not less than five days." Your refusal to make *any* witness available on *any* of the requested dates is a clear indication that Plaintiffs are unwilling to cooperate in moving this case forward.

As to your alleged objections to the Rule 30(b)(6) categories, we are available to discuss these objections at any time. We suggest tomorrow morning at 9AM CDT. Please let us know as soon as possible if you are available to meet and confer at that time.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn C. Borg-Breen

Caryn C. Borg-Breen

EXHIBIT 30

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March 22, 2007

Via Electronic Mail
Confirmation Via Courier

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

Enclosed herewith is a copy of the Expert Report of Dr. Abraham J. Domb, which establishes that Plaintiffs contentions regarding alleged infringement of the '505 and '230 patents are without merit.

Please note that Dr. Domb will be in the United States next week for the spring meeting of the American Chemical Society which is being held in Chicago. Dr. Domb will be available for deposition in Chicago on Monday, Tuesday, and Wednesday of next week (March 26-28). Dr. Domb is not available for deposition between March 30th and April 9th due to the Jewish Passover holiday.

Please let us know as soon as possible if you are able to take Dr. Domb's deposition on either of March 26th, 27th, or 28th.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Robert F. Green

Enclosure
cc: Richard D. Kirk, Esq.
Jack B. Blumenfeld, Esq.
Edgar H. Haug, Esq.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI INC., and ASTRAZENECA LP, Plaintiff, v. DEXCEL, LTD., DEXXON, LTD., DEXCEL PHARMA TECHNOLOGIES LTD., AND CIPLA, LTD. Defendants.	Case No. 1:06-cv-00358 (SLR)

EXPERT REPORT OF DR. ABRAHAM J. DOMB

1. I am submitting this report on behalf of Defendants Dexcel Ltd., Dexxon Ltd, Dexcel Pharma Technologies Ltd., and Cipla Ltd. in the above-captioned action pursuant, I am advised, to Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure.

2. I currently hold the position of Professor of Medicinal Chemistry at the Department of Medicinal Chemistry and Natural Products of The Hebrew University of Jerusalem, School of Pharmacy-Faculty of Medicine.

3. I received a B.Sc. degree in chemistry from Bar-Ilan University in 1978, a diploma in Polymer and Textile Chemistry in 1979 from the School of Applied Sciences at The Hebrew University of Jerusalem, a B.Pharm. degree in pharmacy in 1984 from the School of Pharmacy at The Hebrew University of Jerusalem and I have been licensed as a pharmacist in Israel since then. I received a Ph.D. in from the Organic Chemistry Department at The Hebrew University of Jerusalem in 1984. I received a diploma in executive business administration studies in 1998 from The Hebrew University of

Jerusalem School of Business Administration. My academic and professional pursuits, including my educational background, professional experience, licenses, membership in professional and scientific organizations, honors, national and state committees and appointments, editorial activities, patents, publications, presentations and lectures, graduate committees and students, and funded grants and contracts are set forth in my Curriculum Vitae, a copy of which is attached. (Exh. 1)

4. Over the course of my career, I have developed expertise in the area of pharmaceutics, including dissolution technology, pharmaceutical analysis, and dosage form design and development.

5. The cases in which I have testified as an expert by deposition within the preceding four years is set forth in Exh. 2.

6. The information I have considered in forming my opinions for this report is set forth throughout my report, and includes U.S. Patent Nos. 4,786,505 ("the '505 patent") and 4,853,230 ("the '230 patent"), samples of Dexcel's omeprazole tablets that I understand are the subject of the present litigation ("the Dexcel Tablets"), portions of the Dexcel NDA that I understand are related to the manufacture of the Dexcel Tablets, and a document entitled, "Plaintiffs' Responses to Dexcel Pharma Technologies Ltd.'s Third Set of Interrogatories Relating to the Merits", which I understand to set forth the infringement position taken by the Plaintiffs in the present litigation with respect to the '505 patent and the '230 patent.

7. The compensation paid to me in connection with my consultation in this matter is set forth in Exh. 3.

8. I expect to testify at trial about the matters that are discussed in this report, including the nature of the Dexcel Tablet coating, the acid/base properties of the Dexcel Tablet coating, and the behavior of the Dexcel Tablet upon exposure to acidic media/gastric juice. I may also testify on other topics that are related to my report and analyses, as such topics may arise.

Summary of my Opinion

9. First, I note that Plaintiffs have not contended that the Dexcel Tablets, as manufactured, have a subcoating and an enteric coating. Indeed, it appears that the Plaintiffs acknowledge that, as manufactured, the Dexcel omeprazole tablets have only a core and one coating.

10. The Plaintiffs contend, however, that after a patient swallows the Dexcel Tablets, a third layer forms on the outside surface of the tablet, so that in the stomach of a patient the tablets have a core, a subcoating and an enteric layer. Accordingly, Plaintiffs are alleging that the single coating layer present in the Dexcel Tablets, as manufactured, is not an enteric coating, but is a subcoating layer. I have thoroughly reviewed the technical bases relied upon by the Plaintiffs to reach this conclusion that in the stomach the Dexcel Tablets are chemically converted to have both a subcoating and an enteric layer. It is my opinion that the Plaintiffs are wrong. There is no scientific support for their position. Moreover, I performed tests that prove that the Plaintiffs are wrong, involving only simple chemical testing and analyses. These tests took only a few days to perform and in my opinion Plaintiffs also could have been performed such tests in an equally short period of time.

Background of the Dexcel Tablet

11. The Dexcel Tablet consists of an active core and a single coating layer. Chemically, the coating layer consists primarily of the enteric coating polymer hydroxypropyl methylcellulose acetate succinate ("HPMCAS"). A representation of the structure of the Dexcel Tablet is set forth in Exh. 4. The enteric coating polymer in the single coating layer of the Dexcel Tablet is a cellulose polymer that possesses acid groups. Specifically, the acid groups are known as succinate groups, which contain free carboxylic acid.

12. During tablet manufacture, the enteric coating polymer is applied to the tablet core (which contains the omeprazole) in an aqueous suspension containing ammonia and a very small amount of monoethanolamine ("MEA"). As the neutralized enteric coating is applied, the coating is heated causing evaporation of water and ammonia. Accordingly, the final coating contains the enteric coating of HPMCAS in substantially acidic form. Because the heating step removes both ammonia and water, the dry enteric coating in the acid form can reside adjacent to the omeprazole without causing degradation of the omeprazole. Accordingly, the Dexcel Tablet in its final manufactured form has an acidic enteric coating, which remains in the acidic form upon contact with acidic gastric media in the stomach. A small number of the carboxylic acid groups present in the enteric coating will remain neutralized by MEA which is not removed by evaporation.

13. I understand that Plaintiffs argue that the Dexcel Tablet infringes the '505 and '230 patents, because the Dexcel Tablet allegedly, after ingestion by a patient, is chemically converted in the patient's stomach. The Plaintiffs contend that after ingestion

the Dexcel Tablet contains an active core surrounded by two coating layers: a soluble or rapidly disintegrating subcoat layer and an enteric coating layer. See Plaintiffs' Responses to Dexcel Pharma Technologies Ltd.'s Third Set of Interrogatories Relating to the Merits (Nos. 7, 8). A representation of a structure covered by the claims of Plaintiffs' formulation patents is set forth in Exh. 4. By way of comparison, as discussed above, a structure of the Dexcel tablet is also set forth in Exh. 4. In particular, Plaintiffs argue that "Dexcel's enteric coating layer fully forms *in vivo* as the outer layer of the inert, water soluble subcoating when exposed to acidic environments, including, without limitation, the highly acidic environments to which the formulation is exposed upon digestion."

14. Upon my review of the '505 and the '230 patents, I note that the purpose for the subcoating layer as disclosed and claimed by these patents is to protect the acid-sensitive omeprazole drug from the acidic nature of the enteric coating polymer during production and during long term storage. See, e.g., the '505 patent at col. 4, lines 4-14; col. 5, lines 29-53. I also note that the '505 and the '230 patents require that an enteric coating layer is applied on to the subcoated cores during the course of production by **conventional** coating techniques, such as pan coating or fluidized bed coating. See, e.g. the '505 patent at col. 4 lines 60-65; col. 5 lines 54-56 and 60-62. I note that if a second coating is formed in the outer surface of the tablet in the stomach as the Plaintiffs argue, the purpose of protection of omeprazole during production and during long term storage is not achieved by applying a subcoating layer, as required by the above mentioned patents.

The Acid/Base Properties of the Dexcel Tablet Coating

15. The first step to determining whether the Plaintiffs' contention that the Dexcel Tablet changes to have two layers after ingestion by a patient is to determine the true nature of the Dexcel Tablet enteric coating after tablet manufacture, namely whether the coating is in an acid or neutral form. Plaintiffs allege that if the Dexcel Tablet coating is present in a neutral form, then it may react upon contact with acidic gastric media to form an acidic enteric coating. However, if the coating on the Dexcel Tablet prior to ingestion is already in the acid form, then a second layer cannot be formed upon ingestion, as hypothesized by the Plaintiffs, as the coating is already in the acid form. Based upon my review, it is my opinion that the coating present on the Dexcel Tablet prior to ingestion is in acidic form and not in a neutral form.

16. In order to reach my opinion, I evaluated the acid/base properties of the tablet coating three ways. First, I evaluated the impact of the coating on the pH of water upon immersion. Second, I evaluated the state of the carboxylic acid groups present within the coating using FTIR spectroscopy to determine if they were present in an acid form or neutralized form. Third, I evaluated the elemental makeup of the coating to determine the quantity of residual amine in the coating.

17. pH Evaluation: I inserted two types of omeprazole tablets obtained from Dexcel to water (neutral pH) to evaluate the impact of the coating material on the water pH. The first tablets analyzed were (A) the Dexcel Tablets at issue in this litigation (BN B0415) which contain an enteric coating prepared using ammonia and MEA neutralizing agents. The second type of tablets analyzed were (B) comparative omeprazole tablets (BN 140307/B) which contain an enteric coating prepared without ammonia or MEA neutralizing agents.

18. The pH was measured before and 30 min after the insertion of the tablets. The results are summarized below:

Sample	Temp	Initial Water pH	Final Water pH
A	23° C	6.99	6.70
A	37° C	7.01	6.80
B	23° C	7.00	6.80
B	37° C	7.01	6.81

19. Both the Dexcel Tablets (A) and the comparative omeprazole tablets (B) remained intact after the 30 min period in water. Accordingly only the acid/base properties of the tablet coating influenced the pH of the water. In addition, both the Dexcel Tablets and the comparative tablets prepared without base caused a reduction in the pH of the water upon immersion in the water. Such a reduction in pH from neutral pH to acidic pH indicates that the coating for each of the Dexcel Tablet and the comparative omeprazole tablets is acidic.

20. FT-IR Evaluation: Fourier Transform Infrared Spectroscopy (FT-IR) was performed for each of the tablet coatings to evaluate whether the acid groups of the enteric coating were in acidic form or neutralized form. The enteric coating is comprised of hydroxypropyl methylcellulose acetate succinate (HPMCAS), which is a form of hydroxypropyl methylceullose in which the pendant hydroxyl groups have been reacted with acetic anhydride and succinic anhydride. The resulting product contains pendant acetate groups, succinate groups, and unreacted hydroxyl groups. The succinate group contains a carboxylic acid (C=O(OH)), the stretching frequency of which carbonyl can be observed using FT-IR.

21. Carboxylic acids typically have a pronounced carbonyl stretching frequency between 1690 and 1760 cm^{-1}. See, e.g., IR Spectroscopy Tutorial: Carboxylic Acids, at http://orgchem.colorado.edu/hndbksupport/irtutor/carbacidsir.html, attached at Exh. 5. When a carboxylic acid group is in the presence of a base, the carboxylic acid becomes deprotonated forming a carboxylate anion ($C=O(O^-)$). Such deprotonation causes the carbonyl stretching frequency to shift to a value between 1550 and 1610 cm^{-1}. See, e.g., A.D. Cross, Introduction to Practical Infra-Red Spectroscopy, Second Edition, Butterworths, London, 1964, p. 69 (asymmetric stretch for carboxylate ion, CO_2^-), attached at Exh. 6.

22. The samples for FT-IR were prepared by the following procedure. The tablet coatings were gently separated from the tablet and washed free of tablet core residues. The tablet coatings were ground and combined with a KBr carrier which does not have any absorption in the Infrared region. The resulting mixture was compression molded to form a pellet suitable for FT-IR analysis. The following samples were examined by FT-IR: (A) the Dexcel Tablets (BN B0415) containing an enteric coating prepared with ammonia and MEA neutralizing agents; (B) the comparative omeprazole tablets (BN 140307/B) containing an enteric coating prepared without ammonia and MEA neutralizing agents; and (C) HPMCAS powder, the standard enteric coating material used for the coating of both types of the tablets. The resulting FT-IR spectra for each of samples A-C are shown below in Fig. 6-8.

Fig 6: Sample A - FT-IR (KBr) of the Dexcel Tablet:

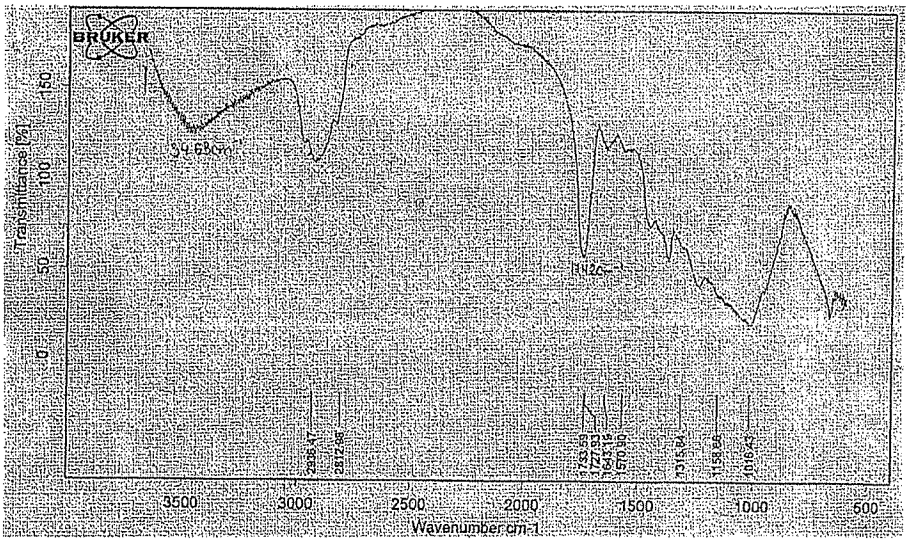


Fig 7: Sample B - FT-IR (KBr) of comparative unneutralized omeprazole tablets:

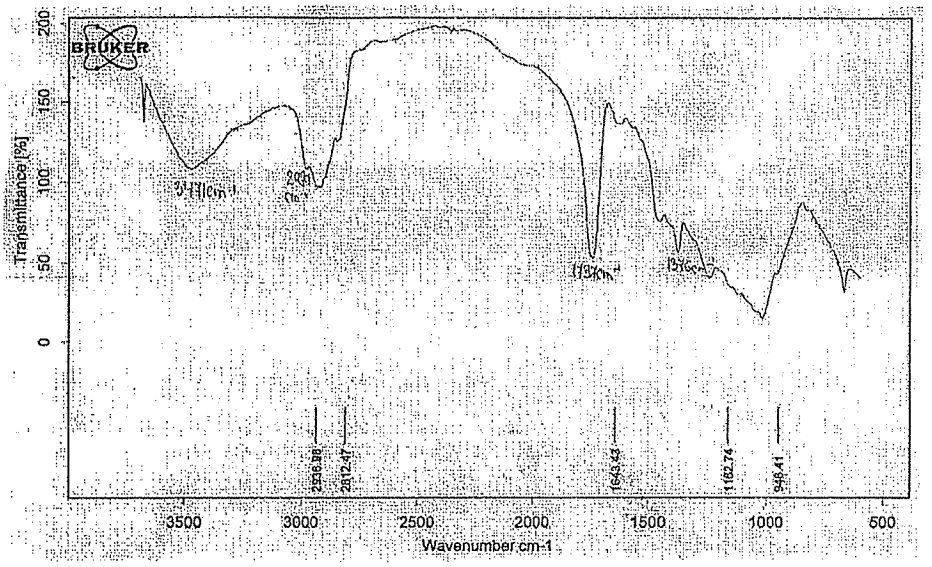
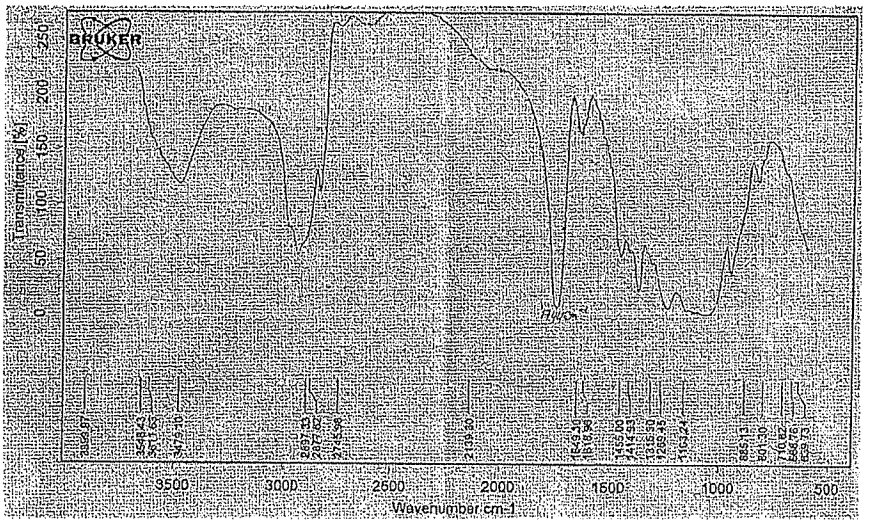


Fig. 8: Sample C - FT-IR (KBr) of HPMCAS enteric coating polymer:



A table summarizing the values for the carbonyl stretching frequencies in each sample is provided below.

Sample	Carbonyl Stretch (cm^{-1})
A	1742
B	1737
C	1744

23. Each of the samples analyzed by FT-IR gave rise to a carbonyl stretching frequency falling within the region expected for a carboxylic acid group in its acid form (between 1690 and 1760 cm^{-1}) and not in a neutralized form in which the acid group has been deprotonated by base (between 1550 and 1610 cm^{-1}). In addition, since no significant differences were found among the carbonyl stretching frequencies for each of the coatings and the acidic enteric coating polymer HPMCAS, I conclude that the coating of the Dexcel Tablet essentially consists of HPMCAS polymer that is acidic.

24. Elemental Analysis: Elemental analysis is an experiment that determines the amount (typically a weight percent) of an element in a compound. It uses a combustion method to convert the sample elements to simple gases. The system uses a steady-state, wave front chromatographic approach to separate the controlled gases. The elemental gases are detected as a function of their thermal conductivity. High speed microprocessor control, solid-state components and built-in diagnostics provide assurance of performance and reliability.

25. Elemental analysis was carried out to determine the nitrogen content in the coating of the Dexcel Tablets. Ammonia and MEA neutralizing agents are the only chemical components used to form the coating that contain nitrogen. Accordingly, the amount of elemental nitrogen present in the coating correlates to the amount of residual ammonia and/or MEA. The limit of detection (LOD) for elemental nitrogen using this technique is $\pm$0.3%. The elemental analysis was carried out using a Perkin-Elmer 2400/II C,H,N analyzer for the following samples: (A) the enteric coating from the Dexcel Tablet (omeprazole OTC tablet (BN B0415)) prepared with ammonia and MEA, (B) the enteric coating from the comparative omeprazole tablet (BN 140307/B) prepared without ammonia and MEA, and (C) HPMCAS, the standard enteric coating material used for the coating of both types of the tablets. The coatings of the tablets were cut off the tablet and cleaned from core residues before the test. The amount of nitrogen detected for each of the samples A-C is shown in the table below.

Sample	% N
A	Below LOD
B	Below LOD
C	Below LOD

26. The elemental analysis testing shows that the amount of elemental nitrogen is less than ±0.3 wt.% (the limit of detection) for each of the samples A-C. The absence of elemental nitrogen is expected for comparative enteric coating sample B which was prepared in the absence of ammonia and monoethanolamine, and for excipient polymer sample C which does not contain any nitrogen. That the amount of nitrogen in the Dexcel Tablet enteric coating sample A is not detectable confirms that the ammonia added during formation of the enteric coating of the Dexcel Tablet is removed by evaporation after the coating is applied such that the acid groups are no longer neutralized in the finished product. While MEA remains in the coating of the Dexcel Tablet in its final form, the amount of MEA used to prepare the tablet is very small such that the molar amount of elemental nitrogen corresponding to the MEA is below the limit of detection.

The Behavior of the Dexcel Tablet Coating in Acidic Gastric Media

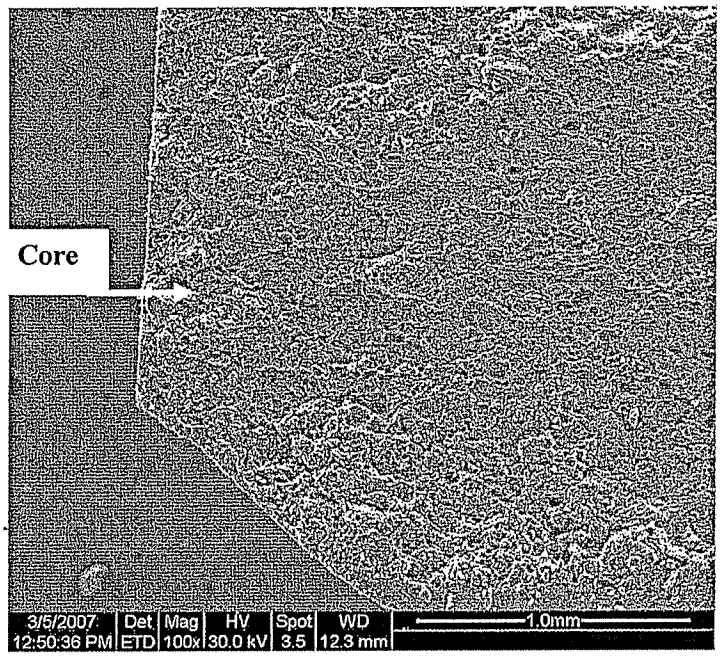
27. Based upon the foregoing experiments one would not expect the Dexcel Tablet to form an additional layer after ingestion by a patient, as theorized by the Plaintiffs. To directly establish whether such a second coating is in fact formed after ingestion, I have performed certain additional tests. These tests were designed to directly determine whether the Dexcel Tablets react upon contact with acidic gastric media to form an additional coating. Based on my tests, it is my opinion that the coating present on the Dexcel Tablets prior to ingestion is a fully formed enteric coating and that no conversion of the coating layer occurs when the coating comes into contact with acidic gastric media.

28. In order to reach my opinion, I visually inspected the Dexcel Tablet following exposure of the tablet to artificial gastric juice using Scanning Electron Microscopy (SEM). The scanning electron microscope is a type of electron microscope capable of producing high-resolution images of a sample surface. Due to the manner in which the image is created, SEM images have a characteristic three-dimensional appearance and are useful for judging the surface structure of the sample.

29. Two different tablets, the Dexcel Tablet (BN B0415) prepared with enteric coating and ammonia and MEA and the comparative omeprazole tablet (BN 140307/B) containing an enteric coating prepared without ammonia or MEA, were exposed to artificial gastric juice (pH = 0.95, prepared by dissolving sodium chloride (2.0 g) in water and then adding hydrochloric acid (80 ml, 1 M) followed by dilution with 1000.0 ml of water) as follows: (A) artificial gastric juice at 37° C for 60 min, and (B) artificial gastric juice at 37° C for 120 min. After exposure, the tablets were dried by evaporation at room temperature, cut to expose the coating cross section, and treated with gold. The SEM visualization was done by Phillips Scanning Electron Microscopy using 500X and 1000X magnification. For additional comparison purposes, uncoated tablets were also visualized by SEM without exposure to artificial gastric juice. The resulting SEM images are shown in Figs. 9-13.

30. The SEM images confirm that the Dexcel Tablets have no additional layer or coating following exposure to acidic gastric media. This is consistent with the coating present on the Dexcel Tablet being already in acidic form.

Fig 9: Uncoated omeprazole tablet (500X and 1000X magnification)



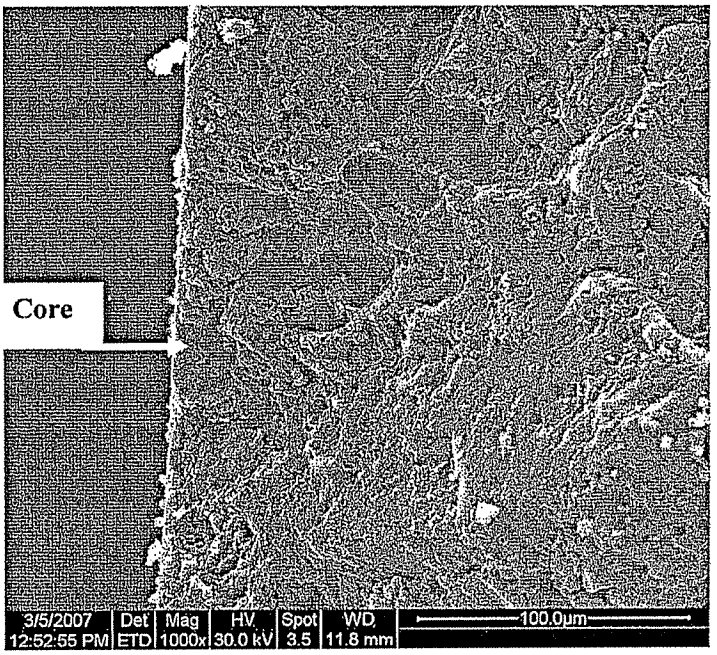
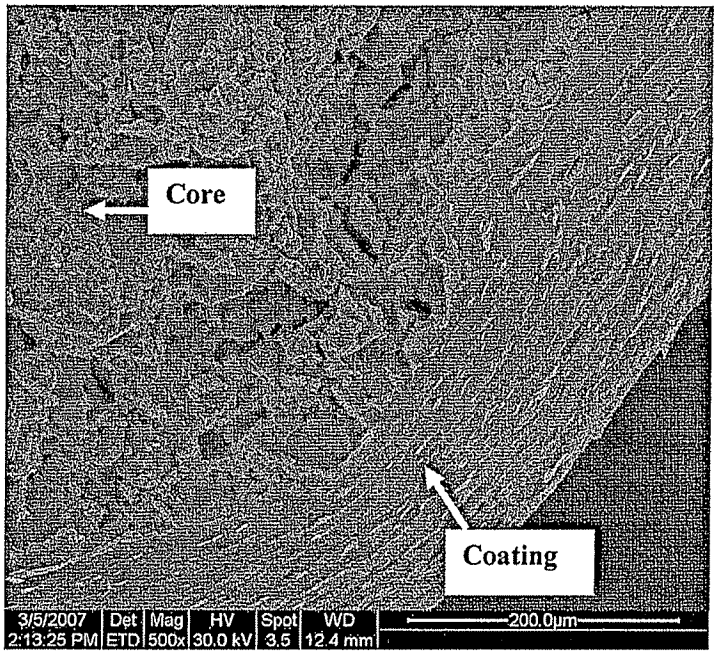


Fig 10: The Dexcel Tablet after exposure to artificial gastric juice at 37° C for 60 min (500X and 1000X magnification)



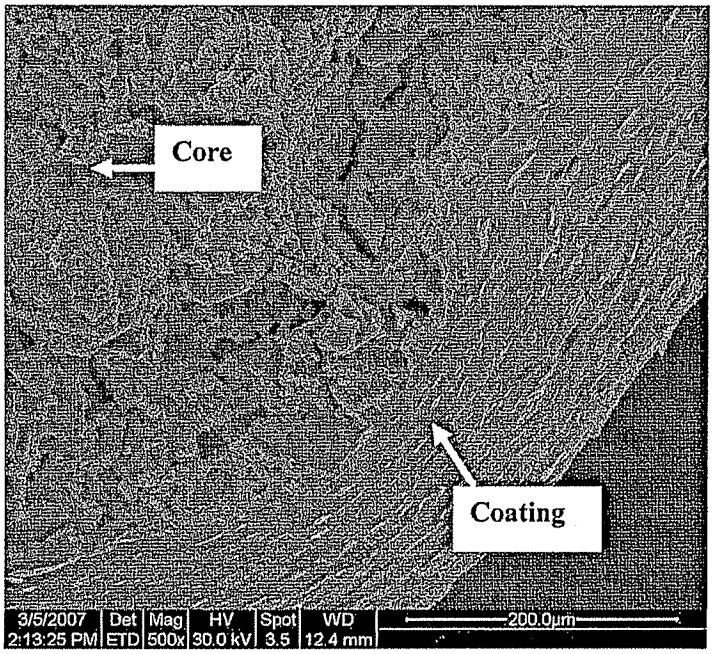
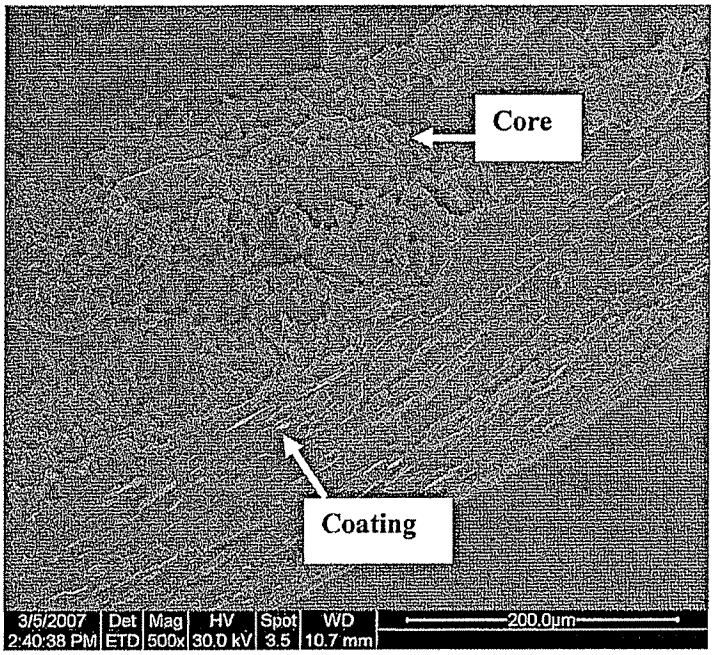


Fig 11: The Dexcel Tablet after exposure to artificial gastric juice at 37° C for 120 min (500X and 1000X magnification)



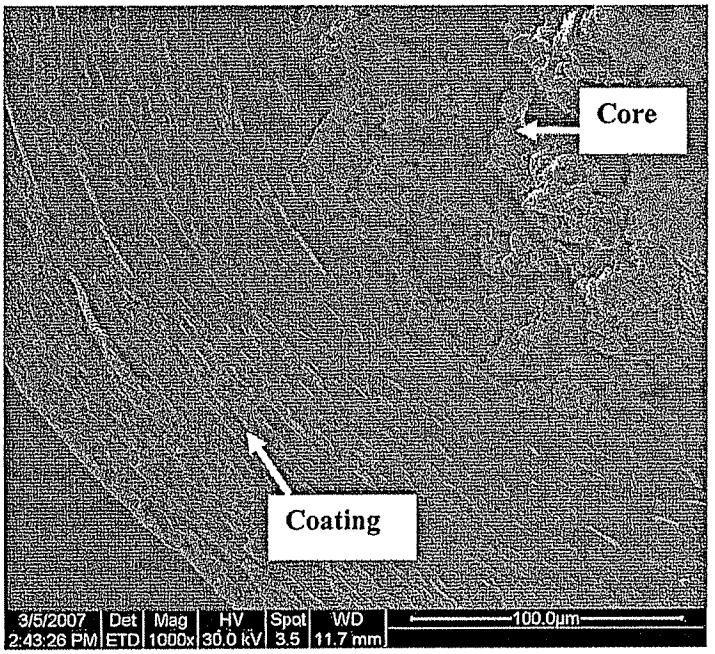
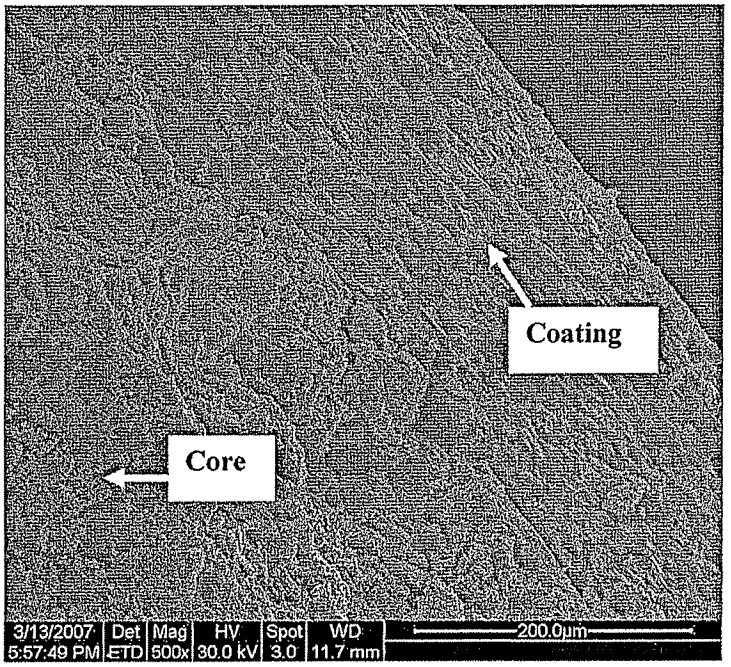


Fig 12: The comparative un-neutralized omeprazole tablet after exposure to artificial gastric juice at 37° C for 60 min (500X and 1000X magnification)



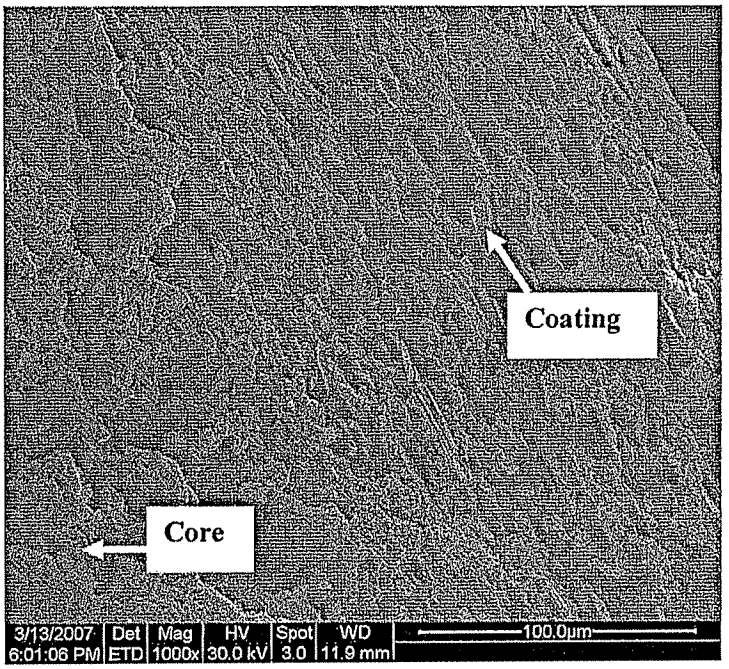
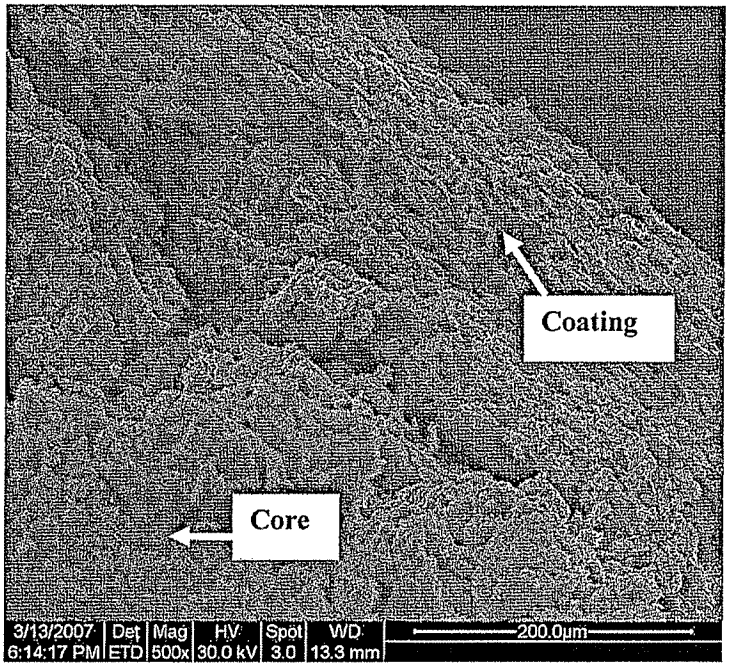
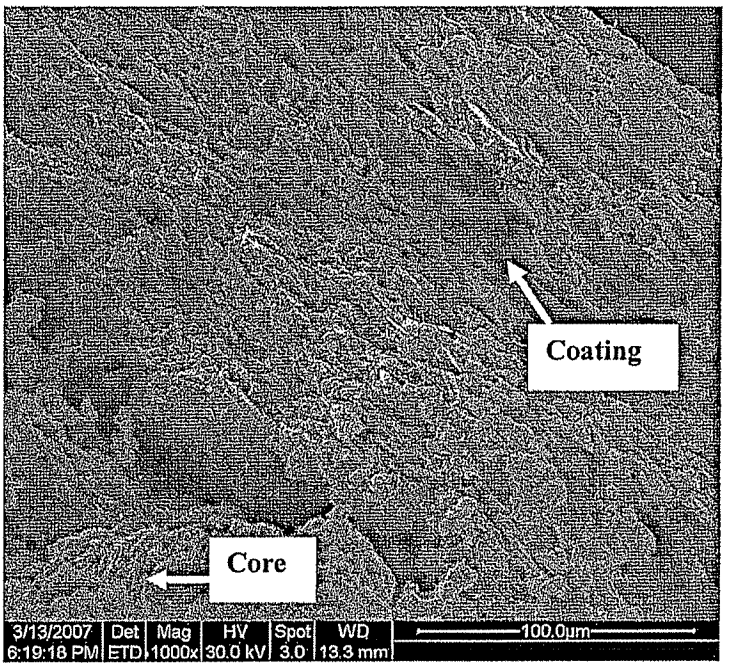


Fig 13: The comparative un-neutralized omeprazole tablet after exposure to artificial gastric juice at 37° C for 120 min (500X and 1000X magnification)





Conclusion Regarding Non-Formation of Additional Coating After Ingestion

31. Based upon the experiments described above, it is my opinion that the Dexcel Tablets, after exposure to gastric juice, do not form any additional coating layer and indeed remain in substantially the same form as they existed prior to such exposure. Thus, both before and after exposure to gastric juice such as the stomach environment, the Dexcel Tablets have a core and an enteric coating layer and do not have an additional subcoating.

Miscellaneous Statements

32. This report is based on my present assessment of material and information currently available to me. My investigation and assessment may continue, which may include review of documents and other information (e.g., oral information, deposition transcripts, tapes, and live testimony, testimony at trial in this or related actions, and other information) that may yet be produced to me, and I reserve the right to continue my study in connection with this matter. Accordingly, I expressly reserve the right to continue this investigation, and I may expand or modify my opinions and conclusions as my investigation continues. I also reserve the right to supplement my opinions in response to any additional material or information made available to me, such as issues addressed by plaintiffs or their experts, and/or any other opinions or reports provided to me. I also reserve the right to prepare charts, graphics, etc. to further illustrate my testimony.

Respectfully Submitted,

Abraham J. Domb

Date March 22, 2007

Abraham J. Domb, Ph.D.

EXHIBIT 31

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March 23, 2007

VIA ELECTRONIC MAIL

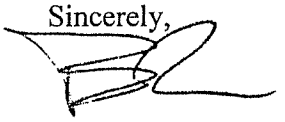
Robert F. Green, Esq.
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

Re: *AstraZeneca AB et al. v. Dexcel Ltd., et al.*, No. 06-358 (SLR) (D. Del.)

Dear Bob:

We received a letter today from Caryn Borg-Breen asking what day next week AstraZeneca intends to take the deposition of Dr. Domb. This letter does not make any sense. AstraZeneca will not be in a position to take Dr. Domb's deposition next week for a number of obvious reasons. AstraZeneca has not received any of the materials considered by Dr. Domb, or had an opportunity to consult with its own experts. Please let us know when we can expect to receive all of the materials considered by Dr. Domb in preparing his expert report, including, for example, all laboratory notebooks, paper and electronic data, and correspondence with Dexcel and its counsel regarding the preparation of the report. Once we have received this material, we will be in a position to begin consultations with AstraZeneca's outside experts. After we have had an adequate time to consult with AstraZeneca's experts, we expect to be in a position to schedule Dr. Domb's deposition at a mutually convenient time.

Sincerely,



Robert J. Koch

cc: David M. Airan, Esq.
Saumil Mehta, Esq.
Edgar H. Haug, Esq.
Richard D. Kirk, Esq.
Jack Blumenfeld, Esq.

EXHIBIT 32

Percent of Patients with Adverse Events in Controlled Trials* of PLENDIL (N=861) as Monotherapy without Regard to Causality (Incidence of discontinuations shown in parentheses)

ystem e Events	Placebo N=334	2.5 mg N=255	5 mg N=581	10 mg N=408
s a Whole				
eral Edema	3.3 (0.0)	2.0 (0.0)	8.8 (2.2)	17.4 (2.5)
ia	3.3 (0.0)	3.9 (0.0)	3.3 (0.0)	2.2 (0.0)
Sensation	0.0 (0.0)	0.0 (0.0)	0.9 (0.2)	1.5 (0.0)
vascular				
ition	2.4 (0.0)	0.4 (0.0)	1.4 (0.3)	2.5 (0.5)
ive				
	1.5 (0.9)	1.2 (0.0)	1.7 (0.3)	1.0 (0.7)
	1.2 (0.0)	3.9 (0.0)	0.7 (0.0)	0.5 (0.0)
sia	0.9 (0.0)	1.2 (0.0)	0.3 (0.0)	1.5 (0.2)
pation				
	10.2 (0.9)	10.6 (0.4)	11.0 (1.7)	14.7 (2.0)
che	2.7 (0.3)	2.7 (0.0)	3.6 (0.5)	3.7 (0.5)
	1.5 (0.3)	1.6 (0.0)	1.2 (0.0)	1.2 (0.2)
nesia				
atory				
Respiratory				
	1.8 (0.0)	3.9 (0.0)	1.9 (0.0)	0.7 (0.0)
	0.3 (0.0)	0.8 (0.0)	1.2 (0.0)	1.7 (0.0)
rhea	0.0 (0.0)	1.6 (0.0)	0.2 (0.0)	0.2 (0.0)
	0.0 (0.0)	1.6 (0.0)	0.0 (0.0)	0.0 (0.0)
	0.9 (0.0)	2.0 (0.0)	0.2 (0.0)	0.2 (0.0)
	0.9 (0.3)	3.9 (0.0)	5.3 (0.7)	6.9 (1.2)

nts in titration studies may have been exposed to more than one dose level of PLENDIL.

DOSAGE

ses of 240 mg/kg and 264 mg/kg in male and female spectively and 2390 mg/kg and 2250 mg/kg in male male rats, respectively, caused significant lethality.

icide attempt, one patient took 150 mg felodipine to- with 15 tablets each of atenolol and spironolactone tablets of nitrazepam. The patient's blood pressure art rate were normal on admission to hospital; he uently recovered without significant sequelae.

age might be expected to cause excessive peripheral lation with marked hypotension and possibly brady-

e hypotension occurs, symptomatic treatment should tinued. The patient should be placed supine with the pated. The administration of intravenous fluids may ul to treat hypotension due to overdosage with cal- ntagonists. In case of accompanying bradycardia, at- (0.5–1 mg) should be administered intravenously. hnommetic drugs may also be given if the physician ney are warranted.

not been established whether felodipine can be re- from the circulation by hemodialysis.

GE AND ADMINISTRATION

commended starting dose is 5 mg once a day. Depend- the patient's response the dosage can be decreased to or increased to 10 mg once a day. These adjustments occur generally at intervals of not less than two The recommended dosage range is 2.5–10 mg once inical trials, doses above 10 mg daily showed an ed blood pressure response but a large increase in the peripheral edema and other vasodilatory adverse (see ADVERSE REACTIONS). Modification of the mended dosage is usually not required in patients with mpairment.

DIL should be swallowed whole and not crushed or

The Elderly or Patients with Impaired Liver Function: r 65 years of age or patients with impaired liver ay develop higher plasma concentrations of refore a starting dose of 2.5 mg once a day is mended. Dosage may be adjusted as described above.

PRECAUTIONS

HOW SUPPLIED

Tablets PLENDIL 2.5 mg, are sage green, round with code 450 on one side and DIL on the other. They are supplied as follows:
NDC 61113-452-28 unit dose packages of 100
NDC 61113-452-58 unit of use bottles of 100
NDC 61113-452-31 unit of use bottles of 30.

Tablets PLENDIL 5 mg, are light red-brown, round with code 451 on one side and DIL on the other. They are supplied as follows:
NDC 61113-451-28 unit dose packages of 100
NDC 61113-451-68 5 mg individually sealed 100's)
NDC 61113-451-58 unit of use bottles of 100
NDC 61113-451-55 5 mg 100's)
NDC 61113-451-31 unit of use bottles of 30

No. 3586—Tablets PLENDIL 10 mg, are red-brown, round convex tablets, with code 452 on one side and PLENDIL on the other. They are supplied as follows:
NDC 61113-452-28 unit dose packages of 100 (6505-01-350-0353, 10 mg individually sealed 100's)
NDC 61113-452-58 unit of use bottles of 100 (6505-01-350-0355, 10 mg 100's).
NDC 61113-452-31 unit of use bottles of 30 (6505-01-350-0357, 10 mg 30's).

Storage

Store below 30°C (86°F). Keep container tightly closed. Protect from light.

Dist by
ASTRA MERCK
Wayne, PA 19087, USA
Manufactured by: MERCK & CO., INC., West Point, PA 19486, USA

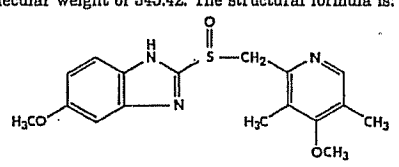
Issued July 1995 7909008

Shown in Product Identification Guide, page 304

PRILOSEC® Rx
(OMEPRAZOLE)
Delayed-Release Capsules

DESCRIPTION

The active ingredient in PRILOSEC* (Omeprazole) Delayed-Release Capsules is a substituted benzimidazole, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1*H*-benzimidazole, a compound that inhibits gastric acid secretion. Its empirical formula is $C_{17}H_{19}N_3O_3S$, with a molecular weight of 345.42. The structural formula is:



Omeprazole is a white to off-white crystalline powder which melts with decomposition at about 155°C. It is a weak base, freely soluble in ethanol and methanol, and slightly soluble in acetone and isopropanol and very slightly soluble in water. The stability of omeprazole is a function of pH; it is rapidly degraded in acid media, but has acceptable stability under alkaline conditions.

PRILOSEC is supplied as delayed-release capsules for oral administration. Each delayed-release capsule contains 20 mg of omeprazole in the form of enteric-coated granules with the following inactive ingredients: cellulose, disodium hydrogen phosphate, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, mannitol, sodium lauryl sulfate and other ingredients. The capsule shell has the following inactive ingredients: gelatin, FD&C Blue #1, FD&C Red #40, titanium dioxide, synthetic black iron oxide, isopropanol, butyl alcohol, FD&C Blue #2, and D&C Red #7 Calcium Lake.

*Registered trademark of AB Astra

CLINICAL PHARMACOLOGY

Pharmacokinetics and Metabolism

PRILOSEC Delayed-Release Capsules contain an enteric-coated granule formulation of omeprazole (because omeprazole is acid-labile), so that absorption of omeprazole begins only after the granules leave the stomach. Absorption is rapid, with peak plasma levels of omeprazole occurring within 0.5 to 3.5 hours. Peak plasma concentrations of omeprazole and AUC are approximately proportional to doses up to 40 mg, but because of a saturable first-pass effect, a greater than linear response in peak plasma concentration and AUC occurs with doses greater than 40 mg. Absolute bioavailability (compared to intravenous administration) is about 30–40% at doses of 20–40 mg, due in large part to presystemic metabolism. In healthy subjects the plasma half-life is 0.5 to 1 hour, and the total body clearance is 500–600 mL/min. Protein binding is approximately 95%.

The bioavailability of omeprazole increases slightly upon repeated administration of PRILOSEC Delayed-Release Capsules.

Following single dose oral administration of a buffered solution of omeprazole, little if any unchanged drug was excreted in urine. The majority of the dose (about 77%) was eliminated in urine as at least six metabolites. Two were identified as hydroxyomeprazole and the corresponding carboxylic acid. The remainder of the dose was recoverable in feces. This implies a significant biliary excretion of the metabolites of omeprazole. Three metabolites have been identified in plasma—the sulfide and sulfone derivatives of omeprazole, and hydroxyomeprazole. These metabolites have very little or no antisecretory activity.

In patients with chronic hepatic disease, the bioavailability increased to approximately 100% compared to an I.V. dose, reflecting decreased first-pass effect, and the plasma half-life of the drug increased to nearly 3 hours compared to the half-life in normals of 0.5–1 hour. Plasma clearance averaged 70 mL/min, compared to a value of 500–600 mL/min in normal subjects.

In patients with chronic renal impairment, whose creatinine clearance ranged between 10 and 62 mL/min/1.73 m^2, the disposition of omeprazole was very similar to that in healthy volunteers, although there was a slight increase in bioavailability. Because urinary excretion is a primary route of excretion of omeprazole metabolites, their elimination slowed in proportion to the decreased creatinine clearance.

The elimination rate of omeprazole was somewhat decreased in the elderly, and bioavailability was increased. Omeprazole was 76% bioavailable when a single 40 mg oral dose of omeprazole (buffered solution) was administered to healthy elderly volunteers, versus 58% in young volunteers given the same dose. Nearly 70% of the dose was recovered in urine as metabolites of omeprazole and no unchanged drug was detected. The plasma clearance of omeprazole was 250 mL/min (about half that of young volunteers) and its plasma half-life averaged one hour, about twice that of young healthy volunteers.

In pharmacokinetic studies of single 20 mg omeprazole doses, an increase in AUC of approximately four-fold was noted in Asian subjects compared to Caucasians.

Dose adjustment, particularly where maintenance of healing of erosive esophagitis is indicated, for the hepatically impaired and Asian subjects should be considered.

Pharmacodynamics

Mechanism of Action

Omeprazole belongs to a new class of antisecretory compounds, the substituted benzimidazoles, that do not exhibit anticholinergic or H_2 histamine antagonistic properties, but that suppress gastric acid secretion by specific inhibition of the H^+/K^+ ATPase enzyme system at the secretory surface of the gastric parietal cell. Because this enzyme system is regarded as the acid (proton) pump within the gastric mucosa, omeprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus. Animal studies indicate that after rapid disappearance from plasma, omeprazole can be found within the gastric mucosa for a day or more.

Antisecretory Activity

After oral administration, the onset of the antisecretory effect of omeprazole occurs within one hour, with the maximum effect occurring within two hours. Inhibition of secretion is about 50% of maximum at 24 hours and the duration of inhibition lasts up to 72 hours. The antisecretory effect thus lasts far longer than would be expected from the very short (less than one hour) plasma half-life, apparently due to prolonged binding to the parietal H^+/K^+ ATPase enzyme. When the drug is discontinued, secretory activity returns gradually, over 3 to 5 days. The inhibitory effect of omeprazole on acid secretion increases with repeated once-daily dosing, reaching a plateau after four days.

Results from numerous studies of the antisecretory effect of multiple doses of 20 mg and 40 mg of omeprazole in normal

Continued on next page

Astra/Merck—Cont.

volunteers and patients are shown below. The "max" value represents determinations at a time of maximum effect (2–6 hours after dosing), while "min" values are those 24 hours after the last dose of omeprazole.

Range of Mean Values from Multiple Studies of the Mean Antisecretory Effects of Omeprazole After Multiple Daily Dosing

Parameter	Omeprazole 20 mg		Omeprazole 40 mg	
	Max	Min	Max	Min
% Decrease in Basal Acid Output	78*	58–80	94*	80–93
% Decrease in Peak Acid Output	79*	50–59	88*	62–68
% Decrease in 24-hr. Intragastric Acidity		80–97		92–94

*Single Studies

Single daily oral doses of omeprazole ranging from a dose of 10 mg to 40 mg have produced 100% inhibition of 24-hour intragastric acidity in some patients.

Enterochromaffin-like (ECL) Cell Effects

In 24-month carcinogenicity studies in rats, a dose-related significant increase in gastric carcinoid tumors and ECL cell hyperplasia was observed in both male and female animals (see PRECAUTIONS, *Carcinogenesis, Mutagenesis, Impairment of Fertility*). Hypergastrinemia secondary to prolonged and sustained hypochlorhydria has been postulated to be the mechanism by which ECL cell hyperplasia and gastric carcinoid tumors develop. Omeprazole may also affect other cells in the gastrointestinal tract (e.g., G cells), either directly or by inducing sustained hypochlorhydria, but this possibility has not been extensively studied.

Human gastric biopsy specimens from about 200 patients treated continuously with omeprazole for an average of over 12 months have not detected ECL cell effects of omeprazole similar to those seen in rats. Longer term data are needed to rule out the possibility of an increased risk for the development of gastric tumors in patients receiving long-term therapy with omeprazole.

Serum Gastrin Effects

In studies involving more than 200 patients, serum gastrin levels increased during the first 1 to 2 weeks of once-daily administration of therapeutic doses of omeprazole in parallel with inhibition of acid secretion. No further increase in serum gastrin occurred with continued treatment. In comparison with histamine H_2-receptor antagonists, the median increases produced by 20 mg doses of omeprazole were higher (1.3 to 3.6 fold vs. 1.1 to 1.8 fold increase). Gastrin values returned to pretreatment levels, usually within 1 to 2 weeks after discontinuation of therapy.

Other Effects

Systemic effects of omeprazole in the CNS, cardiovascular and respiratory systems have not been found to date. Omeprazole, given in oral doses of 30 or 40 mg for 2 to 4 weeks, had no effect on thyroid function, carbohydrate metabolism, or circulating levels of parathyroid hormone, cortisol, estradiol, testosterone, prolactin, cholecystokinin or secretin.

No effect on gastric emptying of the solid and liquid components of a test meal was demonstrated after a single dose of omeprazole 90 mg. In healthy subjects, a single I.V. dose of omeprazole (0.35 mg/kg) had no effect on intrinsic factor secretion. No systematic dose-dependent effect has been observed on basal or stimulated pepsin output in humans. However, when intragastric pH is maintained at 4.0 or above, basal pepsin output is low, and pepsin activity is decreased.

As do other agents that elevate intragastric pH, omeprazole administered for 14 days in healthy subjects produced a significant increase in the intragastric concentrations of viable bacteria. The pattern of the bacterial species was unchanged from that commonly found in saliva. All changes resolved within three days of stopping treatment.

Clinical Studies

Duodenal Ulcer Disease

Active Duodenal Ulcer: In a multicenter, double-blind, placebo-controlled study of 147 patients with endoscopically documented duodenal ulcer, the percentage of patients healed (per protocol) at 2 and 4 weeks was significantly higher with PRILOSEC 20 mg once a day than with placebo ($p \leq 0.01$).

Treatment of Active Duodenal Ulcer
% of Patients Healed

	PRILOSEC 20 mg a.m. (n=99)	Placebo a.m. (n=48)
Week 2	*41	13
Week 4	*75	27

*($p \leq 0.01$)

Complete daytime and nighttime pain relief occurred significantly faster ($p \leq 0.01$) in patients treated with PRILOSEC 20 mg than in patients treated with placebo. At the end of the study, significantly more patients who had received PRILOSEC had complete relief of daytime pain ($p \leq 0.05$) and nighttime pain ($p \leq 0.01$).

In a multicenter, double-blind study of 293 patients with endoscopically documented duodenal ulcer, the percentage of patients healed (per protocol) at 4 weeks was significantly higher with PRILOSEC 20 mg once a day than with ranitidine 150 mg b.i.d. ($p < 0.01$).

Treatment of Active Duodenal Ulcer
% of Patients Healed

	PRILOSEC 20 mg a.m. (n=145)	Ranitidine 150 mg b.i.d. (n=148)
Week 2	42	34
Week 4	*82	63

*($p < 0.01$)

Healing occurred significantly faster in patients treated with PRILOSEC than in those treated with ranitidine 150 mg b.i.d. ($p < 0.01$).

In a foreign multinational randomized, double-blind study of 105 patients with endoscopically documented duodenal ulcer, 20 mg and 40 mg of PRILOSEC were compared to 150 mg b.i.d. of ranitidine at 2, 4 and 8 weeks. At 2 and 4 weeks both doses of PRILOSEC were statistically superior (per protocol) to ranitidine, but 40 mg was not superior to 20 mg of PRILOSEC, and at 8 weeks there was no significant difference between any of the active drugs.

Treatment of Active Duodenal Ulcer
% of Patients Healed

	PRILOSEC 20 mg (n=34)	PRILOSEC 40 mg (n=36)	Ranitidine 150 mg b.i.d. (n=35)
Week 2	* 83	* 83	53
Week 4	* 97	*100	82
Week 8	100	100	94

*($p \leq 0.01$)

Gastroesophageal Reflux Disease (GERD)

In a U.S. multicenter double-blind placebo controlled study of 20 mg or 40 mg of PRILOSEC Delayed-Release Capsules in patients with symptomatic esophagitis and endoscopically diagnosed erosive esophagitis of grade 2 or above, the percentage healing rates (per protocol) were as follows:

Week	20 mg PRILOSEC (n=83)	40 mg PRILOSEC (n=87)	Placebo (n=43)
4	39**	45**	7
8	74**	75**	14

**($p < 0.01$) PRILOSEC versus placebo.

In this study, the 40 mg dose was not superior to the 20 mg dose of PRILOSEC in the percentage healing rate. Other controlled clinical trials have also shown that PRILOSEC is effective in severe GERD. In comparisons with histamine H_2-receptor antagonists in patients with erosive esophagitis, grade 2 or above, PRILOSEC in a dose of 20 mg was significantly more effective than the active controls. Complete daytime and nighttime heartburn relief occurred significantly faster ($p < 0.01$) in patients treated with PRILOSEC than in those taking placebo or histamine H_2-receptor antagonists.

Long Term Maintenance Treatment of Erosive Esophagitis

In a U.S. double-blind, randomized, multicenter, placebo controlled study, two dose regimens of PRILOSEC were studied in patients with endoscopically confirmed healed esophagitis. Results to determine maintenance of healing of erosive esophagitis are shown below.

Life Table Analysis

	PRILOSEC 20 mg q.d. (n=138)	PRILOSEC 20 mg 3 days per week (n=137)	Placebo (n=131)
Percent in endoscopic remission at 6 months	*70	34	11

*($p < 0.01$) PRILOSEC 20 mg q.d. versus PRILOSEC 20 mg 3 consecutive days per week or placebo.

In an international multicenter double-blind study, PRILOSEC 20 mg daily and 10 mg daily were compared to ranitidine 150 mg twice daily in patients with endoscopically confirmed healed esophagitis. The table below provides the results of this study for maintenance of healing of erosive esophagitis.

Life Table Analysis

	PRILOSEC 20 mg q.d. (n=131)	PRILOSEC 10 mg q.d. (n=133)	Ranitidine 150 mg b.i.d. (n=128)
Percent in endoscopic remission at 12 months	*77	‡58	46

*($p=0.01$) PRILOSEC 20 mg q.d. versus PRILOSEC 10 mg q.d. or Ranitidine.

‡($p=0.03$) PRILOSEC 10 mg q.d. versus Ranitidine.

In patients who initially had grades 3 or 4 erosive esophagitis, for maintenance after healing 20 mg daily was effective, while 10 mg did not demonstrate efficacy.

Pathological Hypersecretory Conditions

In open studies of 136 patients with pathological hypersecretory conditions, such as Zollinger-Ellison (ZE) syndrome, with or without multiple endocrine adenomas (MEA), PRILOSEC Delayed-Release Capsules significantly inhibited gastric acid secretion and controlled associated symptoms of diarrhea, anorexia, and pain. Doses ranging from 20 mg per day to 360 mg per day maintained basal acid secretion below 10 mEq/hr in patients without prior gastric surgery and below 5 mEq/hr in patients with prior gastric surgery. Initial doses were titrated to the individual patient need; adjustments were necessary with time in some patients (see DOSAGE AND ADMINISTRATION). PRILOSEC was well tolerated at these high dose levels for prolonged periods (over 5 years in some patients). In most ZE patients, serum gastrin levels were not modified by PRILOSEC. However, in most patients serum gastrin increased to levels greater than those present prior to initiation of omeprazole therapy. All patients with ZE syndrome on long-term treatment with PRILOSEC developed gastric carcinoids. These findings are believed to be a manifestation of the underlying disease, which is known to be associated with such tumors, rather than the result of the administration of PRILOSEC (see ADVERSE REACTIONS.)

INDICATIONS AND USAGE

Short-Term Treatment of Active Duodenal Ulcer

PRILOSEC Delayed-Release Capsules are indicated for short-term treatment of active duodenal ulcer. Most will heal within four weeks. Some patients may require additional four weeks of therapy.

Gastroesophageal Reflux Disease (GERD)

Erosive Esophagitis

PRILOSEC Delayed-Release Capsules are indicated for short-term treatment (4–8 weeks) of erosive esophagitis which has been diagnosed by endoscopy (see CLINICAL PHARMACOLOGY, *Clinical Studies*).

Poorly Responsive Symptomatic GERD

PRILOSEC Delayed-Release Capsules are also indicated for the short-term treatment (4–8 weeks) of symptomatic gastroesophageal reflux disease (esophagitis) poorly responsive to customary medical treatment, usually including adequate course of a histamine H_2-receptor antagonist.

The efficacy of PRILOSEC used for longer than 8 weeks in these patients has not been established. In the rare instance of a patient not responding to 8 weeks of treatment, it may be helpful to give up to an additional 4 weeks of treatment. If there is recurrence of erosive esophagitis or symptoms of GERD poorly responsive to customary medical treatment, additional 4–8 week courses of omeprazole may be considered.

Maintenance of Healing of Erosive Esophagitis

PRILOSEC Delayed-Release Capsules are indicated to maintain healing of erosive esophagitis.

Controlled studies do not extend beyond 12 months.

Pathological Hypersecretory Conditions

PRILOSEC Delayed-Release Capsules are indicated for long-term treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple adenomas and systemic mastocytosis).

CONTRAINDICATIONS

PRILOSEC Delayed-Release Capsules are contraindicated in patients with known hypersensitivity to any component of the formulation.

PRECAUTIONS

General

Symptomatic response to therapy with omeprazole does not preclude the presence of gastric malignancy.

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole.

Information for Patients

PRILOSEC Delayed-Release Capsules should be taken before eating. Patients should be cautioned that the PRILOSEC Delayed-Release Capsule should not be opened, chewed, crushed, and should be swallowed whole.

Drug Interactions

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. Although in normal subjects no interaction with theophylline or propranolol was found, there have been clinical reports of interaction with other drugs metabolized

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...cytochrome P-450 system (e.g., cyclosporine, disulfiram, ...benzodiazepines). Patients should be monitored to determine ...necessary to adjust the dosage of these drugs when ...concomitantly with PRILOSEC.

...of its profound and long lasting inhibition of gastric ...secretion, it is theoretically possible that omeprazole ...interfere with absorption of drugs where gastric pH is ...important determinant of their bioavailability (e.g., ...ampicillin esters, and iron salts). In the clini... ...antacids were used concomitantly with the admin... ...of PRILOSEC.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In two 24-month carcinogenicity studies in rats, omeprazole at daily doses of 1.7, 3.4, 13.8, 44.0 and 140.8 mg/kg/day (approximately 4 to 352 times the human dose, based on a patient weight of 50 kg and a human dose of 20 mg) produced gastric ECL cell carcinoids in a dose-related manner in both male and female rats; the incidence of this effect was markedly higher in female rats, which had higher blood levels of omeprazole. Gastric carcinoids seldom occur in the untreated rat. In addition, ECL cell hyperplasia was present in all treated groups of both sexes. In one of these studies, female rats were treated with 13.8 mg omeprazole/kg/day (approximately 35 times the human dose) for one year, then followed for an additional year without the drug. No carcinoids were seen in these rats. An increased incidence of treatment-related ECL cell hyperplasia was observed at the end of one year (94% treated vs 10% controls). By the second year the difference between treated and control rats was much smaller (46% vs 26%) but still showed more hyperplasia in the treated group. An unusual primary malignant tumor in the stomach was seen in one rat (2%). No similar tumor was seen in male or female rats treated for two years. For this strain of rat no similar tumor has been noted historically but a finding involving only one tumor is difficult to interpret. A 78-week mouse carcinogenicity study of omeprazole did not show increased tumor occurrence, but the study was not conclusive.

Omeprazole was not mutagenic in an *in vitro* Ames *Salmonella typhimurium* assay, an *in vitro* mouse lymphoma cell assay and an *in vivo* rat liver DNA damage assay. A mouse micronucleus test at 625 and 6250 times the human dose and a borderline result, as did an *in vivo* bone marrow chromosome aberration test. A second mouse micronucleus study at 2000 times the human dose, but with different (suboptimal) sampling times, was negative.

In a rat fertility and general reproductive performance test, omeprazole in a dose range of 13.8 to 138.0 mg/kg/day (approximately 35 to 345 times the human dose) was not toxic or deleterious to the reproductive performance of parental animals.

Pregnancy

Pregnancy Category C

Teratology studies conducted in pregnant rats at doses up to 138 mg/kg/day (approximately 345 times the human dose) and in pregnant rabbits at doses up to 69 mg/kg/day (approximately 172 times the human dose) did not disclose any evidence for a teratogenic potential of omeprazole.

In rabbits, omeprazole in a dose range of 6.9 to 69.1 mg/kg/day (approximately 17 to 172 times the human dose) produced dose-related increases in embryo-lethality, fetal resorptions, and pregnancy disruptions. In rats, dose-related embryo/fetal toxicity and postnatal developmental toxicity were observed in offspring resulting from parents treated with omeprazole 13.8 to 138.0 mg/kg/day (approximately 35 to 345 times the human dose). There are no adequate or well-controlled studies in pregnant women. Sporadic reports have been received of congenital abnormalities occurring in infants born to women who have received omeprazole during pregnancy. Omeprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether omeprazole is excreted in human milk. In rats, omeprazole administration during late gestation and lactation at doses of 13.8 to 138 mg/kg/day (35 to 345 times the human dose) resulted in decreased weight gain in pups. Because many drugs are excreted in human milk, because of the potential for serious adverse reactions in nursing infants from omeprazole, and because of the potential for tumorigenicity shown for omeprazole in rat carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

PRILOSEC Delayed-Release Capsules were generally well tolerated during domestic and international clinical trials in 3096 patients.

In the U.S. clinical trial population of 465 patients (including duodenal ulcer, Zollinger-Ellison syndrome and resistant ulcer patients), the following adverse experiences were reported to occur in 1% or more of patients on therapy with PRILOSEC. Numbers in parentheses indicate percentages of the adverse experiences considered by investigators as possibly, probably or definitely related to the drug:

	Omeprazole (n = 465)	Placebo (n = 64)	Ranitidine (n = 195)
Headache	6.9 (2.4)	6.3	7.7 (2.6)
Diarrhea	3.0 (1.9)	3.1 (1.6)	2.1 (0.5)
Abdominal Pain	2.4 (0.4)	3.1	2.1
Nausea	2.2 (0.9)	3.1	4.1 (0.5)
URI	1.9	1.6	2.6
Dizziness	1.5 (0.6)	0.0	2.6 (1.0)
Vomiting	1.5 (0.4)	4.7	1.5 (0.5)
Rash	1.5 (1.1)	0.0	0.0
Constipation	1.1 (0.9)	0.0	0.0
Cough	1.1	0.0	1.5
Asthenia	1.1 (0.2)	1.6 (1.6)	1.5 (1.0)
Back Pain	1.1	0.0	0.5

The following adverse reactions which occurred in 1% or more of omeprazole-treated patients have been reported in international double-blind, and open-label, clinical trials in which 2,631 patients and subjects received omeprazole.

	Incidence of Adverse [Experiences] ≥ 1%, Causal Relationship not Assessed]	
	Omeprazole (n = 2631)	Placebo (n = 120)
Body as a Whole, site unspecified		
Abdominal pain	5.2	3.3
Asthenia	1.3	0.8
Digestive System		
Constipation	1.5	0.8
Diarrhea	3.7	2.5
Flatulence	2.7	5.8
Nausea	4.0	6.7
Vomiting	3.2	10.0
Acid regurgitation	1.9	3.3
Nervous System/Psychiatric		
Headache	2.9	2.5

Additional adverse experiences occurring in <1% of patients or subjects in domestic and/or international trials, or occurring since the drug was marketed, are shown below within each body system. In many instances, the relationship to PRILOSEC was unclear.

Body As a Whole: Fever, pain, fatigue, malaise, abdominal swelling

Cardiovascular: Chest pain or angina, tachycardia, bradycardia, palpitation, elevated blood pressure, peripheral edema

Gastrointestinal: Pancreatitis (some fatal), anorexia, irritable colon, flatulence, fecal discoloration, esophageal candidiasis, mucosal atrophy of the tongue, dry mouth. During treatment with omeprazole, gastric fundic gland polyps have been noted rarely. These polyps are benign and appear to be reversible when treatment is discontinued.

Gastro-duodenal carcinoids have been reported in patients with ZE syndrome on long-term treatment with PRILOSEC. This finding is believed to be a manifestation of the underlying condition, which is known to be associated with such tumors.

Hepatic: Mild and, rarely, marked elevations of liver function tests [ALT (SGPT), AST (SGOT), γ-glutamyl transpeptidase, alkaline phosphatase, and bilirubin (jaundice)]. In rare instances, overt liver disease has occurred, including hepatocellular, cholestatic, or mixed hepatitis, liver necrosis (some fatal), hepatic failure (some fatal), and hepatic encephalopathy.

Metabolic/Nutritional: Hypoglycemia, weight gain

Musculoskeletal: Muscle cramps, myalgia, muscle weakness, joint pain, leg pain

Nervous System/Psychiatric: Psychic disturbances including depression, aggression, hallucinations, confusion, insomnia, nervousness, tremors, apathy, somnolence, anxiety, dream abnormalities; vertigo; paresthesia; hemifacial dysesthesia

Respiratory: Epistaxis, pharyngeal pain

Skin: Rash and, very rarely, cases of severe generalized skin reactions including toxic epidermal necrolysis (TEN; some fatal), Stevens-Johnson syndrome, and erythema multiforme (some severe); skin inflammation, urticaria, angioedema, pruritus, alopecia, dry skin, hyperhidrosis

Special Senses: Tinnitus, taste perversion

Urogenital: Interstitial nephritis (some with positive rechallenge), urinary tract infection, microscopic pyuria, urinary frequency, elevated serum creatinine, proteinuria, hematuria, glycosuria, testicular pain, gynecomastia

Hematologic: Rare instances of pancytopenia, agranulocytosis (some fatal), thrombocytopenia, neutropenia, anemia, leucocytosis, and hemolytic anemia have been reported.

The incidence of clinical adverse experiences in patients greater than 65 years of age was similar to that in patients 65 years of age or less.

OVERDOSAGE

There is no experience to date with deliberate overdosage. Dosages of up to 360 mg/day have been well tolerated. No specific antidote is known. Omeprazole is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

Lethal doses of omeprazole after single oral administration are about 1500 mg/kg in mice and greater than 4000 mg/kg in rats, and about 100 mg/kg in mice and greater than 40 mg/kg in rats given single intravenous injections. Animals given these doses showed sedation, ptosis, convulsions, and decreased activity, body temperature, and respiratory rate and increased depth of respiration.

DOSAGE AND ADMINISTRATION

Short-Term Treatment of Active Duodenal Ulcer

The recommended adult oral dose is 20 mg once daily. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy. (See INDICATIONS AND USAGE.)

Erosive Esophagitis or Poorly Responsive Gastroesophageal Reflux Disease (GERD)

The recommended adult oral dose is 20 mg daily for 4 to 8 weeks (see INDICATIONS AND USAGE).

Maintenance of Healing of Erosive Esophagitis

The recommended adult oral dose is 20 mg daily. (See CLINICAL PHARMACOLOGY, Clinical Studies.)

Pathological Hypersecretory Conditions

The dosage of PRILOSEC in patients with pathological hypersecretory conditions varies with the individual patient. The recommended adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 120 mg t.i.d. have been administered. Daily dosages of greater than 80 mg should be administered in divided doses. Some patients with Zollinger-Ellison syndrome have been treated continuously with PRILOSEC for more than 5 years.

No dosage adjustment is necessary for patients with renal impairment, hepatic dysfunction or for the elderly.

PRILOSEC Delayed-Release Capsules should be taken before eating. In the clinical trials, antacids were used concomitantly with PRILOSEC.

Patients should be cautioned that the PRILOSEC Delayed-Release Capsule should not be opened, chewed or crushed, and should be swallowed whole.

HOW SUPPLIED

No. 3440—PRILOSEC Delayed-Release Capsules, 20 mg, are opaque, hard gelatin, amethyst colored capsules, coded 742 on cap and PRILOSEC 20 on body. They are supplied as follows:

NDC 61113-742-31 unit of use bottles of 30
(6505-01-314-2716, 20 mg 30's)
NDC 61113-742-28 unit dose package of 100
(6505-01-314-2717, 20 mg individually sealed 100's)
NDC 61113-742-82 bottles of 1000.

Storage

Store PRILOSEC Delayed-Release Capsules in a tight container protected from light and moisture. Store between 15°C and 30°C (59°F and 86°F).

Dist. by
ASTRA MERCK
Wayne, PA 19087, USA
Manufactured by:
MERCK & CO., INC., 7910916
West Point, PA 19486, USA *Issued June 1995*

Shown in Product Identification Guide, page 304

TONOCARD® Tablets
(Tocainide HCl)

℞

WARNINGS

Blood Dyscrasias: Agranulocytosis, bone marrow depression, leukopenia, neutropenia, aplastic/hypoplastic

Continued on next page

EXHIBIT 33

Affidavit of Process Server

AstraZeneca AB, et al. vs DEXCEL Ltd., et al. 06-358

PLAINTIFF/PETITIONER DEFENDANT/RESPONDENT CASE #

Being duly sworn, on my oath, I James Reap, declare that I am a citizen of the United States, over the age of eighteen and not a party to this action.

Service: I served Merck & Co. NAME OF PERSON/ENTITY BEING SERVED

with the (documents) ☒ Subpoena with $ 45- witness fee and mileage

☐ _____

by serving (NAME) Merck & Co., Inc.

at ☐ Home _____

☒ Business 1 Merck Drive Whitehouse Station, NJ 08889

☒ on (DATE) 1/26/07 at (TIME) 2:03pm

Thereafter copies of the documents were mailed by prepaid, first class mail on (DATE) _____

from (CITY) _____ (STATE) _____

Manner of Service:

☐ By Personal Service.

☒ By leaving, during office hours, copies at the office of the person/entity being served, leaving same with the person apparently in charge thereof,

namely Joan Dearborn, Admin. Asst.

☐ By leaving a copy at the defendant's usual place of abode, with some person of the family or a person residing there, of the age of 13 years or upwards, and informing that person of the general nature of the papers,

namely _____

☐ By posting copies in a conspicuous manner to the address of the person/entity being served.

Non-Service: After due search, careful inquiry and diligent attempts at the address(es) listed above, I have been unable to effect process upon the person/entity being served because of the following reason(s):

☐ Unknown at Address ☐ Evading ☐ Other: _____

☐ Address Does Not Exist ☐ Service Cancelled by Litigant

☐ Moved, Left no Forwarding ☐ Unable to Serve in a Timely Fashion

Service Attempts: Service was attempted on: ( ) _____ DATE TIME, ( ) _____ DATE TIME,

( ) _____ DATE TIME, ( ) _____ DATE TIME, ( ) _____ DATE TIME

Description:

☐ Male	☒ White Skin	☐ Black Hair	☐ White Hair	☐ 14-20 Yrs.	☐ Under 5'	☐ Under 100 Lbs.
☒ Female	☐ Black Skin	☒ Brown Hair	☐ Balding	☐ 21-35 Yrs.	☐ 5'0"-5'3"	☐ 100-130 Lbs.
	☐ Yellow Skin	☐ Blond Hair		☒ 36-50 Yrs.	☒ 5'4"-5'8"	☒ 131-160 Lbs.
	☐ Brown Skin	☐ Gray Hair	☐ Mustache	☐ 51-65 Yrs.	☐ 5'9"-6'0"	☐ 161-200 Lbs.
☒ Glasses	☐ Red Skin	☐ Red Hair	☐ Beard	☐ Over 65 Yrs.	☐ Over 6'	☐ Over 200 Lbs.

OTHER IDENTIFYING FEATURES: _____

State of ~~Illinois~~ New Jersey County of ~~Cook~~ Bergen

James Reap SERVED BY LASALLE PROCESS SERVERS

Subscribed and sworn to before me, a notary public, this 31st day of January, 2007

Donna Jean Arciuolo NOTARY PUBLIC

DONNA JEAN ARCIUOLO
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 11/27/07

Reyder

CHARTER MEMBER NATIONAL ASSOCIATION OF PROFESSIONAL PROCESS SERVERS.

AO88 (Rev. 12/06) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

DISTRICT OF New Jersey

AstraZeneca AB, et al., Plaintiffs

V.

Dexcel Ltd., et al., Defendants

SUBPOENA IN A CIVIL CASE

Case Number:[1] 06-358 (SLR) District of Delaware

TO: Merck & Co., Inc.,
One Merck Drive, White House Station, New Jersey 08889

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Hilton Newark Airport, 1170 Spring Street, Elizabeth, New Jersey, 07201-2114. (908) 351-3900. See Schedule B for Topics.	2/22/2007 9:00 am

☑ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

See Schedule A

PLACE	DATE AND TIME
Hilton Newark Airport, 1170 Spring Street, Elizabeth, New Jersey, 07201-2114. (908) 351-3900.	2/8/2007 9:00 am

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
	1-24-07

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Attorney for Defendants
Robert F. Green, 180 N. Stetson Ave., Suite 4900, Chicago, IL 60601 (312) 616-5600

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

AO88 (Rev. 12/06) Subpoena in a Civil Case

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), as amended on December 1, 2006:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises — or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) (A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

SCHEDULE A

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "AAIPharma" means AAIPharma Inc., AAIPharma LLC and their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DOCUMENT REQUESTS

1. Samples of each lot of Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

2. For each year starting with 1983 and ending in to 2007, a sample taken from a lot of omeprazole used to make Prilosec™ tablets in that year.

3. Representative samples of each lot of omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

4. All Raman spectra for each sample requested above in Requests 1-3.

5. All x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures, for each sample requested above in Requests 1-3.

6. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

7. All documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

8. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to the '380 patent.

9. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to Examples 1, 2, and 3 of the '380 patent.

10. All documents evidencing, referring or otherwise relating to any product or composition comprising omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-

dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sold or offered for sale in the United States prior to November 10, 1997.

11. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

12. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

13. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997, wherein the omeprazole was prepared by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

14. All documents evidencing, referring or otherwise relating to tautomerization of omeprazole, including but not limited to identification, characterization, purification, or isolation of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.

15. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

17. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

18. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

19. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

20. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-

methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

21. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

22. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

23. Representative samples of omeprazole Form A, including documents sufficient to establish the chain of custody of said omeprazole Form A.

24. Representative samples of omeprazole Form B, including documents sufficient to establish the chain of custody of said omeprazole Form B.

25. Representative samples of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

26. Representative samples of 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

27. Representative samples of each U.S. Pharmacopeia reference standards for omeprazole, including but not limited to any of omeprazole lots A-H.

28. All documents and things evidencing, referring, or otherwise relating to Drug Master File No. 14649, including but not limited to all supplements and amendments thereto.

29. All documents and things evidencing, referring, or otherwise relating to communications between Merck and the United States Food and Drug Administration concerning NDA No. 14649, including but not limited to all supplements and amendments thereof.

30. All documents evidencing, referring or otherwise relating to isomeric forms and relative amounts thereof, of omeprazole sold or offered for sale in the United States prior to November 10, 1997.

31. All documents evidencing, referring or otherwise relating to isomeric forms, and the relative amounts thereof, of omeprazole used to make any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997.

32. All documents evidencing, referring or otherwise relating to license agreements, negotiations relating to any such agreements or potential agreements, relating to omeprazole and AAIPharma.

SCHEDULE B

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "AAIPharma" means AAIPharma Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DEPOSITION TOPICS

1. All documents produced in response to Document Request Nos. 1-32 in Schedule A.

2. The identity of each lot of Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

3. The identity of each lot of omeprazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

4. The Raman spectra for each lot of omeprazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

5. The x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures, for each lot of omeprazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

6. The documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

7. The documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

8. The analyses undertaken and intended to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

9. All manufactures or attempts to manufacture omeprazole by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

10. The correlation of or attempts by Merck to correlate the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or the ratio of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole to 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, with Raman spectra or x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures.

11. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

12. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

13. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

14. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

15. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or

pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

17. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-

pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

18. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma. The nature and identity of analyses undertaken by AAIPharma and intended to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

EXHIBIT 34

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.	)	Civil Action No. 06-358 (SLR)
DEXCEL, LTD., DEXXON, LTD., DEXCEL PHARMA TECHNOLOGIES, LTD. and DEXCEL PHARMA TECHNOLOGIES LTD,	)	
Defendants.	)	

NOTICE OF FED.R.CIV.P. 30(b)(6) DEPOSITION *DUCES TECUM*
AND FED.R.CIV.P. 45 SERVICE OF SUBPOENA
(MERCK & CO., INC.)

TO:

Jack B. Blumenfeld, Esquire
Karen Jacobs Louden, Esquire
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899

Errol B. Taylor, Esquire
Robert J. Koch, Esquire
Jay I. Alexander, Esquire
Milbank, Tweed, Hadley & McCloy L.L.P.
1825 Eye Street, NW, Suite 1100
Washington, DC 20006

PLEASE TAKE NOTICE that defendant Dexcel Pharma Technologies, Ltd. will take the deposition *duces tecum* of Merck & Co., Inc. ("Merck") pursuant to Fed. R. Civ. P. 30(b)(6), on March 9, 2007 at 10:00 a.m. The deposition will take place at the offices of The Bayard Firm, 222 Delaware Avenue, Suite 900, Wilmington, Delaware 19801. The deposition will be videotaped and taken before a notary public or court reporter, duly authorized to administer oaths and transcribe the testimony of the deponent(s) and may use technology that permits the real time display of the deposition transcript for attendees who bring a compatible computer. The deposition may continue from day to day until completed if authorized by the Court or stipulated by the parties.

PLEASE ALSO TAKE NOTICE that defendant is serving Merck with a subpoena (the "Subpoena"), a copy of which is attached hereto. The subjects covered in the deposition will include (but are not limited to) the subjects listed on Attachment A to the Subpoena. Pursuant to Fed. R. Civ. P. 30(b)(6), Merck is required to designate one or more persons to testify at the deposition as to the matters known or reasonably available to Merck concerning all topics listed in Attachment A to the Subpoena. In addition, the Subpoena requires Merck to produce by March 7, 2007 the documents listed in Attachment B to the Subpoena.

You are invited to attend and cross examine.

February 21, 2007

THE BAYARD FIRM

/s/ Richard D. Kirk (rk0922)
Richard D. Kirk (#922)
Ashley B. Stitzer (#3891)
222 Delaware Avenue, Suite 900
Wilmington, DE 19899-5130
(302) 655-5000
Counsel for Defendants

OF COUNSEL:
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David M. Airan, Esquire
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Leydig, Voit & Mayer
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(312) 616-5000

Edgar H. Haug, Esquire
Dillon Kim, Esquire
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Michael F. Brockmeyer, Esquire
Elizabeth A. Leff, Esquire
Frommer Lawrence & Haug LLP
1667 K Street, NW
Washington, D.C. 20006
(202) 292-1530

Issued by 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 CIPLA, LTD., Defendants.	SUBPOENA IN A CIVIL CASE Case Number: 06-358-SLR

TO: Merck & Co., Inc.
c/o The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

☐ YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM / DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. **Pursuant to Fed.R.Civ.P. 30(b)(6), you must designate a witness or witnesses to testify on the subjects set forth in Schedule A attached hereto.**

PLACE OF DEPOSITION	DATE AND TIME
The Bayard Firm 222 Delaware Avenue, Suite 900 Wilmington, DE 19801	March 9, 2007, 10:00 a.m.

☒ YOU ARE COMMANDED to produce and permit inspection and copying of **the documents listed or described in Schedule B attached hereto** at the place, date, and time specified below.

PLACE OF PRODUCTION	DATE AND TIME
The Bayard Firm 222 Delaware Avenue, Suite 900 Wilmington, DE 19801	March 7, 2007, 10:00 a.m.

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
ATTORNEY FOR DEFENDANT DEXCEL PHARMA TECHNOLOGIES, LTD.	February 21, 2007

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER
Richard D. Kirk, The Bayard Firm
222 Delaware Avenue, P. O. Box 25130, Wilmington, DE 19899-5130,
(302)429-4208

652323-1

PROOF OF SERVICE

SERVED	DATE	PLACE

SERVED ON (PRINT NAME) | MANNER OF SERVICE

SERVED BY (PRINT NAME) | TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
SIGNATURE OF SERVER

_____

_____

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing under burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issues shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless command to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copying the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issues. If objection has been made, the part serving the subpoena may, upon notice of the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a part or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issues shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transactions business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the part in whose behalf the subpoena is issues shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assurances that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspondence with the categories in demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

SCHEDULE A

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "AAIPharma" means AAIPharma Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DEPOSITION TOPICS

1. All documents produced in response to Document Request Nos. 1-32 in Schedule B attached hereto.

2. The identity of each lot of Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

3. The identity of each lot of omeprazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

4. The Raman spectra for each lot of omeprazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

5. The x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures, for each lot of omeprazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

6. The documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

7. The documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

8. The analyses undertaken and intended to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

9. All manufactures or attempts to manufacture omeprazole by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

10. The correlation of or attempts by Merck to correlate the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or the ratio of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole to 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, with Raman spectra or x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures.

11. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

12. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

13. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

14. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

15. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or

pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

17. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-

pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

18. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma. The nature and identity of analyses undertaken by AAIPharma and intended to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

SCHEDULE B

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "AAIPharma" means AAIPharma Inc., AAIPharma LLC and their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DOCUMENT REQUESTS

1. Samples of each lot of Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

2. For each year starting with 1983 and ending in to 2007, a sample taken from a lot of omeprazole used to make Prilosec™ tablets in that year.

3. Representative samples of each lot of omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

4. All Raman spectra for each sample requested above in Requests 1-3.

5. All x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures, for each sample requested above in Requests 1-3.

6. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

7. All documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

8. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to the '380 patent.

9. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to Examples 1, 2, and 3 of the '380 patent.

10. All documents evidencing, referring or otherwise relating to any product or composition comprising omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-

dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sold or offered for sale in the United States prior to November 10, 1997.

11. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

12. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

13. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997, wherein the omeprazole was prepared by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

14. All documents evidencing, referring or otherwise relating to tautomerization of omeprazole, including but not limited to identification, characterization, purification, or isolation of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.

15. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

17. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

18. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

19. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

20. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-

methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

21. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

22. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

23. Representative samples of omeprazole Form A, including documents sufficient to establish the chain of custody of said omeprazole Form A.

24. Representative samples of omeprazole Form B, including documents sufficient to establish the chain of custody of said omeprazole Form B.

25. Representative samples of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

26. Representative samples of 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

27. Representative samples of each U.S. Pharmacopeia reference standards for omeprazole, including but not limited to any of omeprazole lots A-H.

28. All documents and things evidencing, referring, or otherwise relating to Drug Master File No. 14649, including but not limited to all supplements and amendments thereto.

29. All documents and things evidencing, referring, or otherwise relating to communications between Merck and the United States Food and Drug Administration concerning NDA No. 14649, including but not limited to all supplements and amendments thereof.

30. All documents evidencing, referring or otherwise relating to isomeric forms and relative amounts thereof, of omeprazole sold or offered for sale in the United States prior to November 10, 1997.

31. All documents evidencing, referring or otherwise relating to isomeric forms, and the relative amounts thereof, of omeprazole used to make any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997.

32. All documents evidencing, referring or otherwise relating to license agreements, negotiations relating to any such agreements or potential agreements, relating to omeprazole and AAIPharma.

CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on February 21, 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:

Jack B. Blumenfeld, Esq.
Karen Jacobs Louden, Esq.
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19801

The undersigned counsel further certifies that, on February 21, 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:

Errol B. Taylor, Esq.
Robert J. Koch, Esq.
Jay I. Alexander, Esq.
Enrique D. Longton, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street NW
Washington, DC 20006

/s/ Richard D. Kirk (rk0922)
Richard D. Kirk

EXHIBIT 35

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Astrazeneca AB, et al. *Plaintiffs*, v. Dexcel, Ltd. et al.,: *Defendants.*	**Case No. 06-358(SLR)** **Pending in U.S. Dist. Ct. D. Del.**

MERCK & CO., INC'S OBJECTIONS TO SUBPOENA

Merck & Co., Inc. ("Merck") objects to the document requests and deposition topics contained in the subpoena served by Defendants in the captioned matter as follows:

OBJECTIONS TO DOCUMENT REQUESTS

REQUEST NO. 1:

Samples of each lot of Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 1:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks samples of "each lot" of Prilosec™ sold or offered for sale in the United States prior to November 10, 1997. Merck is not a party to the captioned litigation. Merck further objects to this request as vague and ambiguous in that it does not further specify the nature or number of "samples" being requested.

REQUEST NO. 2:

For each year starting with 1983 and ending in to 2007, a sample taken from a lot of omeprazole used to make Prilosec™ tablets in that year.

OBJECTION TO REQUEST NO. 2:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks a sample taken from a lot of omeprazole used to make Prilosec™ tablets in each year from 1983 to 2007. Merck is not a party to the captioned litigation. Merck further objects to this request as vague and ambiguous in that it does not further specify the nature or number of "samples" being requested.

REQUEST NO. 3:

Representative samples of each lot of omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methlyl]sulfiny1]-1H-benzimidazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 3:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks samples of "each lot" of omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methlyl]sulfiny1]-1H-benzimidazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997. Merck is not a party to the captioned litigation. Merck further objects to this request as vague and ambiguous in that it does not further specify the nature or number of "samples" being requested.

REQUEST NO. 4:

All Raman spectra for each sample requested above in Requests 1-3.

OBJECTION TO REQUEST NO. 4:

Merck objects to this request as overly broad and unduly burdensome for the reasons stated with respect to Requests Nos. 1-3. Merck further objects to this request as vague and ambiguous in that it does not further specify the nature of the "Raman spectra" being sought and further objects to the request to the extent it appears to seek information not in the possession, custody or control of Merck.

REQUEST NO. 5:

All x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures, for each sample requested above in Requests 1-3.

OBJECTION TO REQUEST NO. 5:

Merck objects to this request as overly broad and unduly burdensome for the reasons stated with respect to Requests Nos. 1-3. Merck further objects to this request as vague and ambiguous in that it does not further specify the nature of the "x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures" being sought and further objects to the request to the extent it appears to seek information not in the possession, custody or control of Merck.

REQUEST NO. 6:

All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 6:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will

undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 7:

All documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 7:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 8:

All documents, notebook records, Infrared data, Raman Data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to the '380 patent.

OBJECTION TO REQUEST NO. 8:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents and other materials relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will

produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 9:

All documents, notebook records, Infrared data, Raman Data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to Examples 1, 2, and 3 of the '380 patent.

OBJECTION TO REQUEST NO. 9:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 10:

All documents evidencing, referring or otherwise relating to any product or composition comprising omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl)-1H-benzimidazole sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 10:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter

exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 11:

All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 11:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 12:

All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 12:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter

exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 13:

All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997, wherein the omeprazole was prepared by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

OBJECTION TO REQUEST NO. 13:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 14:

All documents evidencing, referring or otherwise relating to tautomerization of omeprazole, including but not limited to identification, characterization, purification, or isolation of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.

OBJECTION TO REQUEST NO. 14:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter

exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 15:

All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 15:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 16:

All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 16:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 17:

All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 17:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 18:

All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 18:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 19:

All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 19:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry..

REQUEST NO. 20:

All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 20:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with

Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 21:

All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 21:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 22:

All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTION TO REQUEST NO. 22:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" communications referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 23:

Representative samples of omeprazole Form A, including documents sufficient to establish the chain of custody of said omeprazole Form A.

OBJECTION TO REQUEST NO. 23:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks samples that have been requested of Plaintiffs. Merck is not a party to the captioned litigation. As presently informed, this request to Merck is duplicative of requests made to Plaintiffs in the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether any requested samples exist and will produce same if located upon such a reasonable search and inquiry.

REQUEST NO. 24:

Representative samples of omeprazole Form B, including documents sufficient to establish the chain of custody of said omeprazole Form B.

OBJECTION TO REQUEST NO. 24:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks samples that have been requested of Plaintiffs. Merck is not a party to the

captioned litigation. As presently informed, this request to Merck is duplicative of requests made to Plaintiffs in the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether any requested samples exist and will produce same if located upon such a reasonable search and inquiry.

REQUEST NO. 25:

Representative samples of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing proper conditions for storage and transportation of said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

OBJECTION TO REQUEST NO. 25:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks samples that have been requested of Plaintiffs. Merck is not a party to the captioned litigation. As presently informed, this request to Merck is duplicative of requests made to Plaintiffs in the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether any requested samples exist and will produce same if located upon such a reasonable search and inquiry.

REQUEST NO. 26:

Representative samples of 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing proper conditions for storage and transportation of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-

pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

OBJECTION TO REQUEST NO. 26:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks samples that have been requested of Plaintiffs. Merck is not a party to the captioned litigation. As presently informed, this request to Merck is duplicative of requests made to Plaintiffs in the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether any requested samples exist and will produce same if located upon such a reasonable search and inquiry.

REQUEST NO. 27:

Representative samples of each U.S. Pharmacopeia reference standards for omeprazole, including but not limited to any of omeprazole lots A-H.

OBJECTION TO REQUEST NO. 27:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks samples of "each" U.S. Pharmacopeia reference standards [sic] for omeprazole, including but not limited to any of omeprazole lots A-H. Merck is not a party to the captioned litigation. Merck further objects to this request as vague and ambiguous in that it does not further specify the nature or number of "samples" being requested.

REQUEST NO. 28:

All documents and things evidencing, referring, or otherwise relating to Drug Master File No. 14649, including but not limited to all supplements and amendments thereto.

OBJECTION TO REQUEST NO. 28:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents and things evidencing, referring, or otherwise relating to the requested subject matter. As presently informed, Merck understands that the Delaware Court has directed that a similar request served upon Plaintiffs be limited to an inspection of the identified DMF and a representation as to whether it contains testing relating to the presence of omperazole Form A. This request to Merck is duplicative of the request made to Plaintiffs in the captioned litigation.

REQUEST NO. 29:

All documents and things evidencing, referring, or otherwise relating to communications between Merck and the United States Food and Drug Administration concerning NDA No. 14649, including but not limited to all supplements and amendments thereof.

OBJECTION TO REQUEST NO. 29:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents and things evidencing, referring, or otherwise relating to the requested subject matter. As presently informed, Merck understands that the Delaware Court has directed that a similar request served upon Plaintiffs be limited to an inspection of the identified DMF and a representation as to whether it contains testing relating to the presence of omperazole Form A. This request to Merck is duplicative of the request made to Plaintiffs in the captioned litigation.

REQUEST NO. 30:

All documents evidencing, referring or otherwise relating to isomeric forms and relative amounts thereof, of omeprazole sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 30:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 31:

All documents evidencing, referring or otherwise relating to isomeric forms, and the relative amounts thereof, of omeprazole used to make any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997.

OBJECTION TO REQUEST NO. 31:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents evidencing, referring or otherwise relating to the identified subject matter. Merck is not a party to the captioned litigation. After consultation with Defendants to narrow the scope of the request within reasonable limits, Merck will undertake a reasonable search and inquiry to determine whether such subject matter exists and will produce any non-privileged, responsive material in its possession, custody or control that can be located upon such a reasonable search and inquiry.

REQUEST NO. 32:

All documents evidencing, referring or otherwise relating to license agreements, negotiations relating to any such agreements or potential agreements, relating to omeprazole and AAIPharma.

OBJECTION TO REQUEST NO. 32:

Merck objects to this request as overly broad and unduly burdensome in that the request seeks "all" documents and things evidencing, referring, or otherwise relating to the requested subject matter. As presently informed, Merck understands that Plaintiff and Defendant have agreed to exclude the requested subject matter from Plaintiffs' response to a similar request made of Plaintiff in the captioned litigation. This request to Merck is duplicative of the request made to Plaintiffs in the captioned litigation.

DEPOSITION TOPICS

DEPOSITION TOPIC NO. 1:

All documents produced in response to Document Request Nos. 1-32 in Schedule A.

OBJECTIONS TO DEPOSITION TOPIC NO. 1:

Merck incorporates each and every one of its objections to Document Requests Nos. 1-32 as if fully set forth herein.

DEPOSITION TOPIC NO. 2:

The identity of each lot of Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 2:

Merck incorporates each and every one of its objections to Document Request No. 1 as if fully set forth herein.

DEPOSITION TOPIC NO. 3:

The identity of each lot of omeprazole used to make Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 3:

Merck incorporates each and every one of its objections to Document Requests Nos. 2-3 as if fully set forth herein.

DEPOSITION TOPIC NO. 4:

The Raman spectra for each lot of omeprazole used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 4:

Merck incorporates each and every one of its objections to Document Request No. 4 as if fully set forth herein.

DEPOSITION TOPIC NO. 5:

The x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures, for each lot of omeprazole

used to make any Prilosec™ sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 5:

Merck incorporates each and every one of its objections to Document Request No. 5 as if fully set forth herein.

DEPOSITION TOPIC NO. 6:

The documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 6:

Merck incorporates each and every one of its objections to Document Request No. 6 as if fully set forth herein.

DEPOSITION TOPIC NO. 7:

The documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 7:

Merck incorporates each and every one of its objections to Document Requests Nos. 6-7 as if fully set forth herein.

DEPOSITION TOPIC NO. 8:

The analyses undertaken and intended to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 8:

Merck incorporates each and every one of its objections to Document Request No. 11 as if fully set forth herein.

DEPOSITION TOPIC NO. 9:

All manufactures or attempts to manufacture omeprazole by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of

omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

OBJECTIONS TO DEPOSITION TOPIC NO. 9:

Merck incorporates each and every one of its objections to Document Request No. 13 as if fully set forth herein. Merck further objects to this request as vague and ambiguous in its use of the term "all manufactures."

DEPOSITION TOPIC NO. 10:

The correlation of or attempts by Merck to correlate the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or the ratio of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole to 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, with Raman spectra or x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures.

OBJECTIONS TO DEPOSITION TOPIC NO. 10:

Merck incorporates each and every one of its objections to Document Requests Nos. 8-10, 12 as if fully set forth herein.

DEPOSITION TOPIC NO. 11:

All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTIONS TO DEPOSITION TOPIC NO. 11:

Merck incorporates each and every one of its objections to Document Request No. 15 as if fully set forth herein.

DEPOSITION TOPIC NO. 12:

All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTIONS TO DEPOSITION TOPIC NO. 12:

Merck incorporates each and every one of its objections to Document Request No. 16 as if fully set forth herein.

DEPOSITION TOPIC NO. 13:

All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTIONS TO DEPOSITION TOPIC NO. 13:

Merck incorporates each and every one of its objections to Document Request No. 17 as if fully set forth herein.

DEPOSITION TOPIC NO. 14:

All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10.651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTIONS TO DEPOSITION TOPIC NO. 14:

Merck incorporates each and every one of its objections to Document Request No. 18 as if fully set forth herein.

DEPOSITION TOPIC NO. 15:

All communications referring or otherwise relating to of 6-methoxy-2-{[4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTIONS TO DEPOSITION TOPIC NO. 15:

Merck incorporates each and every one of its objections to Document Request No. 19 as if fully set forth herein.

DEPOSITION TOPIC NO. 16:

All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-

dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck,, and/or AAIPharma.

OBJECTIONS TO DEPOSITION TOPIC NO. 16:

Merck incorporates each and every one of its objections to Document Request No. 20 as if fully set forth herein.

DEPOSITION TOPIC NO. 17:

All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

OBJECTIONS TO DEPOSITION TOPIC NO. 17:

Merck incorporates each and every one of its objections to Document Request No. 21 as if fully set forth herein.

DEPOSITION TOPIC NO. 18:

All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma. The nature and identity of analyses undertaken by AAIPharma and intended to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with of 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

OBJECTIONS TO DEPOSITION TOPIC NO. 18:

Merck incorporates each and every one of its objections to Document Request No. 22 as if fully set forth herein.

Dated: February 8, 2007

By: _____

Robert J. Koch
Jay I. Alexander
MILBANK, TWEED, HADLEY
& McCLOY LLP
1850 K Street, N.W.
Washington, D.C. 20006
(202) 835-7500

Counsel for Merck & Co., Inc.

CERTIFICATE OF SERVICE

I certify that on this 8th day of February 2007, I caused a true and correct copy of the foregoing MERCK & CO., INC'S OBJECTIONS TO SUBPOENA to be served upon counsel for Dexcel in the following manner:

BY ELECTRONIC MAIL AND FIRST CLASS MAIL

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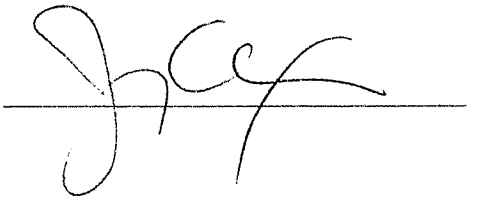


EXHIBIT 36

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ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
*RESIDENT IN WASHINGTON OFFICE ***RESIDENT IN SEATTLE OFFICE
**RESIDENT IN ROCKFORD OFFICE

February 23, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

We've reviewed the objections set forth in Merck & Co. Inc.'s Objections to Subpoena dated February 8, 2007 and we consider all of the objections to be baseless and unfounded. We plan to raise this with Chief Judge Robinson at the earliest possible date.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn C. Borg-Breen

EXHIBIT 37

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March 23, 2007

VIA ELECTRONIC MAIL
David M. Airan, Esq.
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

Re: *AstraZeneca AB et al. v. Dexcel Ltd., et al.*, No. 06-358 (SLR) (D. Del.)

Dear David:

As you are aware, AstraZeneca made an offer to Dexcel regarding Merck discovery at the March 12, 2007 meet and confer. Based on Dexcel's refusal to consider this offer, it is AstraZeneca's understanding that Dexcel is no longer pursuing further discovery from Merck.

Sincerely,

Robert J. Koch

cc: Robert F. Green, Esq.
Saumil Mehta, Esq.
Caryn Borg-Breen, Esq.
Edgar H. Haug, Esq.
Richard D. Kirk, Esq.
Jack Blumenfeld, Esq.

EXHIBIT 38

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JASON A. MILLER
ELIZABETH A. LITZINGER

ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
*RESIDENT IN WASHINGTON OFFICE ***RESIDENT IN SEATTLE OFFICE
**RESIDENT IN ROCKFORD OFFICE

December 21, 2006

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

This will address deficiencies with Plaintiffs' Responses to Dexcel Pharma Technologies Ltd.'s Discovery Requests. These deficiencies are noted below, with additional comments and information intended to allow the parties to narrow any potential areas of dispute and expedite Plaintiffs' production of the requested information:

Third Party Confidentiality and Protective Order Issues

Plaintiffs' formal responses to Defendants' discovery indicate that Plaintiffs have withheld responsive information based on confidentiality agreements with third parties and/or protective orders entered by Courts in other matters.

The existence of a confidentiality agreement between private parties cannot serve as an excuse for Plaintiffs to refuse to the produce information in this lawsuit. Plaintiffs brought this action against Defendants and they cannot now withhold requested information based on a third-party agreement to keep such information confidential. As Chief Judge Robinson explained on December 6, 2006, the Delaware court's default protective order provides adequate protection for third party information. We therefore request Plaintiffs to produce such information without further delay.

To the extent that Plaintiffs have withheld information due to a protective order of another court, Defendants seek a log of all information withheld from production. Your log should be accompanied by the relevant protective order(s) that purportedly preclude production as well as a general identification of the information in Plaintiffs' possession, custody or control, the identity of the third-party whose information is at issue, and efforts made by Plaintiffs to under the relevant protective order(s) to secure the release of such information. Furthermore, if a third-party objects to the production of information within Plaintiffs' possession, custody or control, we ask Plaintiffs to inform us of the third-party's objection so that we may separately contact the third party, take the issue up with Chief Judge Robinson, or seek other relief.

Interrogatory Responses

Interrogatory Nos. 2 and 6: Plaintiffs refer to Rule 33(d) in response to DPT Ltd.'s specific requests for information. In view of Chief Judge Robinson's remarks at the December 6, 2006 conference, Defendants ask Plaintiffs to either provide specific answers to these interrogatories or point to specific documents that are responsive to these requests.

Interrogatory No. 3: Plaintiffs' response is non-responsive to the question asked. This interrogatory seeks the identification of any products *made from the same batch or production lot as* the "bulk substance" referred to in the cited Information Disclosure Statement. Defendants ask Plaintiffs to fully respond to this interrogatory.

Interrogatory No. 4: Plaintiffs' response includes only those testing methodologies used by Plaintiffs in *In re Omeprazole Patent Litig.*, 222 F.Supp.2d 423, 526 (S.D.N.Y. 2002). This interrogatory, however, asks Plaintiffs to describe *all* testing methodologies ever used by Plaintiffs to determine the presence of a subcoating, not only those methods relied upon in previous litigation.

Interrogatory No. 5: This interrogatory is timely and needs to be substantively addressed by Plaintiffs. Defendants seek information related to the types of testing Plaintiffs have actually employed or intend to rely upon to establish the existence of "subcoating" in the DPT Ltd. accused product.

Responses to Requests for Documents

Requests Nos. 9 and 10: Plaintiffs refuse to produce samples of pure bulk omeprazole Form A and pure bulk omeprazole Form B without further definition of those terms. DPT Ltd. defined these terms in its request by referencing terms in Plaintiffs' own '380 patent. Plaintiffs cannot now argue that they do not know what those terms mean. However, in an effort to move this issue along, the terms "pure" and "bulk" are to be given their ordinary meaning as follows: The term "pure" is defined as "unmixed with any other matter." The term "bulk" means that the

sample should be taken from any large scale preparations of omeprazole, such as for preparation of omeprazole to be ultimately used in omeprazole products. Plaintiffs should produce samples of omeprazole Form A as defined by claim 1 of the '380 patent, free of any other matter. In addition, Defendants seek samples of omeprazole Form B as defined by the '380 patent at col. 1, ll. 24-26, free of any other matter that is not considered to be part of "omeprazole Form B".

Requests Nos. 21 and 22: Defendants seek documents or things related to the types of testing Plaintiffs have or intend to employ to establish the existence of "subcoating" in the DPT Ltd. accused product. These requests are timely and need to be substantively addressed by Plaintiffs.

Request No. 26: DPT Ltd. will clarify this request as follows. "All documents evidencing, referring, or otherwise relating to the bioequivalence of *pharmaceutical formulations containing* omeprazole Form A and Prilosec™ previously sold in the United States." Plaintiffs should produce all responsive documents which evidence, refer or relate to bioequivalence of pharmaceutical formulations containing omeprazole Form A as the active ingredient, and the FDA-approved pharmaceutical formulations sold under the brand name Prilosec™.

Request No. 27: Plaintiffs have refused to produce any communications sent by or to AAIPharma referring or otherwise relating to omeprazole, asserting essentially that such documents are not relevant and cannot be produced because they are subject to protective orders and confidentiality agreements. Documents responsive to this request are relevant to Defendants' evaluation of validity and infringement of the '380 patent. Among other things, AAIPharma possesses prior art to the '380 patent and/or information that may lead to prior art to the '380 patent. Please let us know if you intend to rely on your relevance objection as a continuing basis to withhold the requested documents.

Request No. 29: Plaintiffs refuse to produce any documents relating to the tautomerization of omeprazole, including those relating to 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, asserting such information is irrelevant. Documents relating to the 6-methoxy tautomer are relevant insofar as the 6-methoxy tautomer of omeprazole and omeprazole Form A as described by the '380 patent appear to be the same compound. Defendants ask Plaintiffs to produce all documents responsive to this request.

Request No. 33: Plaintiffs refuses to produce any documents relating to isomeric forms of omeprazole asserting that "isomeric forms and relative amounts thereof, of omeprazole" is undefined. Isomers are commonly known as compounds which have the same molecular formula but have different physical and chemical properties as a result of a difference in molecular structure. The tautomerisation of omeprazole is relevant to this action insofar as the 6-methoxy tautomer appears to be the same compound as omeprazole Form A as described by the '380 patent. Defendants therefore ask Plaintiffs to produce all responsive documents relating to isomeric compounds having the molecular formula $C_{17}H_{19}N_3O_3S$.

Request No. 37: Plaintiffs refuses to produce any documents asserting that "polymorphs of omeprazole" and "patents relating to polymorphs of omeprazole" are undefined. Defendants ask Plaintiffs to produce all responsive documents relating to different crystalline forms of omeprazole compounds having the molecular formula $C_{17}H_{19}N_3O_3S$.

We look forward to discussing these issues with you.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

David M. Airan

EXHIBIT 39

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ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
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**RESIDENT IN ROCKFORD OFFICE

January 8, 2007

Via Electronic Mail

Robert J. Koch, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street N.W.
Suite 1100
Washington, D.C. 20006

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Bob:

This will further address deficiencies with Plaintiffs' Responses to Dexcel Pharma Technologies Ltd.'s Discovery Requests. These deficiencies are noted below, with additional comments and information intended to allow the parties to narrow any potential areas of dispute and expedite Plaintiffs' production of the requested information:

Third Party Confidentiality and Protective Order Issues

As an initial matter, we await Plaintiffs' updated Responses to Defendants' Discovery Requests in which Plaintiffs' referred to the existence of confidentiality agreements and/or protective orders entered by Courts in other matters. Such Discovery Requests include:

Plaintiffs' Response to Interrogatory No. 1 on the Merits
Plaintiffs' Response to Request for Admission Nos. 1 and 2 Relating to the Merits
Plaintiffs' Response to Document Request Nos. 5, 6, 7, 8, 11, 12, 19, 20, and 27

Please provide us with your updated Responses by no later the close of business on Thursday, January 11, 2007, so that we may raise any outstanding issues in this regard with Chief Judge Robinson during the January 12, 2007 conference.

Documents in the Control or Possession of Merck and Co.

After a careful review of the documents produced, we note that there do not appear to be any documents originating from Merck and Co. (Merck). According to the Physician's Desk Reference, Merck has been involved in the manufacture of the omeprazole API sold in Prilosec™ since the approval of the drug. Accordingly, documents in the possession of Merck are relevant at least with respect to the validity of the '380 patent. Please let us know if documents from Merck have been or will be produced. If such documents have not and will not be produced, please indicate why such documents cannot be produced so that we can take up this matter with the Court.

Interrogatory Responses

Interrogatory No. 1: Plaintiffs' response states that Plaintiffs are "unaware of any parties' use or sale of omeprazole Form A prior to November 10, 1997 other than use of internally created samples made by AstraZeneca outside of the United States." This response is incomplete insofar as it fails to address Plaintiffs' knowledge regarding any parties' use or sale of *compositions* made from omeprazole containing omeprazole Form A. In addition, please clarify whether the phrase "outside of the United States" modifies AstraZeneca's use of the internally created samples or, alternatively, the location of where the samples were made by Astra Zeneca.

Interrogatory Nos. 2-6: Defendants await Plaintiffs' updated responses to these interrogatories in view of clarifications made in our letter dated December 21, 2006. In particular, interrogatories 4-6 request that Plaintiffs "describe in detail" their responses. Accordingly, Plaintiffs should provide details regarding the testing methodologies and analyses including testing conditions and parameters.

Responses to Requests for Documents

Production of Analytical Data: Many of the documents produced in response to Discovery Requests, in particular Nos. 7, 8, 13, and 14, are spectra or diffraction patterns containing multiple stacked or overlaid plots. These documents are in black and white making interpretation of the documents difficult or impossible. Please provide us with color copies of all documents containing analytical spectra that include stacked spectra.

Requests Nos. 3-6 and 31-32: We have not received any samples relating to these requests. If such samples are not available, Plaintiffs should update their response to so indicate.

Requests Nos. 9-10, 26, 33, 34, and 37: Plaintiffs should update their responses to these requests in view of the clarifications provided in our letter dated December 21, 2006. If

Plaintiffs are still unable to comprehend these requests, Plaintiffs should so indicate as soon as possible so that we may provide additional clarification without delay.

Please let us know when you are available to discuss these issues.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Robert F. Green

EXHIBIT 40

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January 11, 2007

VIA ELECTRONIC MAIL

Robert F. Green, Esq.
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

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

Dear Bob:

We write in response to your letter to me dated January 8, 2007 and David Airan's letter to me dated December 21, 2006 and also in follow-up to my letter to David dated December 20, 2006.

My December 20, 2006 Letter

I note first that we have not received any response to my December 20, 2006 letter (copy attached). As you know, this letter was intended to follow-up directly on the agreements reached and put on the record at the December 6, 2006 discovery conference with the Court. It has now been more than one month since that discovery conference yet no discernable progress has been made with respect to the issues that AstraZeneca has raised.

Three important items mentioned in the letter remain outstanding:

1. Dexcel has not provided a complete list of analytical tests performed on omeprazole and an estimate of the number of documents in each category, nor has Dexcel indicated that it will make available a Rule 30(b)(6) witness on that topic. Dexcel did produce approximately 8,000 pages of documents which we received just a few days ago, on January 8, 2006. Although we appreciate that this production appears to include some information relating

to analytical testing, the documents produced do not likely represent a complete set of all of the analytical tests that Dexcel has run on omeprazole. In particular, none of the documents produced relate to any analytical testing that would have occurred during the development of the tablet formulation that is subject of Dexcel's US NDA, including the development of the coating system and other constituents of the formulation. That development work appears to have begun at least as early as 1999. Moreover, several thousand of the recently-produced pages are in Hebrew, and will require some time to translate.

We therefore reiterate our request for the complete list of tests performed on Dexcel's omeprazole tablet formulation, including testing that occurred during development, and the estimate of volume or, alternatively, a 30(b)(6) witness. We acknowledge Dexcel's production of a "list" of tests on January 10, 2007. However, it is clear that this list is inadequate because it includes only tests performed on the API and finished omeprazole product and does not appear to include any tests that would have been performed during the development of the formulation.

2. Dexcel has refused to produce any documents relating to the development of its tablet formulation having the same coating material (HPMC-AS) as the US NDA product. This information was requested in item #2 of my December 20 letter. This information is of critical relevance to the case because the design of Dexcel's tablet formulation, which as mentioned above apparently dates back at least as far as 1999, appears to have been intended to function equivalently to AstraZeneca's patented formulation. Moreover, Mr. Oren's testimony indicated that Dexcel's formulation for the US product is very similar to that used for the European and the Israeli product. We reiterate our request for production of all documents relating to the development of the Dexcel tablet formulation.

3. Dexcel has still not responded to AstraZeneca's proposed protective order, which was sent to you on December 12, 2006. AstraZeneca had made changes to its initial proposal in the spirit of cooperation in order to reach a compromise on this issue. Without a protective order in place, it is difficult to imagine how fact or expert discovery can be completed in this case.

In addition, we wish to raise the following question: Will you be representing Cipla Ltd. in this case and are you authorized to accept service of the Amended Complaint on Cipla's behalf? If so, please let us know so that we can avoid unnecessary delay in the service of the Amended Complaint on Cipla.

Your December 21, 2006 and January 8, 2007 Letters

AstraZeneca will be serving, under separate cover, Amended Responses to certain of Dexcel's Interrogatories and Document Requests. These amended responses, which take into account the clarifications of certain of your requests made in your December 21 and January 8

letters, should obviate many of the matters raised in your letters. These matters are discussed further below.

Interrogatories: AstraZeneca will be serving Amended Responses to Dexcel's Interrogatories Nos. 1-3, 6 which address the specific points made in your letters regarding these responses and which contain an identification of documents from which the requested information may be ascertained pursuant to Fed. R. Civ. P. 33(d).

With regard to Interrogatories Nos. 4-5, the testing methodologies discussed in testimony at the trial and in the district court's opinion in *In re Omeprazole Litig.*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002) comprise the non-privileged/non-work product tests that have been used in connection with determination of infringement of the '505 and '230 patents. As AstraZeneca's interrogatory responses explain, the selection and execution of the testing methodology is highly context-sensitive and depends on, among other things, the nature of the product being tested and the identity and function of the constituents in its formulation. Dexcel has yet to provide complete information in this regard, especially in connection with the design of its tablet formulation as mentioned above. Any testing that AstraZeneca may perform or may have performed at the direction of counsel and that is not disclosed as part of an expert report or in testimony in this or previous cases is protected by the attorney work product privilege and Dexcel's request for this information is therefore inappropriate.

Document Requests: AstraZeneca will be serving amended responses to Dexcel's Document Requests Nos. 9, 10, 26, 27, 29, 33 and 37. These amended response address the specific points made in your letters regarding these responses. With regard to Requests Nos. 21-22, AstraZeneca maintains its privilege objections at this time.

Third Party Confidentiality: AstraZeneca maintains its objections and will provide a log of any information that is withheld on the basis of this objection. However, at this time, insofar as we are aware, no responsive information is being withheld under this objection.

Information from Merck & Co., Inc.: As you know, Merck is not a party to this lawsuit. Merck does have an interest in plaintiffs KBI, Inc. and KBI-E, Inc. To the extent responsive information is in the possession, custody or control of these entities, or is otherwise in the possession, custody or control of AstraZeneca, it will be produced.

Very truly yours,



Robert J. Koch

Enclosures

cc: Richard D. Kirk, Esq. (w/o encl.)
Jack B. Blumenfeld, Esq. (w/o encl.)
David M. Airan, Esq. (w/o encl.)
Saumil S. Mehta, Esq. (w/o encl.)

EXHIBIT 41

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ASTRAZENECA AB, ARTIEBOLAGET HASSLE, KBI-E, INC., KBI INC., and ASTRAZENECA LP,

Plaintiffs

vs.

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

Defendants

: CIVIL ACTION

: NO 06-358 (SLR)

- - -

Wilmington, Delaware
Friday, January 12, 2007
12:15 o'clock, p.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

- - -

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: JACK B. BLUMENFELD, ESQ. and
KAREN JACOBS LOUDEN, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

APPEARANCES (Continued):

HILBANK, THEED, HADLEY & McCLOY LLP
BY: ROBERT J. KOCH, ESQ.,
ERROLL TAYLOR, ESQ. and
JAY I. ALEXANDER, ESQ
(Washington, D.C.)

Counsel for Plaintiffs

THE BAYARD FIRM
BY: ASHLEY STITZER, ESQ.

-and-

LEYDIG VOIT & MAYER
BY: ROBERT F. GREEN, ESQ. and
DAVID M. AIRAN, ESQ
(Chicago, Illinois)

Counsel for Defendants

PROCEEDINGS

(Proceedings commenced in the courtroom, beginning at 12:15 p.m.)

THE COURT: Good afternoon, counsel.

(Counsel respond, "Good afternoon, your Honor.")

THE COURT: I take it there are issues for us to discuss, so I will let plaintiffs' counsel start us out.

MR. KOCH: Thank you, your Honor. I thought we'd start by just giving you an idea of what has occurred since our last conference on December 6th.

Probably the most significant event is that we filed on January 5th an Amended Complaint adding the Indian company that makes the active pharmaceutical ingredient, Omeprazole, to this litigation. That company is Cipla.

We filed the Amended Complaint to bring them in because at the December 6th conference, we asked Dexcel's counsel to provide us with the drug master file that is in the hands of Cipla and they indicated that they did not have it and they could not produce it, and we asked for the agreements that they had with Cipla, to see whether there was

any possibility for them getting it, and they refused to provide us with those as well.

So we felt we had no alternative but to bring Cipla in as a responding party, because Cipla is the manufacturer of the Omeprazole, the bulk product that goes into the final tablets.

Now, this pertains directly to only one of the three patents in the suit. That is the '380 patent, which is the patent on the Form A of Omeprazole.

So that is probably the most significant thing that has happened.

The second thing that has happened is really a nonevent, and that is at the conference, we -- and we indicated this in our e-mail, in our response to Dexcel's e-mail request for emergency relief, that we thought this conference was perhaps premature because nothing substantive has happened since December 6th.

You may recall at the December 6th conference we had broad discovery complaints that we had articulated to Dexcel in our letter of October 24th, asked for response by November 8th. When we didn't get a response, we, on November 9th, sent a second letter, asking for a meet and confer.

We had our meet and confer on November 14th and were unable to resolve anything prior to the December 6th

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able to enter into a protective order. If there are issues with respect to individuals, I bring them in. I have evidentiary hearings. If there are other issues, then basically, you give me your two versions and I choose one or the other.

MR. GREEN: The issues from Dexcel's standpoint, your Honor, for the most part go to the suggested protective order from Astra, which would bring in two nonparties. P&G is not a party to this litigation. Why do they have standing to be under the protective order?

Merck is not a party. Why do they have standing to be under the protective order?

And with respect to Merck, your Honor, there are perhaps 12 patents listed with the FDA concerning this product. Several of those patents are owned by Merck. They are not in this case.

THE COURT: Who from from Merck is being included? I mean, are these individuals from Merck being included?

MR. GREEN: Yes. It's an individual, as I understand it, in-house counsel from Merck that they want included under the protective order. They are not a party. They have patents which they could have asserted, but they, of course, did not.

So, again, what possible basis is there for P&G

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and Merck to be in this case? And, moreover, we've -- I think really come to a loggerheads with respect to a discovery issue that concerns Merck. Document requests that we sent out, which goes actually back to the '380 patent and other potential invalidity defenses based on what Merck has sold in the way of its Omeprazole product, we've asked for documents from Astra.

They've come back, and as I understand the response, they are producing documents that are directly in the possession or control of Astra or KBI or KBIE. And these are entities that include Merck, but Merck itself is not has not produced any documents. Merck itself manufactures Omeprazole, the product in suit here.

So they want Merck's inside counsel to be involved in the protective order, yet we're not getting documents from Merck, and that's an issue that I do want to raise independently with you, your Honor.

THE COURT: All right. Thank you very much.

When is document production supposed to be done in this case?

MR. KOCH: Document production was supposed to be done December 15th.

THE COURT: All right.

MR. KOCH: Two points, your Honor, with respect to the protective order and the Merck people. There are no

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people listed on that order that are from a nonparty other than the two P&G people. The people that Dexcel referred to as Merck people are KBI people, which is a party.

Now, the fact that they happen to also be Merck lawyers is the fact that KBI has a -- an arrangement between Merck and AstraZeneca.

So they are properly on the order. They're parties. So what we're only talking about is nonparties. We're only talking about two people. And I have not heard any objection to specifically why those people would not be appropriate, which I would address if there were any objections specifically.

Also, with respect to the question if something could be bifurcated, it would seem to me from what -- the response we just heard on that, that if we wanted to try any issue, it would be validity, the validity of the '380. That's the assertion that Dexcel has made, is that there's an on-sale bar.

So that could be tried separately, perhaps.

And then, lastly, if there -- one thing I don't want to overlook is our compromise from December 6th was a list or a 30(b)(6) witness, and perhaps it would be easier if they wanted to produce a 36 witness who would know what kind of testing was done, then we could do it that way. That's just another alternative that I want to throw on the

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table.

THE COURT: All right. As I said, I want to go through this again to make sure everyone is on the same page. Within a week, which is by January 19th, defendant has to either provide a list, a 30(b)(6) witness or actual documents that relate to the research and development surrounding the reformulated commercial product being sold outside the United States.

Depending on what happens, I take it plaintiffs will not sit on their hands and will either arrange a deposition or select the test documents they want promptly so that by the end of January, that, I take it, last piece of document production will be completed so we can move forward.

Within a week of January 31, then, which is, I think, February 7th, plaintiffs have to respond in sufficient detail to the -- I take it there have been contention interrogatories posed about infringement, and they need to respond to those.

And then we're going to meet in person, I suggest, on the following Friday, which is February 9th.

MR. KOCH: Your Honor, I don't believe there have been contention interrogatories issued by Dexcel yet.

THE COURT: Well, then, I suggest they do that.

Page 37

Omeprazole. We know there were communications between Astra or at least Merck to which Astra was privy dealing with Omeprazole.

The patents that are issued to AAI Pharma are quite relevant to the present situation because they use similar methodology for characterizing Omeprazole as does the patent, as does the single patent in suit, the '380 patent, and we are are entitled to discover what it is that Astra and the other plaintiffs have with respect to prior invention by AAI Pharma.

We believe that there is the possibility of prior invention here from AAI Pharma. We've asked for those documents. They say they may be produced, they may not

Astra also has characterized our requests with respect to AAI Pharma as being limited to just prior invention. That's not indeed the case. AAI Pharma has worked on Omeprazole, published documents, and for all we know, there are prior use or sale issues there about which Astra is aware.

They're saying they can't produce them because there's confidentiality here and they raised that last time, and I think your Honor said if there are confidentiality issues, that they should identify them and bring that to you.

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We would also like to know, then, are they withholding documents from AAI Pharma relating to Omeprazole on the basis of confidentiality? Do they have documents that are otherwise under the possession or control of Astra from AAI Pharma they're not producing because they are arguing that, indeed, it's not under the possession, custody or control of Astra when we know there's a license agreement between Astra and AAI Pharma relating to Omeprazole.

And all we're asking for now is: What is the position? Do they have such documents? Have they requested such documents? Are they taking the position that the documents that would otherwise be responsive to our requests can't be requested from especially Merck, because there are contracts between Merck and Astra that deal with this issue.

I think those are the two key document production issues, your Honor, because, again, if we are in a situation where we need to pursue documents through third-party action, then we need to do that soon.

But, again, with respect to Merck, I don't see how they can possibly take that position, but I think we're entitled to know if there are documents that Merck has that they simply haven't even asked for, because I think we can show that, indeed, Astra has the right to request those documents in response to our document requests.

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THE COURT: All right. Thank you.

MR. KOCH: Your Honor, let me just say, first, that we have not had a meet and confer on this. We did respond to their -- Dexcel sent a letter complaining about this to us after the last conference and we responded to it, and we even responded I think further yesterday and we've responded with production as well. I think we've had three productions since then.

So I can say that we have not had a meet and confer, so I don't think -- I think this is premature to bring up here, but I can also say that we're not -- that we're not holding back AAI documents if they're responsive to, you know, the requests -- they've got several requests out for testing of Form A and things like that

We're not holding back those documents. We will produce or schedule them, and the objection goes to the one document request No. 27, which is to all communications between AAI and Astra regarding Omeprazole, which is too broad.

But, you know, we've made some offers on that and we I think need to do a meet and confer.

With respect to the Merck documents, again, we're not holding back documents that are responsive to the request, but Merck is not a party per se. If they're asking for documents from a third party, that is a different animal,

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which we have not had a meet and confer on.

MR GREEN: Your Honor, we asked for a meet and confer on this fact with our December 21st letter. We have not had it. It appears that Astra has not gone to Merck and requested Merck to produce Merck documents in response to our document requests.

There is an agreement, your Honor, that involves parties to this suit and Merck and it specifically requires that there be cooperation. In fact, there's an attachment to this document, Principles for Cooperation on Priolosec Patent Issues, and it says there's to be full cooperation and communication specifically directed to Priolosec.

So I don't know how they can say that Merck documents, then, can't be obtained. They have an agreement that says there must be cooperation between Merck and AstraZeneca with respect to these Priolosec documents. And we would be pleased to provide a copy of that agreement to your Honor, if you wish.

THE COURT: Not at the moment. Thank you.

So Merck seems to have kind of an in and out role here.

MR KOCH: Well, no. Merck is not a party and we don't have control over Merck. We have KBI. KBI is a party, and, you know, if they want third-party discovery, I guess we can talk about that, but that's --

EXHIBIT 42

Affidavit of Process Server

AstraZeneca AB, et al. vs Dexcel Ltd., et al. 06-358

PLAINTIFF/PETITIONER DEFENDANT/RESPONDENT CASE #

)eing duly sworn, on my oath, I _____,
declare that I am a citizen of the United States, over the age of eighteen and not a party to this action.

Service: I served Aaipharma, LLC
NAME OF PERSON/ENTITY BEING SERVED

with the (documents) ☒ Subpoena with $ 45- witness fee and mileage

☒ Schedule A&B

by serving (NAME) Steven Fontana

at ☐ Home

☑ Business

☐ on (DATE) 1-25-07 at (TIME) 3:40 pm

Thereafter copies of the documents were mailed by prepaid, first class mail on (DATE) _____

from (CITY) _____ (STATE) _____

Manner of Service:

☑ By Personal Service.

☐ By leaving, during office hours, copies at the office of the person/entity being served, leaving same with the person apparently in charge thereof,

namely _____

☐ By leaving a copy at the defendant's usual place of abode, with some person of the family or a person residing there, of the age of 13 years or upwards, and informing that person of the general nature of the papers,

namely _____

☐ By posting copies in a conspicuous manner to the address of the person/entity being served.

Non-Service: After due search, careful inquiry and diligent attempts at the address(es) listed above, I have been unable to effect process upon the person/entity being served because of the following reason(s):

☐ Unknown at Address ☐ Evading ☐ Other: _____
☐ Address Does Not Exist ☐ Service Cancelled by Litigant
☐ Moved, Left no Forwarding ☐ Unable to Serve in a Timely Fashion

Service Attempts: Service was attempted on: ( ) _____ DATE TIME, ( ) _____ DATE TIME, ( ) _____ DATE TIME

( ) _____ DATE TIME, ( ) _____ DATE TIME, ( ) _____ DATE TIME

Description:

☒ Male	☒ White Skin	☐ Black Hair	☐ White Hair	☐ 14-20 Yrs.	☐ Under 5'	☐ Under 100 Lbs.
☐ Female	☐ Black Skin	☒ Brown Hair	☐ Balding	☐ 21-35 Yrs.	☐ 5'0"-5'3"	☐ 100-130 Lbs.
	☐ Yellow Skin	☐ Blond Hair		☐ 36-50 Yrs.	☒ 5'4"-5'8"	☐ 131-160 Lbs.
	☐ Brown Skin	☐ Gray Hair	☒ Mustache	☒ 51-65 Yrs.	☐ 5'9"-6'0"	☒ 161-200 Lbs.
☒ Glasses	☐ Red Skin	☐ Red Hair	☐ Beard	☐ Over 65 Yrs.	☐ Over 6'	☐ Over 200 Lbs.

OTHER IDENTIFYING FEATURES: _____

State of Illinois County of Cook

Edith Powell #3325
SERVED BY
LASALLE PROCESS SERVERS

Subscribed and sworn to before me, a notary public, this 26 day of January, 2007

Jodi Croon
NOTARY PUBLIC

Reyes

CHARTER MEMBER NATIONAL ASSOCIATION OF PROFESSIONAL PROCESS SERVERS.

AO88 (Rev. 12/06) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

Eastern DISTRICT OF North Carolina

AstraZeneca AB, et al., Plaintiffs

V.

Dexcel Ltd., et al., Defendants

SUBPOENA IN A CIVIL CASE

Case Number:[1] 06-358 (SLR) District of Delaware

TO: aaiPharma, LLC,
c/o Registered Agent: Albert N. Cavagnaro, 2320 Scientific Park Drive, Wilmington, North Carolina 28404

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Wingate Inn - Wilmington, 5126 Market Street Wilmington, NC, 28403 (910) 395-7011. See Schedule B for Topics.	2/20/2007 9:00 am

☑ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

See Schedule A

PLACE	DATE AND TIME
Wingate Inn - Wilmington, 5126 Market Street Wilmington, NC, 28403 (910) 395-7011	2/8/2007 9:00 am

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
	1-24-07

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Attorney for Defendants
Robert F. Green, 180 N. Stetson Ave., Suite 4900, Chicago, IL 60601 (312) 616-5600

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

AO88 (Rev. 12/06) Subpoena in a Civil Case

PROOF OF SERVICE

DATE PLACE

( ) SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), as amended on December 1, 2006:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises—or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) (A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

SCHEDULE A

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "AAIPharma" means AAIPharma LLC and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DOCUMENT REQUESTS

1. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

2. All documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

3. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole comprising 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sold or offered for sale in the United States prior to November 10, 1997.

4. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to the '380 patent.

5. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to Examples 1, 2, and 3 of the '380 patent.

6. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

7. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-

pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

8. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997, wherein the omeprazole was prepared by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

9. All documents evidencing, referring or otherwise relating to tautomerization of omeprazole, including but not limited to identification, characterization, purification, or isolation of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.

10. All communications sent by or to Plaintiffs referring or otherwise relating to the '380 patent, omeprazole Form A, omeprazole Form B, and/or 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.

11. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

12. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

13. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

14. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

15. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

17. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

18. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

19. Representative samples of omeprazole Form A, including documents sufficient to establish the chain of custody of said omeprazole Form A.

20. Representative samples of omeprazole Form B, including documents sufficient to establish the chain of custody of said omeprazole Form B.

21. Representative samples of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-

benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

22. Representative samples of 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

23. Representative samples of each U.S. Pharmacopeia reference standards for omeprazole, including but not limited to any of omeprazole lots A-H.

24. All documents evidencing, referring or otherwise relating to isomeric forms, and relative amounts thereof, of omeprazole sold or offered for sale in the United States prior to November 10, 1997.

25. All documents evidencing, referring or otherwise relating to isomeric forms, and the relative amounts thereof, of omeprazole used to make any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997.

26. All documents evidencing, referring or otherwise relating to invention of the subject matter claimed in the '380 patent prior to November 10, 1998.

27. All documents evidencing, referring or otherwise relating to the invention of the subject matter disclosed in the WO 01/13919 and its priority document U.S. provisional application No. 60/150,878.

28. All documents evidencing, referring or otherwise relating to license agreements, negotiations relating to any such agreements or potential agreements, relating to omeprazole and AAIPharma.

SCHEDULE B

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "AAIPharma" means AAIPharma LLC and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DEPOSITION TOPICS

1. All documents produced in response to Document Request Nos. 1-28 in Schedule A.

2. The documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

3. The documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

3. The documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sold or offered for sale in the United States prior to November 10, 1997.

4. The analyses undertaken and intended to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

5. The analyses undertaken to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

6. All manufactures or attempts to manufacture omeprazole by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of

any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

7. The correlation of or attempts by AAIPharma to correlate the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or the ratio of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole to 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, with Raman spectra or x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures.

8. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

9. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

10. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

11. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

12. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

13. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

14. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-

methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

15. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. The invention of the subject matter claimed in the '380 patent prior to November 10, 1998.

17. The invention of the subject matter disclosed in the WO 01/13919 and its priority document U.S. provisional application No. 60/150,878.

EXHIBIT 43

Affidavit of Process Server

Astrazeneca AB, et al. vs Dexcel Ltd., et al. 06-358
PLAINTIFF/PETITIONER DEFENDANT/RESPONDENT CASE #

Being duly sworn, on my oath, I _____,
declare that I am a citizen of the United States, over the age of eighteen and not a party to this action.

Service: I served Ajinomoto, Inc.
NAME OF PERSON/ENTITY BEING SERVED
with the (documents) ☒ Subpoena with $ 45 witness fee and mileage
☒ Schedule A&B

by serving (NAME) Steven Fontana

at ☐ Home

☒ Business

☐ on (DATE) 1-25-07 at (TIME) 3:40 pm

Thereafter copies of the documents were mailed by prepaid, first class mail on (DATE) _____

from (CITY) _____ (STATE) _____.

Manner of Service:

☒ By Personal Service.

☐ By leaving, during office hours, copies at the office of the person/entity being served, leaving same with the person apparently in charge thereof,

namely _____

☐ By leaving a copy at the defendant's usual place of abode, with some person of the family or a person residing there, of the age of 13 years or upwards, and informing that person of the general nature of the papers,

namely _____

☐ By posting copies in a conspicuous manner to the address of the person/entity being served.

Non-Service: After due search, careful inquiry and diligent attempts at the address(es) listed above, I have been unable to effect process upon the person/entity being served because of the following reason(s):

☐ Unknown at Address ☐ Evading ☐ Other: _____
☐ Address Does Not Exist ☐ Service Cancelled by Litigant
☐ Moved, Left no Forwarding ☐ Unable to Serve in a Timely Fashion

Service Attempts: Service was attempted on: ( ) _____ DATE TIME, ( ) _____ DATE TIME, ( ) _____ DATE TIME

( ) _____ DATE TIME, ( ) _____ DATE TIME, ( ) _____ DATE TIME

Description:

☒ Male	☒ White Skin	☐ Black Hair	☐ White Hair	☐ 14-20 Yrs.	☐ Under 5'	☐ Under 100 Lbs.
☐ Female	☐ Black Skin	☒ Brown Hair	☐ Balding	☐ 21-35 Yrs.	☐ 5'0"-5'3"	☐ 100-130 Lbs.
	☐ Yellow Skin	☐ Blond Hair		☐ 36-50 Yrs.	☒ 5'4"-5'8"	☐ 131-160 Lbs.
	☐ Brown Skin	☐ Gray Hair	☒ Mustache	☒ 51-65 Yrs.	☐ 5'9"-6'0"	☒ 161-200 Lbs.
☒ Glasses	☐ Red Skin	☐ Red Hair	☐ Beard	☐ Over 65 Yrs.	☐ Over 6'	☐ Over 200 Lbs.

OTHER IDENTIFYING FEATURES: _____

State of Illinois County of Cook

Edith Sprueell #3525
SERVED BY
LASALLE PROCESS SERVERS

Subscribed and sworn to before me, a notary public, this 26 day of January, 2007

Jodi Croom
NOTARY PUBLIC

Reyes

CHARTER MEMBER NATIONAL ASSOCIATION OF PROFESSIONAL PROCESS SERVERS.

AO88 (Rev. 12/06) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

Eastern DISTRICT OF North Carolina

AstraZeneca AB, et al., Plaintiffs

V.

Dexcel Ltd., et al., Defendants

SUBPOENA IN A CIVIL CASE

Case Number:[1] 06-358 (SLR) District of Delaware

TO: aaiPharma, Inc.,
c/o Registered Agent: Albert N. Cavagnaro, 2320 Scientific Park Drive, Wilmington, North Carolina 28404

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Wingate Inn - Wilmington, 5126 Market Street Wilmington, NC, 28403 (910) 395-7011. See Schedule B for Topics.	2/20/2007 9:00 am

☑ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

See Schedule A

PLACE	DATE AND TIME
Wingate Inn - Wilmington, 5126 Market Street Wilmington, NC, 28403 (910) 395-7011	2/8/2007 9:00 am

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
	1-24-07

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Attorney for Defendants
Robert F. Green, 180 N. Stetson Ave., Suite 4900, Chicago, IL 60601 (312) 616-5600

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

AO88 (Rev. 12/06) Subpoena in a Civil Case

PROOF OF SERVICE

DATE PLACE

( ) SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____ SIGNATURE OF SERVER
DATE

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), as amended on December 1, 2006:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises—or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) (A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

SCHEDULE A

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "AAIPharma" means AAIPharma Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DOCUMENT REQUESTS

1. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

2. All documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

3. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole comprising 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sold or offered for sale in the United States prior to November 10, 1997.

4. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to the '380 patent.

5. All documents, notebook records, Infrared data, Raman data, x-ray crystal or powder diffraction data, or other analytical or spectroscopic data evidencing, referring or otherwise relating to Examples 1, 2, and 3 of the '380 patent.

6. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

7. All documents evidencing, referring or otherwise relating to any analyses undertaken to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-

pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

8. All documents evidencing, referring or otherwise relating to any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997, wherein the omeprazole was prepared by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

9. All documents evidencing, referring or otherwise relating to tautomerization of omeprazole, including but not limited to identification, characterization, purification, or isolation of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.

10. All communications sent by or to Plaintiffs referring or otherwise relating to the '380 patent, omeprazole Form A, omeprazole Form B, and/or 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.

11. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

12. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

13. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

14. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

15. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

17. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

18. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

19. Representative samples of omeprazole Form A, including documents sufficient to establish the chain of custody of said omeprazole Form A.

20. Representative samples of omeprazole Form B, including documents sufficient to establish the chain of custody of said omeprazole Form B.

21. Representative samples of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-

benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

22. Representative samples of 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, including documents sufficient to establish the chain of custody of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole from the date of manufacture to the date of production; also including documents detailing the proper conditions for storage and transportation of said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and documents certifying that said 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole was stored and transported under said proper conditions from the date of manufacture to the date of production.

23. Representative samples of each U.S. Pharmacopeia reference standards for omeprazole, including but not limited to any of omeprazole lots A-H.

24. All documents evidencing, referring or otherwise relating to isomeric forms, and relative amounts thereof, of omeprazole sold or offered for sale in the United States prior to November 10, 1997.

25. All documents evidencing, referring or otherwise relating to isomeric forms, and the relative amounts thereof, of omeprazole used to make any product or composition containing omeprazole sold or offered for sale in the United States prior to November 10, 1997.

26. All documents evidencing, referring or otherwise relating to invention of the subject matter claimed in the '380 patent prior to November 10, 1998.

27. All documents evidencing, referring or otherwise relating to the invention of the subject matter disclosed in the WO 01/13919 and its priority document U.S. provisional application No. 60/150,878.

28. All documents evidencing, referring or otherwise relating to license agreements, negotiations relating to any such agreements or potential agreements, relating to omeprazole and AAIPharma.

SCHEDULE B

DEFINITIONS

A. "Plaintiffs" means Plaintiffs, ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

B. "AAIPharma" means AAIPharma Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

C. "Merck" means Merck and Co., Inc. and its past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.

D. "the '380 patent" means U.S. Patent No. 6,150,380.

E. "omeprazole Form A" means a form of omeprazole as defined by claim 1 of the '380 patent.

F. "omeprazole Form B" means a form of omeprazole as described in Col. 1 of the '380 patent.

DEPOSITION TOPICS

1. All documents produced in response to Document Request Nos. 1-28 in Schedule A.

2. The documents evidencing, referring or otherwise relating to any product or composition containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

3. The documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing omeprazole Form A sold or offered for sale in the United States prior to November 10, 1997.

3. The documents evidencing, referring or otherwise relating to any product or composition made from omeprazole containing 94% or more 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sold or offered for sale in the United States prior to November 10, 1997.

4. The analyses undertaken and intended to determine the presence of omeprazole Form A alone or together with omeprazole Form B in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

5. The analyses undertaken to determine the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole alone or together with 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any omeprazole product or composition sold or offered for sale in the United States prior to November 10, 1997.

6. All manufactures or attempts to manufacture omeprazole by a process comprising the steps of (a) dissolving or suspending omeprazole of any form, or a mixture of omeprazole of

any form, in a suitable solvent at 15-25° C and (b) allowing the solution to crystallize for at least 2 hours as defined by the '380 patent.

7. The correlation of or attempts by AAIPharma to correlate the presence of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or the ratio of 6-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole to 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, with Raman spectra or x-ray crystal or powder diffraction data, including but not limited to raw electronic data, diffractograms, and single crystal structures.

8. All communications referring or otherwise relating to the '380 patent, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

9. All communications referring or otherwise relating to omeprazole Form A or omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

10. All communications referring or otherwise relating to the analytical characterization of omeprazole Form A and omeprazole Form B, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

11. All communications referring or otherwise relating to WO 01/13919, U.S. Patents Nos. 6,262,085, 6,262,086, 6,268,385, 6,312,712, 6,312,723, 6,316,020, 6,326,384, 6,369,087, 6,444,689, 6,608,091, 6,653,329, 6,667,321, 6,667,323, 6,667,324, 6,673,936, 6,706,737, 6,780,880, as well as any of the applications upon which they are based, and U.S. Patent Application No. 10/651,225, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

12. All communications referring or otherwise relating to 6-methoxy-2-{[(4-methoxy-3,5-dimethyl(2-pyridyl))methyl]sulfinyl} benzimidazole in pure form in a solid state, or pharmaceutically acceptable salts, hydrates, or combinations thereof, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

13. All communications referring or otherwise relating to a pharmaceutical formulation comprising as active ingredient a non-toxic amount of a composition of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and, optionally, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said composition is essentially the same as the ratio of said 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in the active pharmaceutical ingredient used in said pharmaceutical formulation, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

14. All communications referring or otherwise relating to a dry blend pharmaceutical formulation in unit dosage form comprising per dosage unit an amount of active pharmaceutical ingredient within the range of about 5 mg to about 60 mg of 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, or one or more pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, in pure form, and at least one pharmaceutically acceptable carrier, diluent, or excipient, wherein said 6-methoxy-2-[[(4-

methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole in said pharmaceutical formulation remains pure or is essentially free of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, said pharmaceutical formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

15. All communications referring or otherwise relating to an omeprazole API composition fixed with a ratio of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole and 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benz imidazole, including but not limited to communications sent by or to Plaintiffs, Merck, and/or AAIPharma.

16. The invention of the subject matter claimed in the '380 patent prior to November 10, 1998.

17. The invention of the subject matter disclosed in the WO 01/13919 and its priority document U.S. provisional application No. 60/150,878.

EXHIBIT 44

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January 30, 2007

VIA ELECTRONIC MAIL

Robert F. Green, Esq.
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

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

Dear Bob:

It has recently come to our attention that certain documents responsive to certain of Dexcel's document requests are covered by confidentiality obligations to a third party, AAI Pharma. We are currently attending to those obligations and will inform you if AAI Pharma has any objections to our producing the materials in this litigation.

Very truly yours,

Robert J. Koch

cc: Edgar H. Haug, Esq.
David M. Airan, Esq.
Richard D. Kirk, Esq.
Jack B. Blumenfeld, Esq.

EXHIBIT 45

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Declaration of Caryn Borg-Breen

I, Caryn Borg-Breen, declare under the penalty of perjury that the following is true and correct:

1. I am an attorney with the law firm of Leydig, Voit & Mayer, Ltd. who is representing Dexcel Ltd., Dexxon Ltd., and Dexcel Pharma Technologies Ltd. (collectively "Defendants") in the above-captioned action.

2. This declaration is submitted in support of "DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO LIFT THE STAY ON FDA APPROVAL OF DEXCEL PHARMA TECHNOLOGIES, LTD.'S OMEPRAZOLE DELAYED-RELEASE TABLETS."

3. On January 25, 2007, Defendants subpoenaed documents and FED. R. CIV. P. 30(b)(6) deponents from AAIpharma, Inc., and AAIpharma, LLC (collectively "AAIpharma").

4. On February 2, 2007, I spoke with Mr. James Gumina, counsel for AAIpharma, regarding the scope of the document requests. In our conversation, Mr. Gumina indicated that most of the documents Defendants' requested were sitting in his office, and that he needed to

check with his client regarding a few requests, but expected he could produce the documents by the end of February.

5. On February 14, 2007, Mr. Gumina corresponded to clarify his understanding of which documents Defendants requested.

6. On February 22, 2007, Defendants' responded that Mr. Gumina properly identified the documents Defendants sought produced.

7. On March 13, 2007, Defendants telephoned and left a voice message for Mr. Gumina regarding the status of AAIpharma's document production. Mr. Gumina never returned Defendants' phone call.

8. I hereby declare that all statements made herein of my own knowledge are true, that all statements of opinion or those made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18 of the United States Code.

DATE: 3/29/07

Caryn Borg-Breen

EXHIBIT 46

mbhb McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive
Chicago, Illinois 60606-6709
www.mbhb.com

312 913 0001 phone
312 913 0002 fax

February 14, 2007

Sent Via Facsimile
312-616-5700

Robert F. Green
Leydig Voit
Two Prudential Plaza
180 N. Stetson Avenue, Suite 4900
Chicago, IL 60601

Re: AstraZeneca v. Dexcel

Dear Robert:

As a follow-up to our conversation last week on the documents responsive to the subpoena you served in the above referenced case, I have detailed below the documents you indicated you were looking for. Associated with each are my comments with respect the scope of any production. Please confirm that you agree with the limitations and that I will not have to seek a protective order.

1. Documents supporting the AAI's date of invention on its omeprazole patents

AAI has not done the analysis or identified all documents that would potentially underlie the inventions claimed in its omeprazole patents. Therefore there would be a substantial burden associated with fully producing all documents responsive to this category. As we understand it, your interest is ascertaining how, if at all these documents may affect the validity of the '380 patent. The '380 patent has a priority date in the U.S. of December 10, 1998, the date of the filing of the PCT priority document in Europe. It seems to me that only document dated earlier than this priority date would be relevant to your inquiry. Therefore, we will produce documents reflecting development work on omeprazole dated prior to December 10, 1998.

2. Prior art to the '380 (Lovqvist) patent in the form of AAI prior invention

We understand that you are looking for any documents relating to omeprazole that qualify as prior art under 35 U.S.C. §§102 and 103 as it relates to the '380 patent. We will

produce all omeprazole publications that can be located after a reasonable search of AAI's documents that are dated prior to December 10, 1998, the filing of date of the PCT priority document.

3. Correspondence associated with the licensing of the AAI patents to AZ

We understand that you want the license agreement between AAI and AstraZeneca relating to AAI patents on omeprazole and the documents associated with the exercise of rights under that license. We do not understand how this agreement has any impact on the validity of the '380 patent or for that matter any issue in your case. Moreover, copies of these documents would be the possession on AZ. It seems to us that it is more appropriate to seek these documents from AZ than to put AAI through the burden of producing them. Therefore, we decline to produce these documents

4. Any correspondence with Merck relating to omeprazole including the receipt of samples

We will produce communications with Merck relating to omeprazole including, to extent they exist and can be located, any documents associated with the transfer of samples of omeprazole.

5. Sample of any Form A or Form B omeprazole

To the extent that AAI ever had and still has any samples of omeprazole that were identified as either Form A or Form B, we will produce a portion of those samples. As I noted on the phone, AAI no longer does any research with respect to omeprazole so any samples that exist would be old and likely degraded. Therefore, AAI can make no representation that any product still conforms with what it is labeled.

6. Documents relating to Form A and its analysis

It is not clear that AAI ever did any analysis of any product identified as Form A omeprazole. Most, if not all, of the data that AAI would have on any product identified as Form A would have come from AZ. They would seem to be a better source of this information. However, AAI is willing to produce the documents it has identified that set out how AZ manufactured the various lots it identified as Form A omeprazole and any documents associated with the analysis of those lots.

7. USP reference sample for omeprazole particularly Lot F

As presently informed AAI does not have any USP reference samples of omeprazole. Should such a sample be located, we will provide you with a portion of the sample.

8. Sample of Pure 6 methoxy isomer

It is not clear to me what you mean by "pure" 6-methoxy omeprazole, but at one time AAI did have samples that were greater than 95% 6-methoxy omeprazole To the extent any such sample still exists we will produce to you a portion of it. However, as noted above, AAI is no longer involved in research associated with omeprazole and has not done any such research in some time. It is believed that over the course of time product may degrade. Therefore, although the sample was once greater than 95% 6-methoxy omeprazole, AAI cannot make any representation that it is still of the same composition.

9. Sample of high 5 methoxy isomer

At one time AAI did have samples that were greater than 14% 5-methoxy omeprazole. To the extent any such samples still exist we will produce to you a portion of representative samples. However, like with the 6-methoxy sample, it is believed that over the course of time product may degrade. Therefore, although the sample was once greater than 14% 5-methoxy omeprazole, AAI cannot make any representation that it is still of the same composition

10. XRD and Raman spectra series for a series of standards

As I noted during our phone conversation, AAI has done a great deal of work characterizing the solid state structure of omeprazole using methods such as single crystal x-ray diffraction and Raman spectroscopy. Some of this work was done to establish a standard curve for the AAI Raman spectroscopy method. AAI is willing to produce the single crystal x-ray and the Raman spectra associated with those standards. This should provide you with the series data you are seeking.

Of course all of this information will produced subject to an acceptable protective order that adequately preserves the confidentiality of the information.

Let me know if the above creates any issues for you.

Very truly yours,

James C. Gumina
312 913 2116 direct
gumina@mbhb.com

mbhb

McDonnell Boehnen Hulbert & Berghoff LLP

Fax transmittal

To	Robert F. Green	Date	February 14, 2007
Company	Leydig Voit	From	James C. Gumina
Fax	312-616-5700	Direct	312 913 2116 x direct
Phone		Email	gumina@mbhb.com
Copy To		C/M	581/67
Pages, with cover	4		
Re	AstraZeneca v. Dexcel		

ORIGINAL

300 South Wacker Drive
Chicago, Illinois 60606-6709
www.mbhb.com

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312 913 0002 fax

This transmittal is strictly for delivery only to the person listed above. It may contain confidential or privileged information, the disclosure of which is prohibited.

Please contact us if all pages are not received. If you received this fax in error, please contact us to arrange for return of the document.

EXHIBIT 47

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ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
*RESIDENT IN WASHINGTON OFFICE ***RESIDENT IN SEATTLE OFFICE
**RESIDENT IN ROCKFORD OFFICE

February 22, 2007

Via Electronic Mail

James C. Gumina, Esq.
McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606-6709

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear James,

In response to your letter dated February 14, 2007, we can agree that you will not need to seek a protective order for production falling within numbered paragraphs 1, 2, and 4-10 of your letter.

With respect to paragraph 3, we believe that your client is obligated to produce the license agreement between AAI and AstraZeneca as well as the correspondence associated with the license agreement regardless of your client's view as to the relevance of such documents to the action between Dexcel and AstraZeneca. In addition, AstraZeneca's possession of such documents is not a ground for AAI's noncompliance with the subpoena and moreover, there is no certainty that the agreements and correspondence related thereto in the possession of AAI are the same as those in the possession of AstraZeneca.

Please feel free to contact us to discuss the production of documents described in paragraph 3. In the meantime, we would appreciate your providing us with the documents and samples falling within paragraphs 1, 2 and 4-10. Once we have reviewed the documents

provided to us, we will contact you if there are any further documents that we believe we are entitled to under the subpoena.

We appreciate your cooperation in this matter.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Caryn C. Borg-Breen

EXHIBIT 48

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ELIZABETH M. CROMPTON*
JASON A. MILLER
ELIZABETH A. LITZINGER

ALL RESIDENT IN CHICAGO EXCEPT AS NOTED
*RESIDENT IN WASHINGTON OFFICE **RESIDENT IN ROCKFORD OFFICE ***RESIDENT IN SEATTLE OFFICE

March 19, 2007

Via Electronic Mail

James C. Gumina, Esq.
McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606-6709

Re: AstraZeneca AB et al. v. Dexcel Ltd. et al. - Civil Action No. 06-358

Dear Jim,

I have not had any response from you in response to my voice message of March 13, 2007. As I indicated in my voice message, we expected by now to have received at least some documents responsive to the subpoena which was served nearly two months ago. When we spoke on February 2, 2007, you indicated that most of the documents we requested were sitting in your office and that you anticipated you could complete production by the end of February. As you know, we have received absolutely nothing from you to date.

We had hoped for more cooperation from you and, unfortunately, we are now running out of time. Please let us know by close of business tomorrow whether you will complete production by Friday, March 23, 2007 of the documents you agreed to produce in your February 14, 2007 letter. If we do not hear from you, we will seek assistance from the Eastern District of North Carolina.

Very truly yours,

LEYDIG, VOIT & MAYER, LTD.

Robert F. Green

EXHIBIT 49

mbhb McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive
Chicago, Illinois 60606-6709
www.mbhb.com

312 913 0001 phone
312 913 0002 fax

March 21, 2007

Sent Via Facsimile

Robert Green
Leydig Voit & Mayer, Ltd.
Two Prudential Plaza
180 N. Stetson Avenue, Suite 4900
Chicago, IL 60601

Re: AstraZeneca v. Dexcel

Dear Robert:

In response to you letter of March 19, 2007 please be advised that the documents responsive to the subpoena and as described in my letter of February 14, 2007 have been collected. Please note, however, that pursuant to aaiPharma's agreement with AstraZeneca, Astra has objected to our production of the documents related to the agreement and any document that may contain Astra confidential information. We still believe you ought to obtain these documents from AstraZeneca and aaiPharma should not have to be involved. However, if you want to pursue the production of the documents from AAI, it will be necessary for you to have Astra withdraw its objections.

We are still trying to track down samples but I hope to have them this week.

In addition, before the documents can be produced we will need to have a written protective order to protect AAI's confidential information. When last we discussed the issue the Court had not yet entered a protective order. Absent an order of the Court, a confidentiality agreement signed by all parties should suffice. I request that you prepare such an agreement for our review.

Very truly yours,

James C. Gumina
312 913 2116 direct
gumina@mbhb.com

cc: Steve Fontana
Jack M. Griem, Jr.

EXHIBIT 50

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Declaration of Saumil S. Mehta

I, Saumil S. Mehta, declare under the penalty of perjury that the following is true and correct:

1. I am an attorney with the law firm of Leydig, Voit & Mayer, Ltd. who is representing Dexcel Ltd., Dexxon Ltd., and Dexcel Pharma Technologies Ltd. (collectively "Defendants") in the above-captioned action.

2. This declaration is submitted in support of "DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO LIFT THE STAY ON FDA APPROVAL OF DEXCEL PHARMA TECHNOLOGIES, LTD.'S OMEPRAZOLE DELAYED-RELEASE TABLETS."

3. On March 16, 2007, Defendants subpoenaed documents from and noticed the depositions of Mr. John M. Genova and a FED. R. CIV. P. 30(b)(6) witness on behalf of White & Case LLP.

4. On March 23, 2007, I contacted the offices of White & Case by telephone in regards to the noticed depositions of Mr. Genova and a 30(b)(6) deponent for White & Case.

5. During my telephone call with White & Case, I spoke with Mr. Genova who forwarded my call to Mr. John Scheibeler. Mr. Scheibeler seemed surprised that I was inquiring about the status of the scheduled deposition, because according to him, Plaintiffs' counsel had indicated that the depositions of White & Case employees had been postponed.

6. The conversation with Mr. Scheibeler was the first time Defendants or Defendants' counsel were made aware that the noticed depositions of Mr. Genova and White & Case would be delayed, specifically, delayed until after the close of fact discovery.

7. Plaintiffs' counsel never conferred or even conveyed to Defendants' counsel that the depositions of Mr. Genova and White & Case would be unilaterally delayed.

8. I hereby declare that all statements made herein of my own knowledge are true, that all statements of opinion or those made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18 of the United States Code.

DATE:

3-29-07

Saumil S. Mehta

EXHIBIT 51

Westlaw.

H

Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court, N.D. Illinois, Eastern Division.
GLAXO, INC., Glaxo Group Limited, Plaintiffs, Counterdefendants,
v.
TORPHRAM, INC., Apotex USA, Inc., Apotex, Inc., Defendants, Counterclaimants.
No. 95 C 4686.

May 30, 1996.

MEMORANDUM OPINION AND ORDER
HART, District Judge.

***1** Plaintiffs ("Glaxo") [FN1] own the patent rights for an ulcer medicine marketed under the trademark Zantac, which contains as its active ingredient Form 2 ranitidine hydrochloride. Defendants ("Apotex") seek to market a generic equivalent to Zantac, making use of Form 1 ranitidine hydrochloride, following the expiration of Glaxo's United States Letter Patent No. 4,128,658 (the " '658 patent") in July 1997. Pursuant to 21 U.S.C. § 355(j)(2), Apotex filed an abbreviated new drug application ("ANDA") in which it certified non-infringement based on an intention not to market its product until expiration of the '658 patent. As required, it notified Glaxo of its intentions.

> FN1. For present purposes there is no need to distinguish between plaintiffs Glaxo Group Limited, a United Kingdom corporation, and its United States affiliate, Glaxo, Inc. They will be referred to singularly as "plaintiff" or "Glaxo." Similarly, defendants will be referred to singularly as "Apotex" or "defendant" except in the portion of the opinion discussing Apotex, Inc., a Canadian corporation.

Following receipt of the notice, Glaxo brought this suit. At the heart of plaintiff's complaint is the allegation that defendant's production of Form 1 ranitidine hydrochloride necessarily requires use of the Form 2 process set forth in United States Letter Patent No. 4,672,133 (the " '133 patent"). The Memorandum Opinion and Order issued on November 17, 1995 in this case contains a discussion of the relevant background, and it will not be repeated here.

Presently pending is plaintiff's motion to add two defendants to its complaint, Signa S.A. de C.V. ("Signa"), a Mexican corporation which manufactures the ranitidine hydrochloride defendant intends to use in the production of its product, and ACIC (Canada), Inc. ("ACIC"), a Canadian corporation which sold Signa's product to defendant. Plaintiff believes that the manufacturer and supplier are acting in concert with defendant to market a product which infringes on Glaxo's patent rights.

As plaintiff notes, Fed.R.Civ.P. 15(a) requires that leave to amend "shall be freely given when justice so requires." But leave to amend is not automatic; it is within the court's discretion to deny a motion to amend when factors such as undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice to the opposing party, or futility of the amendment are present. *Garner v. Kinnear Mfg. Co.*, 37 F.3d 263, 269 (7th Cir.1994); *Johnson v. Methodist Medical Center of Illinois*, 10 F.3d 1300, 1303 (7th Cir.1993), *cert denied*, 114 S.Ct. 2102 (1994); *Foman v. Davis*, 371 U.S. 178, 182 (1962).

The significance of any particular factor may also be affected by the type of case at issue. For example, parties involved in patent cases arising from the filing of an ANDA have a duty to conduct expeditious litigation under that section of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), which governs the procedure for obtaining expedited approval of generic drugs. Section 355 was adopted to enable new drugs to be marketed more cheaply and quickly by shortening the time and effort needed to obtain marketing approval for certain drugs that are the same or significantly equivalent to "pioneer" drugs--the original, patented formulation of a drug. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676

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. Approval of an ANDA involving a paragraph IV certification of non-infringement (as in this case) may become effective after 45 days of giving notice to the holder of the patent, unless the patent owner initiates suit under 35 U.S.C. § 271(e)(2)(A) during that time. *Id.* at 677. If suit is filed within that period, the FDA must suspend approval of the application:

> ***2** The suspension continues--and the FDA cannot approve the ANDA--until the earliest of three dates: (i) if the court decides that the patent is invalid or not infringed, the date of the court's decision; (ii) if the court decides that the patent has been infringed, the date that the patent expires; or (iii) subject to modification by the court the date that is thirty months from the patent owner's receipt of notice of the filing of the paragraph IV certification. 21 U.S.C. § 355(j)(4)(B)(iii)(I)-(III); 35 U.S.C.A. § 271(e)(4)(A).

Bristol-Myers Squibb v. Royce Laboratories, 69 F.3d 1130, 1132 (Fed.Cir.1995).

"While it is pending, such a suit can have the effect of barring ANDA approval for two and a half years." *Id.* Consequently, in such an action, "each of the parties shall reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(4)(B)(iii). To ensure that the parties take their duty to expedite matters seriously, the court is empowered to increase or decrease the thirty month suspension, where applicable, in those cases in which a party fails to reasonably cooperate in expediting matters. *Id.; see In re Nifedipine Capsule Patent Litigation. Bayer AG & Pfizer, Inc. v. Siegfried AG and Siegried Pharmaceuticals, Inc.*, 13 U.S.P.Q.2d 1574 (S.D.N.Y.1989) (noting that discovery delays may trigger court's power to modify or extend 30-month suspension); *Imperial Chemicals Industries, PLC v. Barr Laboratories, Inc.*, 126 F.R.D. 467, 474 (S.D.N.Y.1989) (statute does not obligate court to place lawsuit on expedited schedule, but imposes serious obligations on the parties to expedite the litigation).

The question of reasonable cooperation *per se* is not before the court, and the court takes no position on the parties' performance thus far. It is presumed, however, that litigation arising from the ANDA procedure will be treated with dispatch by the parties. Motions to amend which potentially prolong litigation brought under these provisions should, therefore, be scrutinized with great care.

In this case, timing, motive and prejudice are all relevant factors which, on balance, favor defendant. Plaintiff brought suit on August 14, 1995. Although discovery was originally scheduled to close on April 5, 1996, it has been extended twice, the second time at plaintiff's request, and is now scheduled to close on June 17, 1996. Plaintiff's motion to add new parties comes near the close of discovery. While plaintiff correctly points out discovery is not yet closed and no trial date has been set, it fails to note that the discovery close date has already been extended twice and the addition of two new defendants--foreign ones at that--would inevitably extend the discovery schedule even further.

The addition of foreign defendants at this stage in the litigation also suggests additional delay because of the difficulty of achieving service on foreign defendants and the likelihood of jurisdictional disputes. The procedural history of the case thus far, which includes a four-month delay in bringing Apotex, Inc., the Canadian defendant, into the case as well as a foray into a dispute over personal jurisdiction, does not present an encouraging picture. Apotex, Inc. voluntarily withdrew its motion to dismiss for lack of personal jurisdiction precisely because such a motion would delay the lawsuit. Permitting addition of foreign defendants at this time would inevitably delay the proceedings for a significant period.

***3** Plaintiff's motion, presented on April 3, 1996, also comes several months after plaintiff first learned of the relationships between the present and proposed defendants, raising the problem of undue delay. Plaintiff argues that it brought the motion to amend soon after it learned of the relationship between defendant, ACIC, and Signa, but the record does not support this claim. In the First Request for Documents and Things, dated November 22, 1995, plaintiff specifically requested all correspondence between defendant and ACIC. Plaintiff was also aware of the relationship between defendant and SIGNA on the basis of defendant's written answers to interrogatories dated December 22, 1995. Plaintiff received further information regarding Signa and

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ACIC from depositions taken during early January 1996. Plaintiff states that it was loathe to bring its amendment based solely on the knowledge that Signa manufactured, and ACIC sold, ranitidine to defendant. This argument is flawed, however, given plaintiff's allegation that the potential infringement is based on a process patent. Once it learned that defendant did not manufacture the product, plaintiff could have made the same arguments to add the manufacturer and distributor expressed in the present motion.

Plaintiff's initial interest in ACIC and Signa appeared to be in discovering certain information it has so far been unable to learn from defendant. Following the early January depositions, plaintiff sought to discover information relating to Signa's production of ranitidine hydrochloride, including its drug master file. When defendant failed to respond to this request, plaintiff threatened to issue letters rogatory to ACIC and Signa to discover the information. Rather than doing this, however, plaintiff filed the present motion.

Defendant has stated in open court and in its briefs that every day's delay is prejudicial because it permits plaintiff to continue to monopolize the market. This is exaggerated, given defendant's admitted inability to market its proposed product until July 1997, the expiration date of the '658 patent. However, should defendants prevail on their counterclaim, their entry into the market could be gained sooner. Also, prolonged uncertainty may create delays in the development and marketing of defendant's product.

Plaintiff has delayed in bringing its motion to add parties. To permit amendment at this time would likely delay the proceedings by at least six months, would impose additional burdens in the litigation, and would ignore plaintiff's failure to make use of available discovery methods to obtain information. Given the requirements that the parties act expeditiously under 21 U.S.C. § 355(j)(4)(B) and the purpose of the ANDA process to facilitate the entry of generic drugs on the market, it is not appropriate to permit an amendment at this time. Delay prejudices both defendant and the public by preventing early resolution of disputes over necessary and significant pharmaceuticals.

***4** Defendant has stated a willingness to exchange samples of ranitidine hydrochloride in order to permit plaintiff to conduct its own tests on the product. This may be sufficient to satisfy plaintiff's discovery concerns. It is not unreasonable, however, for plaintiff to seek information regarding Signa's production of the Form I product; Apotex is cautioned that it, too, is bound to follow the mandate of reasonable cooperation set forth in Section 355.

Defendant, as a sidenote to its brief, has requested that the court reconsider its motion to dismiss Count II, in which Glaxo seeks declaratory and injunctive relief with respect to the '133 process patent, based on representations made by Glaxo in other litigation. The issues raised by defendant go only to the question of declaratory judgment and do not address plaintiff's claim for injunctive relief which, as noted in the Memorandum Opinion and Order dated November 17, 1995, is a separate basis for retaining jurisdiction. The motion to dismiss will not be reconsidered.

IT IS THEREFORE ORDERED that plaintiffs' motion to add ACIC and Signa as defendants [65] is denied.

Not Reported in F.Supp., 1996 WL 288524 (N.D.Ill.)

Motions, Pleadings and Filings **(Back to top)**

• 1:95CV04686 (Docket) (Aug. 14, 1995)

END OF DOCUMENT

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EXHIBIT 52

Westlaw.
1989 WL 111112
Not Reported in F.Supp., 1989 WL 111112 (S.D.N.Y.), 13 U.S.P.Q.2d 1574
(Cite as: 1989 WL 111112 (S.D.N.Y.))

▷

United States District Court, S.D. New York.
In re NIFEDIPINE CAPSULE PATENT LITIGATION.
BAYER AG & PFIZER, INC., Plaintiffs,
v.
SIEGFRIED AG & Siegried Pharmaceuticals, Inc., Defendants.
MDL No. 774.
No. M21-51 (JFK).
No. 88 Civ. 1374 (JFK).

Sept. 20, 1989.

MEMORANDUM OPINION AND ORDER

KEENAN, District Judge:

Background

***1** The parties to this multidistrict patent litigation seek the Court's intervention in the resolution of two discovery disputes. First, defendants Siegfried AG and Siegfried Pharmaceuticals, Inc. ("Siegfried") request that plaintiff Bayer AG ("Bayer"), a German corporation, make available for deposition pursuant to the Federal Rules of Civil Procedure four inventors named on the patent that is the subject of these infringement actions. [FN*] Second, Bayer seeks production from Siegfried of certain requested documents.

While the Court intervenes in these disputes in order to expedite discovery, it wishes to impress upon the parties its unwillingness to do so in the future. It is, after all, the purpose of discovery to *advance* the litigation so that it may proceed in an orderly manner within reasonable time constraints. It is not the purpose of discovery to harass the adversary with subterfuge and delay. Counsel are advised to consider long and hard before entering into any further discovery disputes.

Discussion

A. *Inventors*

The four inventors whose depositions Siegfried wishes to obtain, Drs. Frederich Bessert, Wulf Vater, Kurt Bauer and Karl Heinz Adams, are former employees of Bayer who reside in Germany. Siegfried asserts that the four were major participants in the invention of the drug whose patent is at issue in this case. (Siegfried August 21, 1989 letter to the Court, at 2). On March 27, 1989, Siegfried served on the parties a notice of deposition of these four inventors. In a letter from Bayer to Siegfried dated April 21, 1989, Bayer notified Siegfried that the four were no longer employed with Bayer, thus Bayer presumably could not exert control over them to be deposed. (Siegfried August 21, 1989 letter to the Court, Exhs. A & B). Siegfried has demonstrated its need for deposing the inventors; their testimony is logically relevant to the determination of this action. In addition to the relevance of their testimony, the four inventors entered into a written assignment with Bayer which states in pertinent part, "we hereby agree, whenever requested, to ... testify in any legal proceedings." (Siegfried August 21, 1989 letter to the Court, Exh. J). The Court interprets this clause to mean that the four inventors have agreed to testify in *any* legal proceedings, not just those proceedings in which Bayer would like them to testify.

Bayer argues that it is powerless to compel the inventors to testify in an American-style deposition and suggests that Siegfried request Letters Rogatory pursuant to German law and the Hague Convention. The Court disagrees with Bayer's position. The contract clause is clear. It makes no mention of an expiration of the inventors' obligation to testify nor does it invoke German law as controlling. Siegfried points out correctly that "Bayer ... has come to a U.S. court, as a U.S. plaintiff, asserting a U.S. patent" (Siegfried August 6, 1989 letter to the Court, at 2), and therefore, in the interests of justice, must proceed according to the Federal Rules of Civil Procedure. The Court directs the parties to its decision in *Campagnie Francaise D'Assurance v. Phillips Petroleum Co.*, 105 F.R.D. 16 (S.D.N.Y.1984). In that case, two French companies brought suit in the Southern District of New York for breach of contract, then sought protection under the Hague Convention from discovery requests pursuant to the Federal Rules of Civil Procedure. This Court held, among other

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things, that plaintiffs were subject to discovery pursuant to the Federal Rules. The Court stated:

***2** Plaintiffs come into this court seeking the protection of United States laws that enable injured persons to recover for breach of contract. Plaintiffs cannot avail themselves of these benefits, yet neglect their accompanying responsibility to disclose all relevant facts to their adversary.

Compagnie Francaise, 105 F.R.D. at 32. The Court finds this logic to be wholly applicable to plaintiff Bayer.

In addition, Bayer is under a statutory injunction pursuant to the Food and Drug Laws, specifically 21 U.S.C. § 355, which permits it to delay for 30 months Federal Drug Administration approval of Siegfried's pending application for permission to sell its product. Siegfried correctly indicates that 21 U.S.C. § 355(j)(4)(B)(iii) requires that "the parties shall reasonably cooperate in expediting the action," and empowers the court to shorten the 30 month injunctive period for failure of either party to cooperate in expediting the action. The Court finds that Bayer's actions concerning the inventors does not constitute "reasonable cooperation." Bayer's further refusal to make the four inventors available for deposition pursuant to the Federal Rules of Civil Procedure will result in this Court exercising its aforementioned powers, thus shortening the period of injunctive relief which Bayer is presently enjoying.

For the reasons set forth above, Bayer is ordered to make the four inventors available for deposition by Siegfried pursuant to the Federal Rules of Civil Procedure.

B. *Document Request*

In a letter to the Court dated August 29, 1989, Bayer alleges difficulty in obtaining requested documents from Siegfried. To the extent that Bayer is already in possession of some of the documents at issue, the Court's intervention is unnecessary. However, as to those documents which Siegfried has failed to produce and to which Siegfried has admitted their "marginal relevance" (Siegfried September 12, 1989 letter to the Court), the Court orders that they be produced to Bayer no later than October 2, 1989.

SO ORDERED.

FN* Defendant Chase Chemical Company, by letter to the Court dated September 1, 1989, indicates its desire to participate in any depositions taken of the four inventors in this action.

Not Reported in F.Supp., 1989 WL 111112 (S.D.N.Y.), 13 U.S.P.Q.2d 1574

END OF DOCUMENT

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EXHIBIT 53

MILBANK, TWEED, HADLEY & McCLOY LLP

INTERNATIONAL SQUARE BUILDING

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WASHINGTON, D.C. 20006

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FAX: 202-835-7586

NEW YORK
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FAX: 212-530-5219

LOS ANGELES
213-892-4000
FAX: 213-629-5063

LONDON
44-207-448-3000
FAX: 44-207-448-3029

FRANKFURT
49-69-71914-3400
FAX: 49-69-71914-3500

MUNICH
49-89-25559-3600
FAX: 49-89-25559-3700

TOKYO
813-3504-1050
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HONG KONG
852-2971-4888
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SINGAPORE
65-6428-2400
FAX: 65-6428-2500

March 22, 2007

VIA ELECTRONIC MAIL
David M. Airan, Esquire
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780

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

Dear David:

In its March 21, 2007 letter, Dexcel makes a series of unfounded accusations against AstraZeneca, none of which is correct.

As an initial matter, AstraZeneca's statements to the Court were entirely accurate. AstraZeneca has produced all documents in its possession that it agreed to provide as responsive to Document Request #27. It did not withhold any such documents on confidentiality grounds. We confirmed that AstraZeneca had produced all such documents in our latest meet and confer, before the March 12 discovery conference. These documents bear bates ranges:

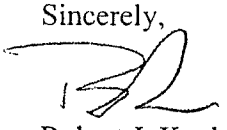
POTC0000639-POTC0000658; POTC0000770-POTC0000815; POTC0000891-POTC0000963; POTC0000972-POTC0001003; POTC0001010-POTC0001033; POTC0001101-POTC0001109; POTC0001200-POTC0001258; POTC0001261-POTC0001262; POTC0001303-POTC0001317; POTC0001372-POTC0001383; POTC0001385-POTC0001398; POTC0001433-POTC0001438; POTC0001558-POTC0001561; POTC0001638-POTC0001643; POTC0001657-POTC0001675; POTC0001777-POTC0001788; POTC0001791-POTC0001795; POTC0002214-POTC0002231; POTC0002239-POTC0002252; POTC0002260-POTC0002261;

POTC0002282-POTC0002314; POTC0002366-POTC0002415; POTC0002507-POTC0002528; POTC0002910-POTC0002920; POTC0002956-POTC0002960; POTC0003103-POTC0003172; POTC0003186-POTC0003505; POTC0003551-POTC0003675; POTC0003676-POTC0003682; POTC0003685-POTC0003690; POTC0003693-POTC0003766; POTC0003770-POTC0003901; POTC0003949-POTC0003951; and POTC0004190-POTC0004200.

The issue we have is that Dexcel has attempted to circumvent the parties' agreement by seeking to obtain directly from AAIPharma the production of agreements and related non-technical correspondence between non-party AAIPharma and AstraZeneca that AstraZeneca has consistently opposed. These documents are not relevant to the patent claims and defenses in this action. We believed that Dexcel understood and accepted AstraZeneca's position on production of these documents, and Dexcel has not contested AstraZeneca's position in any of the many discovery conferences before the Court. Dexcel's attempt to now seek these AstraZeneca documents through a third party is improper.

We now understand that AAIPharma also has responsive technical information in its possession that is not in AstraZeneca's files. AstraZeneca does not oppose the production of that information, provided that AstraZeneca has a chance to confirm prior to its production that it does not include irrelevant AstraZeneca confidential information. Moreover, Dexcel should provide a suitable amendment to the Protective Order to include AAIPharma, for signature by all parties, so that these documents can be produced once this review is completed.

Sincerely,



Robert J. Koch

cc: Robert F. Green, Esq.
Saumil Mehta, Esq.
Caryn Borg-Breen, Esq.
Edgar H. Haug, Esq.
Richard D. Kirk, Esq.
Jack Blumenfeld, Esq.
James C. Gumina, Esq.

EXHIBIT 54

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2005 WL 3578120 (C.D.Cal.)
(Cite as: 2005 WL 3578120 (C.D.Cal.))

C

Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
C.D. California,
Southern Division.
DEY, L.P., Plaintiff,
v.
EON LABS, INC., Defendant.
And Related Counterclaims.
No. SACV 04-00243 CJC (FMOx).

Dec. 22, 2005.

Alan Peter Block, Kevin I. Shenkman, Khannan Suntharam, Marc Morris, Roderick G. Dorman, Hennigan Bennett & Dorman, Los Angeles, CA, James P. Doyle, Cohen Pontani Lieberman and Pavane, New York, NY, for Plaintiff.

David P. Badanes, Martin B. Pavane, William A. Alper, James P. Doyle, Cohen Pontani Lieberman and Pavane, New York, NY, John A. Scillieri, Seldon & Scillieri, Robert A. Seldon, Robert A. Seldon Law Offices, Los Angeles, CA, for Defendant.

ORDER DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION OF THIS COURT'S NOVEMBER 4, 2005 ORDER GRANTING DEFENDANT'S MOTION TO SHORTEN 30-MONTH STATUTORY STAY ON FDA APPROVAL OF DEFENDANT'S ABBREVIATED NEW DRUG APPLICATION

CORMAC J. CARNEY, District Judge.

*1 Plaintiff and Counterdefendant Dey, L.P. ("Dey") moves pursuant to Federal Rule of Civil Procedure 60(b) for reconsideration of this Court's Order issued November 4, 2005, granting a motion filed by Defendant and Counterclaimant Eon Labs, Inc. ("Eon") to shorten the automatic 30-month statutory stay of FDA approval on Eon's Abbreviated New Drug Application under 21 U.S.C. § 355(j)(5)(B)(iii). In its Order, the Court ruled that Dey had failed to reasonably cooperate in expediting this action by acting unreasonably in identifying the individuals who invented the subject matter claimed in the patent in suit. [FN1] Because Dey has not shown that reconsideration is warranted by new evidence or the need to correct a clear error or prevent manifest injustice, its motion for reconsideration is DENIED. A party suing under a patent has an obligation to conduct a good-faith investigation into inventorship. While 35 U.S.C. § 256 allows a patentee to move to correct innocent mistakes in inventorship, this right does not excuse the patentee from making an informed decision on the issue at the time it files its patent, when it initiates litigation, and during the course of that litigation. In this case, Dey cannot continue to reap $200,000,000 [FN2] per year from its patent, free from generic competition, where it has failed and continues to fail to take a reasonable position on the critical issue of inventorship.

FN1. The Court also found that Dey failed to reasonably cooperate in expediting this action by not timely disclosing a 2003 study involving Combivent MDI, a drug solution which Eon contends is prior art to the ' 842 patent, and producing after the close of discovery certain documents pertaining to the study.

FN2. Eon's Memorandum in Support of its Motion to Shorten 30-Month Statutory Stay, p. 2.

A. Background

This patent infringement action involves Dey's U.S. Patent No. 6,632,842 B2 ("the '842 patent"), and Eon's attempts to market a generic version of a commercial drug described therein. The '842 patent does not claim the drug, but rather "a method of reducing medication error and enhancing therapeutic compliance of an individual suffering from chronic obstructive pulmonary disease," ("COPD"), a lung disease common in smokers. (Exhibit 1 to Complaint.) The claimed method sets forth a procedure by which COPD patients are administered single-dose contain-

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ers containing a combination solution consisting of albuterol and ipratropium bromide and meeting certain other criteria [FN3] (the "administering step"). (Exhibit 1 to Complaint.) In addition to the administering step, the '842 patent's claims require that patients be provided with specific prescribing, contraindication, and adverse reaction information (the "providing step"). (*Id.*) Dey currently markets the albuterol/ipratropium bromide solution described in the '842 patent under the name "DuoNeb." (Complaint, ¶ 6.)

> FN3. For instance, the claims prescribe that the volume of the solution is about 3 ml and that it be sterile, BAC free, satisfy certain stability criteria and contain specified amounts of ipratropium bromide and albuterol. (MFR, p. 12; Marc Morris Decl., ¶ 10, Exh. D thereto.)

1. Dey's Development of the Patented Subject Matter

The '842 Patent was the culmination of a long development process by Dey. In the 1990s, Dey began developing an inhalation solution that had many characteristics of the solution described in the '842 patent's administering claims, but with some differences. (Motion for Reconsideration, "MFR," pp. 12- 13.) A number of individuals employed by Dey contributed to the development of the product. (*Id.*, p. 13.) Dey was unable to obtain FDA approval for the original product, despite years of trying. (*Id.*)

***2** In the late 1990s several new people came to work for Dey, and made changes to the inhalation solution and its delivery system. Among other things, these new employees contributed to the definition of "albuterol" contained in the '842 patent and made the product "stable" by using a foil overwrap which is described in the patent. (MFR, pp. 13-14.) Dey received FDA approval for the inhalation solution, "DuoNeb," in the late 1990s. Dey subsequently filed a patent application with the U.S. Patent and Trademark Office ("USPTO"), and, on December 28, 2001 filed a "continuation in part" ("CIP") application. [FN4] (MFR, p. 5, n. 6.) The '842 Patent was issued on October 14, 2003, based on the CIP application. *Id.*; Complaint, ¶ 9.) By the time Dey filed the applications leading to the '842 patent's issuance, the developers who had developed the inhalation solution in the early 1990s no longer worked for Dey. (MFR, p. 14.)

> FN4. "A CIP application contains subject matter from a prior application and may also contain additional matter not disclosed in the prior application." *Augustine Medical, Inc. v. Gaymar Industries, Inc.*, 181 F.3d 1291, 1302, 50 U.S.P.Q.2d 1900, 1908 (Fed.Cir.1999) (*citing Waldemar Link v. Osteonics Corp.*, 32 F.3d 556, 558, 31 U.S.P.Q.2d 1855, 1857 (Fed.Cir.1994)). Different claims in a CIP application may receive different filing dates. *Id.* The part of a CIP application that duplicates material contained in the original application (and specified in the original in a manner that satisfies the description requirement of 35 U.S.C. § 112) is credited with the filing date of the original application. *Therma-Tru Corp. v. Peachtree Doors, Inc.*, 44 F.3d 988, 992, 33 U.S.P.Q.2d 1274, 1276 (Fed.Cir.1995). The part of the CIP application containing new material is treated as a new application and is given the CIP application's filing date. *Augustine*, 181 F .3d at 1302, 50 U.S.P.Q. at 1908.

2. Eon's Abbreviated New Drug Application

In early 2004, Eon sought to market a generic version of DuoNeb. Pursuant to 21 U.S.C. § 355(j), Eon filed an Abbreviated New Drug Application ("ANDA") with the FDA to obtain approval to engage in the commercial manufacture, use, and sale of a generic copy of DuoNeb for the treatment of symptoms of COPD. [FN5] The Drug Price Competition and Patent Term Restoration Act of 1984, also called the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, Pub.L. No. 98-417, 98 Stat. 1585, codified in relevant part at 21 U.S.C. § 355, allows a generic drug manufacturer such as Eon to file an ANDA, in lieu of a full New Drug Application, regarding the generic drug's safety and efficacy. 21 U.S.C. § 355(j). By filing an ANDA, the generic

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manufacturer avoids the need to submit full information regarding the generic drug, and may instead rely on safety and efficacy studies previously submitted to the FDA by the manufacturer of an already-listed drug (the "pioneer manufacturer"), so long as the ANDA applicant provides information showing that the generic drug is bioequivalent to the listed drug and is identical to it in certain other ways. 21 U.S.C. §§ 355(j)(1); 355(j)(2)(A)(i)-(v).

> FN5. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, prohibits the introduction into interstate commerce of any drug unless an application has been filed with respect to the drug and been approved by the FDA. 21 U.S.C. § 355(a).

A pioneer manufacturer that holds a New Drug Application ("NDA") must notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application or which claim[ ] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1); (c)(2). These patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the "Orange Book." *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371, 61 U.S.P.Q.2d 1414, 1415 (Fed.Cir.2002).

An ANDA applicant must make one of the following four certifications as to each patent that claims either the listed drug or a use for the listed drug for which the ANDA applicant seeks approval and for which information was required to be filed under 21 U.S.C. § 355 subsections (b) or (c): (I) that such patent information has not been filed; (II) that the patent has expired, (III) of the date on which the patent will expire; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). When the generic manufacturer makes a subpart (IV) certification, the ANDA applicant must notify the NDA holder and explain the basis for its subpart IV certification. 21 U .S.C. § 355(j)(2)(B)(i)-(iv); 21 C.F.R. 314.95(c)(6). If the NDA holder sues the ANDA applicant for patent infringement within 45 days of the notification, the FDA may not approve the ANDA until the earlier of thirty months after the patentee's receipt of notice or entry of a court judgment reflecting a determination that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii). The court in which the infringement suit is pending may, however, lengthen or shorten the stay on FDA approval if "either party to the action fail[s] to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

***3** Here, Eon made a subpart IV certification in connection with its ANDA, stating that Dey's '842 patent was invalid or would not be infringed by Eon's COPD product. Dey received that letter on January 20, 2004. (Complaint, ¶ 8.) Within 45 days of receiving the letter, on March 3, 2004, Dey sued Eon for patent infringement. As Dey sued Eon within 45 days of being notified of the subpart IV certification, the 30-month stay is now in effect.

3. Eon's Motion to Terminate the 30-Month Stay on FDA Approval

On September 22, 2005, Eon filed a motion with this Court to terminate the 30- month stay on the basis that Dey had failed to reasonably cooperate in expediting this action by, among other things, repeatedly changing its position on the inventorship of the '842 patent, and failing to produce in discovery documents related to a 2003 study comparing DuoNeb to a drug that Eon claims is prior art to the '842 patent. Eon asserted that neither of the two individuals listed as inventors on the '842 patent, Imtiaz Chaudry and Partha Banerjee, worked for Dey during Dey's initial development of the inhalation solution described in the '842 patent in the mid-1990s. Eon pointed out that, in 2004, Dey submitted and subsequently withdrew a petition to the USPTO to correct inventorship by adding Charles Rice as a named inventor. (Eon's Points and Authorities re Shortening Stay, p. 6.) After Dey withdrew the petition, Dey stated that it planned to ask the Court, at the conclusion of evidence at trial, to add Dr. John Siebert as an inventor and remove Dr. Partha Banerjee as a co-inventor. (Dey's Case Status Report, August 8, 2005, ¶ 3.) Dey has since argued that it had no way of knowing the identity of the

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'842 patent's inventors "until after discovery was over and all of the sworn testimony of the many people involved in the development could be properly considered." (MFR, p. 16.)

In an Order dated November 4, 2005, the Court granted Eon's motion to shorten the 30-month stay. (Court's Order, Nov. 4.2005.) The Court based its holding on a finding that Dey's failure to form a clear position on inventorship at the beginning of this action, as reflected by its repeated changes of position on the issue, was unreasonable and would likely delay the action. (*Id.*) The Court further held that Dey had shown no legitimate basis for its delay in disclosing the 2003 study and producing documents pertaining to it. (*Id.*) Dey now seeks reconsideration of the Court's decision pursuant to Federal Rule of Civil Procedure 60.

B. Standard on a Motion for Reconsideration

Federal Rule of Civil Procedure 60(b) provides, "the court may relieve a party ... from a final judgment, order, or proceeding for ... (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); [or] (6) any other reason justifying relief from the operation of the judgment." Fed.R.Civ.P. 60(b). A motion for reconsideration may be based on the availability of new evidence or the need to correct a clear error or prevent manifest injustice. *School Dist. No. 1J, Multnomah Cty., Oregon v. ACandS, Inc.*, 5 F.3d 1255, 1262 (9th Cir.1993). Local Rule 7-18 provides that a motion for reconsideration of a court's decision on a motion "may be made only on the grounds of "(a) a material difference in fact or law from that presented to the Court ... that in the exercise of reasonable diligence could not have been known to the party moving for reconsideration at the time of [the Court's previous] decision, or (b) the emergence of new material facts or a change of law occurring after the time of such decision, or (c) a manifest showing of a failure to consider material facts presented to the Court before such decision." L.R. 7-18.

C. Dey's Motion for Reconsideration

***4** Dey argues that reconsideration is warranted because "(a) material facts were not considered or were overlooked by the Court in forming its decision; (b) the November 4th Order incorrectly applie[d] the law of inventorship and the facts of this case; and (c) facts which became available after the hearing further demonstrate the failure to timely produce the 2003 study was unimportant and did not draw out discovery." (MFR, p. 5.) The Court will address each of these arguments in turn.

1. Failure to Consider Material Facts

Dey's first argument is that the Court's decision failed to consider certain facts material to the question whether Dey failed reasonably to cooperate in expediting this action. This argument relies on alleged errors in the Court's discussion of (1) Dey's changing position on inventorship, and (2) Dey's delay in disclosing the 2003 study and producing documents pertaining to it.

a. Inventorship

Dey takes issue with the Court's discussion of inventorship on several grounds. First, Dey argues that the Court based its ruling on a "wrong impression that there were only a few people who worked on the [development of the material in the '842 patent] over a short period of time ... [but that] there were in fact many people involved in the development process leading to the claimed invention and the development occurred over a period of about 8 years." (MFR p. 8.) Dey further argues that the Court's decision incorrectly "presupposes that (a) correction of inventorship can only occur with respect to a few inventors, among many and (b) Dey had sufficient facts in its possession from which it concluded that inventorship was wrong and that it believed Dr. Siebert was an inventor and Dr. Banerjee was not prior to the close of discovery." (MFR, pp. 9-10.)

Dey mischaracterizes the Court's decision. The Court's finding that Dey unreasonably failed to take a clear position on inventorship was not based on a perception that only a few individuals were involved in the process leading to the invention of the '842 patent's subject matter, or that Dey necessarily decided to correct inventorship before discovery closed.

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Nor was the decision based on a legal conclusion that inventorship can only be corrected as to a few inventors. The problem the Court identified with Dey's conduct was that Dey apparently made an insufficient effort to determine the true identity of the patented subject matter's inventors before initiating this litigation. Throughout this case Dey has denied that it has any obligation to investigate or acquire an informed opinion as to who the inventors are of the method claimed in the '842 patent, such as through witness interviews or examination of its own internal records. Not only does Dey contend that it was entitled to wait until after the close of discovery to identify the inventors, but it also claims it is entitled to wait to do so until after the close of the evidence at trial. (Dey's Case Status Report, August 8, 2005, ¶ 3.)

***5** Dey's position is unreasonable. There is no reason Dey could not have conducted an investigation into the inventors' identity or formed a good faith opinion on the issue before it filed its Complaint. By Dey's own admission, its employees had been attempting to obtain FDA approval of the inhalation solution that was a precursor to DuoNeb since the early 1990s. Presumably Dey has documents indicating who was involved in the project's development and/or the process of seeking FDA approval during that time. Nor does Dey explain why it did not have a clearer position on inventorship before it filed the applications leading to the '842 patent. Dey fails to explain its inability to identify the individuals most centrally involved in the conception of the claimed subject matter at any time prior to trial. For Dey to wait until the close of evidence at trial to assert its "true" position on inventorship will likely raise a host of new disputed issues and prolong this action--a result that could have been avoided by an adequate prefiling inquiry.

Dey argues that it could not discover the patented material's inventors before the close of discovery because many of the people involved in the development process leading to the '842 patent no longer worked for Dey as of the start of this litigation. (MFR, p. 16.) Dey further argues that, due to those possible contributors' "potential self-interest," Dey could not determine inventorship before receiving "sworn testimony" from them. (*Id.*) This argument, however, does not excuse Dey's failure to conduct a diligent investigation and make a reasonable determination on the issue of inventorship. Potential inventors' self-interest notwithstanding, there is no reason Dey could not have contacted and interviewed the people involved in the patented material's development process before bringing this action. Dey's concern regarding "self interest" could be addressed by investigating the bases of interviewees' statements and seeking corroboration from internal documents or from other former employees involved in the inhalation solution's development. Finally, Dey's assertion that it is entitled to postpone taking a position on inventorship until the close of evidence at trial is illogical even under its own reasoning: Even if Dey did need to obtain "sworn testimony" in discovery to determine the identity of the patented material's inventors, there appears to be no basis for Plaintiff's position that, having obtained such testimony, it still needed to wait until after the close of the evidence at trial.

Dey further argues that its changes of position on inventorship were not prejudicial to Eon because (1) Eon never propounded discovery to Dey asking Dey to identify the inventors, and (2) Dey made all information regarding conception of the patented material available to Eon by making Dr. Siebert available for a deposition and identifying all the people involved in the development process for DuoNeb. (MFR, p. 13.) These arguments are unpersuasive. First, the most likely reason Eon never asked Dey to identify the inventors of the material in the '842 patent is that the patent itself already listed two named inventors. Eon was entitled to assume that Dey had named those two individuals for good reason, and that Dey had a factual basis for doing so. Second, the fact that Dey identified all of the people involved in the development of DuoNeb during discovery does not mean that Eon would not likely have asked those individuals different questions had it known that Dey regarded them as potential or actual inventors. (Eon's Motion to Shorten Stay, p. 7; Reply in Support of Motion to Shorten Stay, p. 6.)

***6** Moreover, this case's history shows that Dey's failure to inform itself as to the identity of the '842 patent's inventors created problems in discovery. In

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March, 2005, Eon complained to Dey that the witness Dey had designated as its 30(b)(6) expert on the issue of inventorship and one of the people listed as an inventor on the '842 patent, Dr. Imtiaz Chaudry, did not even work for Dey during the time Dey was developing DuoNeb, and had no knowledge as to who had been involved in its initial development. (Eon's Supplemental Reply Brief in Support of Motion to Shorten Statutory 30-Month Stay, Exh. H thereto.) Dey refused to designate any other 30(b)(6) witness, let alone anyone employed during DuoNeb's development, and stated that all individuals who were "still employed by Dey [who were involved in the development of DuoNeb] have been made available to you," and that Eon was "free to depose anyone you choose." (*Id.*). Dey also reiterated its position that "inventorship of the '842 patent is presumptively correct as a matter of law." (*Id.*). Dey's position appears to have been that it had no obligation to designate any additional 30(b)(6) witness with information regarding the initial development process, or to make sure that Dr. Chaudry was informed about individuals involved in DuoNeb's development.

That is not the law. An entity designating a 30(b)(6) witness to testify on its behalf has an obligation to "make a conscious good faith endeavor to designate the persons having knowledge of the matters sought by [the interrogator] and to prepare those persons in order that they can answer fully [and] completely ... the questions posed by [the interrogator] as to the relevant subject matters." *Protective National Insurance Co. of Omaha v. Commonwealth Insurance Co.*, 137 F.R.D. 267, 278 (D.Neb.1989) (*quoting Mitsui & Co. v. Puerto Rico Water Resources Authority*, 93 F.R.D. 62, 67 (D.P.R.1981)). This duty to prepare witnesses extends not only to matters *actually* known by the designating party, but also to matters that "should be reasonably known" by it. *Alexander v. F.B.I.*, 186 F.R.D. 148, 152 (D.D.C.1999). If it becomes clear that a designated deponent is unable to respond to relevant areas of inquiry specified by the inquiring party with reasonable specificity, the responding party must designate an additional 30(b)(6) witness. *Id.* at 151. Certainly, it is "reasonable" to expect that Dey would know the roles played by various of its own employees in the development of the inhalation solution described in the '842 patent. Thus, if Dr. Chaudry was unable to provide information regarding who was involved in the development of DuoNeb in the years before he began working for Dey, Dey was obligated either to prepare him to provide such information or designate an additional 30(b)(6) witness. Its refusal to do either was unreasonable.

Finally, Dey argues that Eon is the one that has refused to cooperate in discovery. Dey argues that when it propounded discovery to Eon in June, 2005, asking Eon to identify who *Eon* believed were the patented material's true inventors and the factual basis supporting that belief, Eon asserted "a host of objections, including attorney-client privilege and the work product doctrine, and made no attempt to identify any person it believed to be an inventor." (MFR, p. 17.) This argument also is unavailing. Dey's "unreasonable delay" in this case is not merely a failure to reveal facts in discovery but a failure to commence this litigation with an adequately-formed idea as to the identity of the '842 patent's inventors. While Eon might have been more forthcoming in response to Dey's discovery request, Eon is not the party that initiated this action. Dey, by filing suit before understanding the factual basis for its own position on inventorship, has created confusion and the potential for delay of the trial. [FN6]

> FN6. Dey also takes issue with this Court's statement that, "Dey's failure to have a clearer understanding on the identity of the actual inventors of the subject matter claimed in the '842 patent ... raises questions regarding its ownership rights under that patent." (MFR, p. 7; Nov. 4 Order, p. 4.) Dey argues that the Court should not have considered ownership because ownership is not in issue in this case. While Dey is correct that ownership per se is not in issue, in the sense that no person claiming to have been omitted as an inventor on the '842 patent has made any claim of ownership in this case, the identity of the inventors under the '842 patent could well bear on the fundamental question whether Dey has any rights under that patent. This is because "[i]nventorship provides the starting point for determining ownership

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> of patent rights." 8 DONALD S. CHISUM, CHISUM ON PATENTS § 22.02 (2005) (*citing* University Patents Inc. v. Kligman, 762 F.Supp. 1212, 1218-19 (E.D.Pa.1991)). "[A]bsent some effective transfer or other obligation to assign patent rights, the individual inventor owns the right to apply for and obtain a patent." *Id.* Dey also argues that ownership is not in issue because "each [person who might claim to have been omitted as an inventor on the '842 patent] is obligated to assign his rights, if any, to Dey." (MFR, p. 7.) However, this is far from a foregone conclusion. Absent some exception based on contract or the nature of one's employment, an employee owns patent rights in the subject matter of which he or she is the sole or joint inventor despite having conceived the invention or reduced it to practice in the course of her employment. 8 CHISUM, § 22.03; *Banks v. Unisys Corp.*, 228 F.3d 1357, 1359, 56 U.S.P.Q.2d 1222, 1224 (Fed.Cir.2000). Two exceptions to this rule are where the inventing employee is party to a contract giving the employer ownership rights in the invention, or where the employee was hired to invent something or solve a particular problem. *Banks,* 228 F.3d at1359, 56 U.S.P.Q.2d at 1224. Dey provides no evidence or argument indicating that either exception applies in this case, or substantiating its claim that all potential inventors under the '842 patent would be obligated to assign their rights to it.

b. Delayed Production of 2003 Study

***7** Dey also challenges the Court's finding that Dey acted unreasonably in failing timely to disclose in discovery a study (the "DART Study") that it conducted in 2003 comparing DuoNeb to a drug known as Combivent MDI, and waited until after fact discovery had closed to produce documents pertaining to the study. Specifically, Dey takes issue with this Court's statement that:

> Dey fails to provide any justification other than inadvertence for its failure to produce in discovery documents relating to a study it conducted in 2003 comparing DuoNeb to Combivent MDI, which Defendants characterize as prior art to the '842 patent and on which they say they will rely to prove patent invalidity.

(November 4 Order, p. 6.) Dey asserts that the Order incorrectly "conclu[ded] that the DART study was 'prior art.' " (MFR, p. 5.) According to Dey, the DART study could not be prior art to the '842 patent, because the study was published in 2003, "several years after the 2001 effective date of the patent." (*Id.*) Thus, Dey argues, "the DART study cannot be used to invalidate [Plaintiff's] patent." (*Id.*)

Dey clearly does not understand the Court's reasoning on this issue. First, the Court's use of the term "prior art" did not refer to the DART study itself but to Combivent MDI. Second, the Court did not express any opinion as to whether Combivent MDI actually *was* "prior art" to the '842 patent, but merely pointed out that *Eon* has taken the position in this action that it was. Indeed, Eon contends that Boehringer-Ingelheim's ("BI's") marketing of Combivent prior to Dey's obtaining the '842 patent renders the '842 patent invalid. Eon stated in its moving papers:

> One of the items which is prior art to the '842 patent, and on which defendants will rely to prove invalidity of that patent, is a combination albuterol/ipratropium bromide product made and sold by Boehringer-Ingelheim, a competitor of [Dey's], under the name Combivent. [FN7]
>
> > FN7. Eon states that Combivent MDI is Combivent administered through a device known as a "multi dose inhaler." (Eon's Memorandum of Points and Authorities in Support of Motion to Shorten the 30-Month Statutory Stay, p. 5.)

(Eon's Memorandum of Points and Authorities in Support of Motion to Shorten the 30-Month Statutory Stay, pp. 4-5.) The Court thus did not err when it pointed out that Eon characterizes *Combivent MDI* as invalidating prior art. Moreover, as Eon contends that BI was marketing Combivent MDI in 1999 (and perhaps earlier), and Dey contends that the '842 patent's effective date was December 28, 2001, [FN8] Dey's argument that the alleged prior art post-dated the '842 patent is simply wrong.

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FN8. Plaintiff's MFR, p. 5 n. 6.

Dey cites *Glaxo, Inc. v. Torpharm, Inc.*, 1997 U.S. Dist. LEXIS 12816 (N.D.Ill., Aug. 28, 1997) for the proposition that "a failure to timely produce documents where, as here, thousands of documents were produced, was held not to constitute a failure to expedite justifying shortening of the stay." (MFR, p. 6.) *Glaxo* is inapposite. In *Glaxo,* the court held that the plaintiff did not fail to reasonably cooperate in expediting the litigation where it was still producing documents two months after the close of discovery, because "both parties [had] conducted a tremendous amount of discovery within a relatively short period of time," both parties had been forced to seek judicial intervention to resolve discovery disputes, some of the requesting party's discovery requests had been overbroad, and the plaintiff had otherwise cooperated in expediting the litigation. *Glaxo,* 1997 U.S. Dist. LEXIS 12816, at *8-9. The court did not say whether the late-produced documents were central to the claims in the case. In this case, by contrast, the late-produced study is central to Eon's contention that prior art invalidates the '842 patent, Dey has given no explanation other than inadvertence for late disclosure of the study, and, as explained above, Dey has otherwise drawn out this case and created discovery disputes by commencing this litigation without a clear idea as to the inventors of the '842 patent's subject matter.

***8** Dey further argues that Eon has not shown that Dey's delay in producing the 2003 study impeded the progress of this action. Dey argues that Eon did not take advantage of Dey's offer, upon producing the 2003 study, to provide Eon with additional discovery relating to the study at Dey's own expense. (MFR, p. 6.) Dey also argues that Eon has not propounded any discovery to Dey relating to the study in the four months since the DART study and related documents were produced. (MFR, p. 6.)

These arguments miss the point. First, the test under 21 U.S.C. § 355(j)(5)(B)(iii) is whether a party "reasonably failed to cooperate in expediting" the litigation--not whether it affirmatively delayed it. Moreover, fact discovery already had closed on all issues except those raised by Eon's newly-asserted counterclaims by the time Dey disclosed the DART study in July 2005. (2nd Amended Joint Stipulation Regarding Case Management Order.) Thus, that Eon has not propounded new discovery based on the DART study is not surprising.

2. Incorrect Application of Law

Dey further argues that the Court's decision incorrectly applied the law. First, Dey argues that the Court erred in failing to recognize that the law of inventorship is complex and that, as a result, Congress has allowed inventorship to be easily corrected under 35 U.S.C. § 256 as to any or all inventors listed on a patent. [FN9] Dey cites numerous cases for the proposition that inventorship is one of the most difficult and complex issues in patent law. (MFR, p. 10.) It also argues that inventorship is a question of law reviewed without deference by the Federal Circuit, that the inventors as named in an issued patent are presumed to be correct, and that a party seeking to be added to a patent as a co-inventor has the burden of proving by clear and convincing evidence that the inventor listed in the patent derived the invention from the claimant's work. (MFR, p. 10.) Although Dey does not explain how it believes these legal principles relate to its position that it did not fail reasonably to cooperate in expediting this action, Dey's argument presumably is that it should not be expected to have any position on inventorship prior to trial because inventorship is such a complex thicket.

FN9. 35 U.S.C. § 256 provides:

Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order cor-

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> rection of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

Without disputing Dey's characterization of the law on inventorship, the Court disagrees that those legal rules justify Dey's conduct in this case. Contrary to Dey's allegations, the only "law" that this Court applied in granting Eon's motion to lift the 30-month stay was the clause in 21 U.S.C. § 355(j)(5)(B)(iii) allowing the Court to lift the stay where a party "fail[s] to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). That inventorship is a difficult legal issue does not excuse Dey's failure to conduct a thorough investigation, before suing for infringement, into the roles played by its various employees and former employees in the process culminating in the patented subject matter. Nor does the fact that inventorship is decided as a matter of law based on underlying facts. Dey's legal position on inventorship should have been informed by an adequate factual investigation from the start. Indeed, the fact that inventors as named in a patent are presumed to be correct cuts against Dey's argument that it is entitled to delay investigating the factual basis for its assertions of inventorship until after the close of the evidence at trial: That a patentee's assertion of inventorship is presumed correct presupposes that it is supported by a valid factual basis. That an opponent must produce clear and convincing evidence to overcome the presumption of correctness makes it all the more reasonable that the opponent should be informed prior to the close of discovery who the alleged inventors are as to whom it bears that evidentiary burden.

***9** The legislative history of the Hatch-Waxman Amendments suggests that failure to conduct an adequate prefiling investigation should come within 21 U.S.C. § 355(j)(5)(B)(iii)'s scope. Those amendments were passed to smooth the "cumbersome drug approval process [which] delayed the entry of relatively inexpensive generic drugs into the market place." *In re Cardizem CD Antitrust Litigation*, 105 F.Supp.2d 618, 627 (E.D.Mich.2000) (*quoting Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F.Supp.2d 30, 32 (D.D.C.2000)). The amendments reflect a Congressional intent "to make available more low cost generic drugs" and an effort "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Id.* (*quoting Mylan*, 81 F.Supp.2d at 32.). [FN10] To permit a name-brand drug maker to derive hundreds of thousands of dollars each month from a patent, when it does not know who made the most significant contributions to the patented invention's conception, during an uninterrupted 30-month period following its filing suit on the patent, would frustrate Congress' intent to expedite the entry of less expensive drugs into the marketplace.

> FN10. The Act's purpose of encouraging generic drug makers to market their products is demonstrated by the fact that the Act awards the first generic drug manufacturer to make a paragraph IV certification with an uninterrupted 180-day period free from competition from other generic competitors. That is, once the first generic manufacturer submits an ANDA, no other ANDA can be approved for the same generic product for 180 days, running from the date the prior ANDA applicant begins commercially marketing its drug. *Cardizem*, 105 F.Supp.2d at 628-29 (*quoting Mylan*, 81 F.Supp.2d at 33.). 21 U.S.C. § 355(j)(5)(B)(iv) provides: "[I]f the [ANDA] contains a [subpart IV] certification, and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant." 21 U.S.C. § 355(j)(5)(B)(iv)(I). "First applicant" is defined as "an applicant that, on the first day on which a substantially complete application containing a [subpart IV] certification ... is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certifica-

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> tion described in paragraph (2)(A)(vii)(IV) for the drug." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

Dey also argues that the Court's decision is mistaken because Dey's conduct in this case was "far less egregious than the patentee's conduct in *U.S. Indust., Inc. v. Norton Co.*, [FN11] where the corporate patent holder knew that there was a problem with inventorship, knew the name of the inventor more than a year before litigation commenced, and, despite failing to move for correction of inventorship until long after litigation commenced, still was not found to have delayed the case." (MFR, p. 18.) *Norton,* however, addressed significantly different circumstances from those present here. Most obviously, the issue in *Norton* was not whether to lift a statutory stay (indeed, the Hatch-Waxman Amendments creating the statutory stay had not even been passed at the time *Norton* was decided). Rather, the defendant patentee in *Norton* sought to correct inventorship by adding an inventor pursuant to 35 U.S.C. § 256, and the plaintiff sought to prevent amendment on the grounds of laches. (*Id.* at *1- 2, 8-9.) The court held that any prejudice from the patentee's delay in moving to amend inventorship would be more appropriately addressed by allowing for additional discovery than by "summary invalidation of the patent." *Id.* at * 11.

> FN11. No. 71-CV-359, 1974 U.S. Dist. LEXIS 6377, 184 U.S.P.Q. (BNA) 187 (N.D.N.Y. Nov. 7, 1974) (as amended).

Unlike in *Norton,* no party in this case seeks "summary invalidation" of the ' 842 patent. Indeed, no party even argues that Dey should not be permitted to amend inventorship pursuant to 35 U.S.C. § 256. Eon only seeks to terminate the statutory stay on FDA approval of its generic drug on the ground that Dey's failure to enter this litigation with a clear picture on inventorship has constituted a failure to reasonably cooperate in expediting the action. There is nothing inconsistent about holding both (1) that Dey may seek to correct inventorship if new facts demonstrate a need to do so, and also (2) that Dey nevertheless should be required to inform itself of the facts underlying its claims of inventorship early in the action rather than waiting until the close of the evidence at trial to discover the role played by each of its own current and former employees in the development of the patented material. Had the Hatch-Waxman Amendments been in effect at the time *Norton* was decided, and had the plaintiff sought to have the stay lifted, the *Norton* court might well have reached the same result that this Court reached in its decision.

***10** Finally, Dey asserts that the Court's decision improperly penalizes Dey for engaging in a "non-frivolous assertion of its legal rights" to petition the Court and the PTO to correct inventorship pursuant to 35 U.S.C. § 256. (MFR, p. 20.) It cites *Zeneca Ltd. v. Pharmachemie B.V.*, 16 F.Supp.2d 112 (D.Mass.1998) for the proposition that 21 U.S.C. § 355(j)(5)(B)(iii)'s standard of "fail[ing] to reasonably cooperate in expediting the action" is " 'not be construed so as to encompass nonfrivolous assertions of legal rights." (MFR, p. 20.) *Zeneca,* however, did not involve a party's failure to enter the case with an informed position on a key issue. Rather, the defendant in that case was alleged to have "failed reasonably to cooperate in expediting the action" by filing a motion (which ultimately was successful) contesting the court's exercise of personal jurisdiction over it. *Zeneca,* 16 F.Supp.2d at 116. The court held that the defendant had a due process right not to be sued in a court that had no personal jurisdiction over it, that its motion had legal and factual support, and, thus, that the challenge to personal jurisdiction did not constitute unreasonable failure to cooperate in expediting the litigation. *Id.* In this case, by contrast, the challenged conduct is not Dey's exercise of its right to seek correction of inventorship under 35 U.S.C. § 256 per se, nor is it the filing of any motion with solid legal and factual support. This Court does not dispute that Dey has the right to correct inventorship under appropriate circumstances. The Court only takes issue with Dey's assertion that it did not have to make a good faith effort to identify the inventors of the subject matter claimed by the '842 patent at the time it filed its application, before it initiated this litigation, and during the course of this litigation. [FN12]

> FN12. Dey further argues that reconsideration is warranted based on facts that became available after the hearing on Eon's Motion

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> to Shorten the 30-Month Stay. Specifically Dey argues that Eon's expert reports, produced after the hearing, did not rely on or refer to the DART study or documents associated with it. (MFR, p. 1.) However, Dey does not produce copies of those expert reports. Moreover, that Eon' experts may not have relied on or referred to the DART study does not decrease the high likelihood that Eon would not have conducted its discovery in a different way had the study been timely disclosed.

D. Conclusion

For the foregoing reasons, Dey's motion for reconsideration of this Court's November 4, 2005 Order granting Eon's motion to shorten the statutory 30-month stay is DENIED.

Not Reported in F.Supp.2d, 2005 WL 3578120 (C.D.Cal.)

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on March 30, 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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