UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

NOTICE OF SUBPOENA (BYRON CHEMICAL COMPANY, INC.)

PLEASE TAKE NOTICE that the attached subpoena will be served on Byron Chemical Company, Inc., 40-11 23rd Street, Long Island City, NY 11101.

BY HAND & E-MAIL

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

BY FEDERAL EXPRESS & E-MAIL

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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

Attorneys for Plaintiffs

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1850 K Street NW
Washington, DC 20006
(202) 835-7500

Date: April 2, 2007

CERTIFICATE OF SERVICE

I hereby certify that on April 2, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to Richard D. Kirk.

I further certify that I caused to be served copies of the foregoing document on April 2, 2007 upon the following in the manner indicated:

BY HAND & E-MAIL

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

BY FEDERAL EXPRESS & E-MAIL

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Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza
180 N. Stetson Avenue, Suite 4900
Chicago, IL 60601

/s/ Jack B. Blumenfeld
Jack B. Blumenfeld (#1014)

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

Issued by the

UNITED STATES DISTRICT COURT

DISTRICT OF Eastern District of New York

AstraZeneca AB, Aktiebolaget Hassle, et al.

V.

Dexcel Pharma Technologies, Ltd., Dexcel, Ltd., Dexxon. Ltd.. Cipla. Ltd.

SUBPOENA IN A CIVIL CASE

Case Number:[1] 1:06cv358 (SLR)
District of Delaware

TO: Nicholas Cola, President of Byron Chemical Company, Inc.
40-11 23rd St
Long Island City, NY 11101

☐ 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 on the topics identified in Schedule A.

PLACE OF DEPOSITION	DATE AND TIME
Milbank, Tweed, Hadley & McCloy, One Chase Manhattan Plaza, New York City, NY, 10005	5/10/2007 10:00 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 B

PLACE	DATE AND TIME
Milbank, Tweed, Hadley & McCloy, One Chase Manhattan Plaza, New York City, NY, 10005	5/2/2007 10:00 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
	4/2/2007

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER
Robert J. Koch, Milbank, Tweed, Hadley & McCloy, One Chase Manhattan Plaza, New York City, NY, 10005

(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.

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. "Byron" refers to Byron Chemical Company, Inc., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

B. "Andrx" refers to Andrx Pharmaceuticals, Inc., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

C. "Cipla" refers to Cipla, Ltd., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

D. "Dexcel" refers to Dexcel, Ltd., Dexxon, Ltd., and/or Dexcel Pharma Technologies, Ltd., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

E. "Plaintiff" refers to AstraZeneca AB, Aktiebolaget Hässle, KBI Inc., KBI-E Inc. and/or AstraZeneca LP.

F. The "'380 patent" means U. S. Patent No. 6,150,380, all applications to which U. S. Patent No. 6,150,380 claims or is entitled to the benefit of a filing date, in whole or in part, and including all Related parent, continuation, continuation-in-part and divisional applications and including all reissues, reexaminations and extensions.

G. "Patents-in-suit" refers to U. S. Patent Nos. 6,150,380, 4,786,505, and 4,853,230 and all applications to which these patents claim or are entitled to the benefit of a filing date, in whole or in part, and including all Related parent, continuation, continuation-in-part and divisional applications and including all reissues, reexaminations and extensions.

H. "NDA" means a New Drug Application as used in 21 U.S.C. § 355 and regulations issued by the Food and Drug Administration pursuant thereto. "ANDA" means an Abbreviated New Drug Application as used in 21 U.S.C. § 355 and regulations issued by the Food and Drug Administration pursuant thereto.

I. "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.

J. "Omeprazole" means 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any form, including bulk omeprazole, including any salt thereof.

K. "Omeprazole Formulation" means 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole combined, mixed or otherwise present with at least one other pharmaceutically acceptable compound. An "omeprazole formulation" may include without limitation an oral dosage form comprising omeprazole, pharmaceutical suspensions comprising omeprazole, and/or other pharmaceutical preparations comprising omeprazole, such as the Dexcel NDA Product as defined herein. "Omeprazole Formulation" does not mean bulk omeprazole alone but does include without limitation omeprazole (including bulk omeprazole) with any other pharmaceutically acceptable compound.

L. "Dexcel NDA Product" means the drug product described in Dexcel's New Drug Application No. 22-032 for which FDA approval is sought for marketing in the United States.

M. "Drug master file" or "DMF" has the meanings set forth in 21 C.F.R. §314.

N. "Relating" or "Related" to any given subject means comprising constituting, containing, concerning, embodying, reflecting, identifying, stating, referring to, dealing with, or in any way pertinent to that subject.

TOPICS FOR DEPOSITION

1. DMF 12827, including but not limited to the original text and all annual reports, updates, supplements and amendments thereto.

2. Documents Relating to any DMF owned by Cipla concerning Omeprazole.

3. Communications between Byron and the FDA concerning DMF 12827.

4. Communications between Byron and the FDA concerning the approvable letter and all requested changes proposed, suggested or required by the FDA, and all such changes in fact made or suggested or discussed with FDA.

5. Communications between Byron and any third party concerning DMF 12827.

6. Communications between Byron and Cipla concerning DMF 12827.

7. Communications between Byron and Andrx or Dexcel concerning DMF 12827.

8. Communications between Byron and Dexcel concerning Dexcel NDA No. 22-032.

9. Communications between Byron and Dexcel, Andrx, or Cipla concerning Omeprazole.

10. Communications between Byron and any third party concerning Omeprazole.

11. All agreements between Byron and Dexcel, Andrx, or Cipla concerning Omeprazole.

12. Documents Relating to the Dexcel NDA Product.

13. Communications between Byron and Dexcel concerning the Dexcel NDA Product.

14. Communications between or among Byron employees and/or employees of Byron parents, subsidiaries or affiliates concerning any Omeprazole Formulation, including but not limited to the Dexcel NDA Product.

15. Communications between or among Byron employees and/or employees of Byron parents, subsidiaries or affiliates concerning Omeprazole.

16. Documents Relating to any Omeprazole Formulation.

17. Documents Relating to Dexcel's Omeprazole Formulation.

18. Batch records for each batch and lot of Omeprazole made by Cipla since 1996.

19. Batch records for each batch and lot of Omeprazole made by Cipla since 1996.

20. All research and development Relating to Omeprazole.

21. The importation and exportation of Omeprazole to the United States by Byron since 1996.

22. The importation and exportation of Omeprazole by Byron on behalf of or to Cipla or Dexcel.

23. Results or data (including electronic results and data in electronic form) concerning any testing, studies or analyses of the structure, identity or solid state properties of any omeprazole including but not limited to any testing, studies or analyses of the crystallinity, crystal form or crystal structure of said omeprazole, the chemical purity of said omeprazole; and

any testing, studies or analyses using or relying on fourier transform infrared spectroscopy, Raman spectroscopy, x-ray powder diffraction, single crystal x-ray crystallography, solid state NMR and the like of said omeprazole; including any such testing or analysis as described herein done on behalf of Byron by a third party or by Byron.

24. Results or data (including electronic results and data in electronic form) concerning any testing, studies or analyses of the structure, identity or solid state properties of any omeprazole used in a Dexcel NDA Product including but not limited to any testing, studies or analyses of the crystallinity, crystal form or crystal structure of said omeprazole, the chemical purity of said omeprazole; and any testing, studies or analyses using or relying on Fourier transform infrared spectroscopy, Raman spectroscopy, x-ray powder diffraction, single crystal x-ray crystallography, solid state NMR and the like of said omeprazole; including any such testing or analysis as described herein done on behalf of Byron by a third party or by Byron.

25. Testing or analyses that addresses any issue Relating to infringement of any Patent-in-Suit.

26. The validity of any of the Patents-in-Suit.

27. Documents Relating to any Patent-in-Suit.

28. The ownership, inventorship, patentability, enforceability and infringement of any Patent-in-Suit.

29. Documents Relating to any property of any Omeprazole Formulation, including but not limited to the physical structure, chemical purity, optical purity, chemical composition and structure of any omeprazole formulation, solid state properties, crystallinity, water content, solvent content, potency and bioavailability.

30. Documents Relating to any property of the Dexcel NDA Product, including but not limited to the physical structure, chemical purity, optical purity, chemical composition and structure of any omeprazole formulation, solid state properties, crystallinity, water content, solvent content, potency and bioavailability.

31. Testing or analysis and interpretation of data, including but not limited to solid state analysis, solid state NMR, x-ray powder diffraction, fourier transform infrared spectroscopy, Raman spectroscopy and single crystal x-ray diffraction of all lots of Cipla omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443; FX9274; FX0323; FX90458; FX9566; FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

32. Communications between Byron and Dexcel concerning all lots of Cipla omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443; FX9274; FX0323; FX90458; FX9566; FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

33. Communications between Byron and Andrx or Cipla concerning all lots of Byron omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443; FX9274; FX0323; FX90458; FX9566;

FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

34. Communications between Byron and any third party concerning all lots of Cipla omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443; FX9274; FX0323; FX90458; FX9566; FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

35. Determination of the 5-methoxy and/or 6-methoxy isomer content of any Omeprazole.

36. Determination of the 5-methoxy and/or 6-methoxy isomer content of any Omeprazole sold or offered for sale to Dexcel.

37. Determination of the 5-methoxy and/or 6-methoxy isomer content of any Omeprazole sold or offered for sale in the United States prior to November 10, 1997.

38. Determination of the ratio of 6-methoxy to 5-methoxy isomers in any Omeprazole.

39. Determination of the ratio of 6-methoxy to 5-methoxy isomers in any Omeprazole sold or offered for sale to Dexcel.

40. Determination of the ratio of 6-methoxy to 5-methoxy isomers in any Omeprazole sold or offered for sale in the United States prior to November 10, 1997.

41. Determination of the Form A and/or Form B content, as defined by the '380 patent, in any Omeprazole.

42. Determination of the Form A and/or Form B content, as defined by the '380 patent, in any Omeprazole sold or offered for sale to Dexcel.

43. Determination of the Form A and/or Form B content, as defined by the '380 patent, in any Omeprazole sold or offered for sale in the United States prior to November 10, 1997.

44. Each step in any process used by Cipla for the manufacture of omeprazole.

45. Each and every process step used to make the Cipla omeprazole that Dexcel contends was sold in the United States prior to November 10, 1997.

46. Each and every process used by Cipla to manufacture omeprazole from 1996 to present, including any changes made in such processes.

47. Each and every crystallization conditions used in the production and/or manufacture of omeprazole from 1996 to present, including any changes made in such conditions.

48. The crystallization conditions used in the production and/or manufacture of omeprazole by Cipla including, but not limited to solvent or solvent system, solution components, seed crystals, temperature, time, volume, mass, pH, evaporation conditions and the like.

49. The crystallization conditions used in the production and/or manufacture of omeprazole by Cipla for sale or offer for sale to Dexcel including, but not limited to, solvent or solvent system, solution components, seed crystals, temperature, time, volume, mass, pH, evaporation conditions and the like.

50. The crystallization conditions used in the production and/or manufacture of omeprazole by Cipla for sale or offer for sale in the United States prior to November 10, 1997

including, but not limited to, solvent or solvent system, solution components, seed crystals, temperature, time, volume, mass, pH, evaporation conditions and the like.

51. The importation into the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole.

52. The importation into the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole on behalf of Dexcel.

53. The importation into the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole on behalf of Andrx.

54. The importation into the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole on behalf of Cipla.

55. Any shipment or sale or offer for sale of Omeprazole to the United States on or before November 10, 1997.

56. All communications Relating to any shipment or sale or offer for sale of Omeprazole to the United States on or before November 10, 1997.

57. Documents Relating to AstraZeneca concerning Omeprazole.

58. Documents Relating to AstraZeneca concerning the Dexcel NDA Product.

59. The identity, position and responsibility of all Byron personnel involved in interacting with the United States Food and Drug Administration with regard to Omeprazole.

60. The identity, position and responsibility of all Byron personnel involved in interacting with the United States Food and Drug Administration with regard to DMF 12827.

61. The identity of all persons involved in or responsible for the development of any process used to make Omeprazole used or contemplated for use in any Omeprazole Formulation

including but not limited to organizational charts and documents identifying each such person's position, responsibilities and time period position was held.

62. The identity of all persons involved in or responsible for the development, drafting, research or advice directed to DMF 12827 including but not limited to organizational charts and documents identifying each such person's position, responsibilities and time period position was held.

63. The corporate, management and personnel organizational structure of Byron, including each parent, subsidiary or affiliate.

64. The licensing or approval of any production facility or plant by any agency of any State or Federal government of the United States for the production of omeprazole.

65. Any business or scientific collaboration between Byron and any third party Relating to Omeprazole.

66. All electronic databases owned or controlled by Byron containing information Relating to Omeprazole.

67. All communications, including electronic mail communications, Relating to the Dexcel NDA product to or from any employee of Byron, including any corporate parent, subsidiary or affiliate.

SCHEDULE B

DEFINITIONS

As used in these Requests, the following terms have the indicated meaning:

A. "Byron" refers to Byron Chemical Company, Inc., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

B. "Andrx" refers to Andrx Pharmaceuticals, Inc., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

C. "Cipla" refers to Cipla, Ltd., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

D. "Dexcel" refers to Dexcel, Ltd., Dexxon, Ltd., and/or Dexcel Pharma Technologies, Ltd., and any owners, officers, directors, employees, agents, representatives, principals, partners, corporate parent, divisions, predecessors, subsidiaries or affiliates thereof either directly or indirectly as any of the above.

E. "Plaintiff" refers to AstraZeneca AB, Aktiebolaget Hässle, KBI Inc., KBI-E Inc. and/or AstraZeneca LP.

F. The "'380 patent" means U. S. Patent No. 6,150,380, all applications to which U. S. Patent No. 6,150,380 claims or is entitled to the benefit of a filing date, in whole or in part, and including all Related parent, continuation, continuation-in-part and divisional applications and including all reissues, reexaminations and extensions.

G. "Patents-in-suit" refers to U. S. Patent Nos. 6,150,380, 4,786,505, and 4,853,230 and all applications to which these patents claim or are entitled to the benefit of a filing date, in whole or in part, and including all Related parent, continuation, continuation-in-part and divisional applications and including all reissues, reexaminations and extensions.

H. "NDA" means a New Drug Application as used in 21 U.S.C. § 355 and regulations issued by the Food and Drug Administration pursuant thereto. "ANDA" means an Abbreviated New Drug Application as used in 21 U.S.C. § 355 and regulations issued by the Food and Drug Administration pursuant thereto.

I. "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.

J. "Omeprazole" means 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any form, including bulk omeprazole, including any salt thereof.

K. "Omeprazole Formulation" means 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole combined, mixed or otherwise present with at least one other pharmaceutically acceptable compound. An "omeprazole formulation" may include without limitation an oral dosage form comprising omeprazole, pharmaceutical suspensions comprising omeprazole, and/or other pharmaceutical preparations comprising omeprazole, such as the Dexcel NDA Product as defined herein. "Omeprazole Formulation" does not mean bulk omeprazole alone but does include without limitation omeprazole (including bulk omeprazole) with any other pharmaceutically acceptable compound.

L. "Dexcel NDA Product" means the drug product described in Dexcel's New Drug Application No. 22-032 for which FDA approval is sought for marketing in the United States.

M. "Drug master file" or "DMF" has the meanings set forth in 21 C.F.R. §314.

N. "Relating" or "Related" to any given subject means comprising constituting, containing, concerning, embodying, reflecting, identifying, stating, referring to, dealing with, or in any way pertinent to that subject.

REQUESTS

DOCUMENT REQUEST NO. 1:

DMF 12827, including but not limited to the original text and all annual reports, updates, supplements and amendments thereto.

DOCUMENT REQUEST NO. 2:

All documents and things Relating to DMF 12827 and any annual report, update, supplement or amendment thereto.

DOCUMENT REQUEST NO. 3:

All documents and things Relating to any DMF owned by Cipla concerning Omeprazole.

DOCUMENT REQUEST NO. 4:

All documents and things Relating to communications between Byron and the FDA concerning DMF 12827.

DOCUMENT REQUEST NO. 5:

All documents and things relating to communications between Byron and the FDA concerning the approvable letter and all requested changes proposed, suggested or required by the FDA, and all such changes in fact made or suggested or discussed with FDA.

DOCUMENT REQUEST NO. 6:

All documents and things Relating to communications between Byron and any third party concerning DMF 12827.

DOCUMENT REQUEST NO. 7:

All documents and things Relating to communications between Byron and Cipla concerning DMF 12827.

DOCUMENT REQUEST NO. 8:

All documents and things Relating to communications between Byron and Andrx or Dexcel concerning DMF 12827.

DOCUMENT REQUEST NO. 9:

All documents and things Relating to Dexcel NDA No. 22-032.

DOCUMENT REQUEST NO. 10:

All documents and things Relating to communications between Byron and Dexcel concerning Dexcel NDA No. 22-032.

DOCUMENT REQUEST NO. 11:

All documents and things Relating to communications between Byron and Dexcel Relating to Omeprazole.

DOCUMENT REQUEST NO. 12:

All agreements between Byron and Dexcel concerning Omeprazole.

DOCUMENT REQUEST NO. 13:

All documents and things Relating to all agreements between Byron and Dexcel concerning Omeprazole.

DOCUMENT REQUEST NO. 14:

All documents and things Relating to communications between Byron and Andrx concerning Omeprazole.

DOCUMENT REQUEST NO. 15:

All documents and things Relating to communications between Byron and Cipla concerning Omeprazole.

DOCUMENT REQUEST NO. 16:

All agreements between Byron and Andrx concerning Omeprazole.

DOCUMENT REQUEST NO. 17:

All agreements between Byron and Cipla concerning Omeprazole.

DOCUMENT REQUEST NO. 18:

All documents and things Relating to any agreements between Byron and Andrx concerning Omeprazole.

DOCUMENT REQUEST NO. 19:

All documents and things Relating to any agreements between Byron and Cipla concerning Omeprazole.

DOCUMENT REQUEST NO. 20:

All documents and things Relating to communications between Byron and any third party concerning Omeprazole.

DOCUMENT REQUEST NO. 21:

All documents and things Relating to the Dexcel NDA Product.

DOCUMENT REQUEST NO. 22:

All documents and things Relating to communications between Byron and Dexcel concerning the Dexcel NDA Product.

DOCUMENT REQUEST NO. 23:

All documents and things Relating to communications between or among Byron employees and/or employees of Byron parents, subsidiaries or affiliates concerning any Omeprazole Formulation, including but not limited to the Dexcel NDA Product.

DOCUMENT REQUEST NO. 24:

All documents and things Relating to communications between or among Byron employees and/or employees of Byron parents, subsidiaries or affiliates concerning Omeprazole.

DOCUMENT REQUEST NO. 25:

All documents and things Relating to any Omeprazole Formulation.

DOCUMENT REQUEST NO. 26:

All documents and things Relating to the Dexcel Omeprazole Formulation.

DOCUMENT REQUEST NO. 27:

All batch records for each batch and lot of Omeprazole made by Cipla since 1996.

DOCUMENT REQUEST NO. 28:

All documents and things Relating to all batch records for each batch and lot of Omeprazole made by Cipla since 1996.

DOCUMENT REQUEST NO. 29:

All documents and things Relating to research and development Relating to Omeprazole.

DOCUMENT REQUEST NO. 30:

All documents and things Relating to the importation and exportation of Omeprazole to the United States by Byron since 1996.

DOCUMENT REQUEST NO. 31:

All documents and things Relating to the importation and exportation of Omeprazole by Byron on behalf of or to Cipla or Dexcel.

DOCUMENT REQUEST NO. 32:

All documents and things Relating to results or data (including electronic results and data in electronic form) concerning any testing, studies or analyses of the structure, identity or solid state properties of any omeprazole including but not limited to any testing, studies or analyses of the crystallinity, crystal form or crystal structure of said omeprazole, the chemical purity of said omeprazole; and any testing, studies or analyses using or relying on fourier transform infrared spectroscopy, Raman spectroscopy, x-ray powder diffraction, single crystal x-ray crystallography, solid state NMR and the like of said omeprazole; including any such testing or analysis as described herein done on behalf of Byron by a third party or by Byron.

DOCUMENT REQUEST NO. 33:

All documents and things Relating to results or data (including electronic results and data in electronic form) concerning any testing, studies or analyses of the structure, identity or solid state properties of any omeprazole used in a Dexcel NDA Product including but not limited to any testing, studies or analyses of the crystallinity, crystal form or crystal structure of said omeprazole, the chemical purity of said omeprazole; and any testing, studies or analyses using or relying on fourier transform infrared spectroscopy, Raman spectroscopy, x-ray powder diffraction, single crystal x-ray crystallography, solid state NMR and the like of said omeprazole;

including any such testing or analysis as described herein done on behalf of Byron by a third party or by Byron.

DOCUMENT REQUEST NO. 34:

All documents and things Relating to any testing or analyses that addresses any issue Relating to infringement of any Patent-in-Suit.

DOCUMENT REQUEST NO. 35:

All documents and things Relating to the validity of any of the Patents-in-Suit.

DOCUMENT REQUEST NO. 36:

All documents and things Relating to any Patent-in-Suit.

DOCUMENT REQUEST NO. 37:

All documents and things Relating to the ownership, inventorship, patentability, enforceability and infringement of any Patent-in-Suit.

DOCUMENT REQUEST NO. 38:

All documents and things Relating to any property of any Omeprazole Formulation, including but not limited to the physical structure, chemical purity, optical purity, chemical composition and structure of any Omeprazole Formulation, solid state properties, crystallinity, water content, solvent content, potency and bioavailability.

DOCUMENT REQUEST NO. 39:

All documents and things Relating to any property of the Dexcel NDA Product, including but not limited to the physical structure, chemical purity, optical purity, chemical composition and structure of any omeprazole formulation, solid state properties, crystallinity, water content, solvent content, potency and bioavailability.

DOCUMENT REQUEST NO. 40:

All documents and things (including electronic data in electronic form) Relating to any testing or analysis and interpretation of data, including but not limited to solid state analysis, solid state NMR, x-ray powder diffraction, fourier transform infrared spectroscopy, Raman spectroscopy and single crystal x-ray diffraction of all lots of Cipla omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443; FX9274; FX0323; FX90458; FX9566; FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

DOCUMENT REQUEST NO. 41:

All documents and things Relating to any communications between Byron and Dexcel concerning all lots of Cipla omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443; FX9274; FX0323; FX90458; FX9566; FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

DOCUMENT REQUEST NO. 42:

All documents and things Relating to any communications between Byron and Andrx or Cipla concerning all lots of Byron omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443;

FX9274; FX0323; FX90458; FX9566; FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

DOCUMENT REQUEST NO. 43:

All documents and things Relating to any communications between Byron and any third party concerning all lots of Cipla omeprazole batch numbers FX7061; FX6107; FX6273; FX7246; F80453; F80463; FX9311; FX9593; FX0284; FX0341; F10034; F10035; F10128; F10129; F40615, F40618; F50071; F20070; FX8128; F90165; FX9329; F90105; F90443; FX9274; FX0323; FX90458; FX9566; FX1066; F20789; F20897; F20453; FX7061; FX8212; FX8213; FX7268; FX6311; FX7341; FX6346; FX1231; FX1232; FX1233; FX31213; FX31214; and FX31215.

DOCUMENT REQUEST NO. 44:

All documents and things Related to the determination of the 5-methoxy and/or 6-methoxy isomer content of any Omeprazole.

DOCUMENT REQUEST NO. 45:

All documents and things Related to the determination of the 5-methoxy and/or 6-methoxy isomer content of any Omeprazole sold or offered for sale to Dexcel.

DOCUMENT REQUEST NO. 46:

All documents and things Related to the determination of the 5-methoxy and/or 6-methoxy isomer content of any Omeprazole sold or offered for sale in the United States prior to November 10, 1997.

DOCUMENT REQUEST NO. 47:

All documents and things Related to the determination of the ratio of 6-methoxy to 5-methoxy isomers in any Omeprazole.

DOCUMENT REQUEST NO. 48:

All documents and things Related to the determination of the ratio of 6-methoxy to 5-methoxy isomers in any Omeprazole sold or offered for sale to Dexcel.

DOCUMENT REQUEST NO. 49:

All documents and things Related to the determination of the ratio of 6-methoxy to 5-methoxy isomers in any Omeprazole sold or offered for sale in the United States prior to November 10, 1997.

DOCUMENT REQUEST NO. 50:

All documents and things Related to the determination of the Form A and/or Form B content, as defined by the '380 patent, in any Omeprazole.

DOCUMENT REQUEST NO. 51:

All documents and things Related to the determination of the Form A and/or Form B content, as defined by the '380 patent, in any Omeprazole sold or offered for sale to Dexcel.

DOCUMENT REQUEST NO. 52:

All documents and things Related to the determination of the form A and/or form B content, as defined by the '380 patent, in any Omeprazole sold or offered for sale in the united states prior to November 10, 1997.

DOCUMENT REQUEST NO. 53:

All documents and things Related to each step in any process used by Cipla for the manufacture of omeprazole.

DOCUMENT REQUEST NO. 54:

All documents and things Related to each and every process step used to make the Cipla omeprazole that Dexcel contends was sold in the United States prior to November 10, 1997.

DOCUMENT REQUEST NO. 55:

All documents and things Related to each and every process used by Cipla to manufacture omeprazole from 1996 to present, including any changes made in such processes.

DOCUMENT REQUEST NO. 56:

All documents and things Related to each and every crystallization conditions used in the production and/or manufacture of omeprazole from 1996 to present, including any changes made in such conditions.

DOCUMENT REQUEST NO. 57:

All documents and things Related to the crystallization conditions used in the production and/or manufacture of Omeprazole by Byron including, but not limited to solvent or solvent system, solution components, seed crystals, temperature, time, volume, mass, pH, evaporation conditions and the like.

DOCUMENT REQUEST NO. 58:

All documents and things Related to the crystallization conditions used in the production and/or manufacture of omeprazole by Byron for sale or offer for sale to Dexcel including, but not limited to, solvent or solvent system, solution components, seed crystals, temperature, time, volume, mass, pH, evaporation conditions and the like.

DOCUMENT REQUEST NO. 59:

All documents and things Related to the crystallization conditions used in the production and/or manufacture of Omeprazole by Byron for sale or offer for sale in the United States prior

to November 10, 1997 including, but not limited to, solvent or solvent system, solution components, seed crystals, temperature, time, volume, mass, pH, evaporation conditions and the like.

DOCUMENT REQUEST NO. 60:

All documents and things Relating to the importation to the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole.

DOCUMENT REQUEST NO. 61:

All documents and things Relating to the importation into the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole on behalf of Dexcel.

DOCUMENT REQUEST NO. 62:

All documents and things Relating to the importation into the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole on behalf of Andrx.

DOCUMENT REQUEST NO. 63:

All documents and things Relating to the importation into the United States; use, sale, offer for sale; purchase and preparation of any Omeprazole on behalf of Cipla.

DOCUMENT REQUEST NO. 64:

All documents and things Relating to any shipment or sale or offer for sale of Omeprazole to the United States on or before November 10, 1997.

DOCUMENT REQUEST NO. 65:

All communications Relating to any shipment or sale or offer for sale of Omeprazole to the United States on or before November 10, 1997.

DOCUMENT REQUEST NO. 66:

All documents and things Relating to AstraZeneca concerning Omeprazole.

DOCUMENT REQUEST NO. 67:

All documents and things Relating to AstraZeneca concerning the Dexcel NDA Product.

DOCUMENT REQUEST NO. 68:

Documents and things sufficient to ascertain the identity, position and responsibility of all Byron personnel involved in interacting with the United States Food and Drug Administration with regard to Omeprazole.

DOCUMENT REQUEST NO. 69:

Documents and things sufficient to ascertain the identity, position and responsibility of all Byron personnel involved in interacting with the United States Food and Drug Administration with regard to DMF 12827.

DOCUMENT REQUEST NO. 70:

Documents sufficient to ascertain the identity of all persons involved in or responsible for the development of any process used to make Omeprazole used or contemplated for use in any Omeprazole Formulation including but not limited to organizational charts and documents identifying each such person's position, responsibilities and time period position was held.

DOCUMENT REQUEST NO. 71:

Documents sufficient to ascertain the identity of all persons involved in or responsible for the development, drafting, research or advice directed to DMF 12827 including but not limited to organizational charts and documents identifying each such person's position, responsibilities and time period position was held.

DOCUMENT REQUEST NO. 72:

Documents sufficient to show the corporate, management and personnel organizational structure of Byron, including each parent, subsidiary or affiliate.

DOCUMENT REQUEST NO. 73:

All documents and things Relating to the licensing or approval of any production facility or plant by any agency of any State or Federal government of the United States for the production of omeprazole.

DOCUMENT REQUEST NO. 74:

All documents and things Relating to any business or scientific collaboration between Byron and any third party Relating to Omeprazole.

DOCUMENT REQUEST NO. 75:

Electronic copies of all electronic databases owned or controlled by Byron containing information Relating to Omeprazole.

DOCUMENT REQUEST NO. 76:

All communications, including electronic mail communications, Relating to the Dexcel NDA product to or from any employee of Byron, including any corporate parent, subsidiary or affiliate.

DOCUMENT REQUEST NO. 77:

All software and instructions necessary to access any of the databases and electronic mail referred to in the previous requests.

DOCUMENT REQUEST NO. 78:

All documents Relating to Byron's policies for maintaining, destroying, updating, or retaining documents or files, whether in its computer system, email system, telephone system, or paper copies.