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 CIPLA LTD,,	)	
Defendants.	)	

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

Richard D. Kirk (rk0922)
THE BAYARD FIRM
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899-5130
(302) 655-5000
rkirk@bayardfirm.com

Counsel for Defendants Dexcel Ltd., Dexxon Ltd., and Dexcel Pharma Technologies Ltd.

Of Counsel
Robert F. Green
David M. Airan
Saumil S. Mehta
Caryn C. Borg-Breen
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
Chicago, IL 60601-6780
(312) 616-5600

TABLE OF CONTENTS

I. INTRODUCTION 1

II. NATURE AND STAGE OF THE PROCEEDINGS 1

III. SUMMARY OF ARGUMENT 2

IV. STATEMENT OF FACTS 3

A. Plaintiffs' Failure to Take Meaningful Discovery 4

B. Plaintiffs' Negation of Discovery Sought by Defendants 6

C. Plaintiffs' Interference with Discovery of Merck Documents and Samples 9

D. Plaintiffs' Interference with Discovery of AAIpharma Documents and Samples 10

E. Plaintiffs' Interference with Discovery from White & Case 13

V. ARGUMENT 13

A. Plaintiffs Have Breached Their Affirmative Duty To Expedite This Litigation 13

1. The Hatch-Waxman Act Imposes An Affirmative Duty For Plaintiffs To Expedite This Action 14

2. Plaintiffs' Actions In Affirmatively Delaying This Litigation Are A Violation Of Their Duty To Expedite Resolution Of This Action And Warrant Relief 15

B. The Court Should Immediately Lift The Statutory Stays To Prevent Plaintiffs From Unfairly Benefiting From Their Violation Of Their Duty To Expedite This Case 19

1. The Appropriate Remedy For Plaintiffs' Violation Of The Hatch-Waxman Duty To Expedite Is Lifting Of The Stay 19

2. The Stay Should Be Lifted Immediately To Prevent Plaintiffs From Unfairly Profiting From Their Litigation Misconduct 20

VI. CONCLUSION 24

TABLE OF AUTHORITIES

Cases

21 U.S.C. § 355(c)(3)(C) ..... passim

Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368 (Fed. Cir. 2002) 21

Dey L.P. v. Eon Labs., Inc., 2005 WL 3578120 (C.D. Cal. Dec. 22, 2005) 22

Dey, L.P. v. Ivax Pharms., Inc., 233 F.R.D. 567 (C.D. Cal. 2005) 22

Glaxo, Inc. v. Torpharm, Inc., 1996 WL 288524 (N.D. Ill. May 30, 1996) 15

Imperial Chem. Indus., PLC v. Barr Labs., Inc., 126 F.RD. 467 (S.D.N.Y. 1989) 15

In re Nifedipine Capsule Patent Litig., 1989 WL 111112 (S.D.N.Y. Sept. 20, 1989) 15, 18, 21

Mylan Pharms., Inc. v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000) 22

Statutes

21 U.S.C. § 355(c)(3)(C) ..... passim

21 U.S.C. § 355a 19

Other Authorities

H.R. Rep. 98-857(I), 1984 U.S.C.C.A.N. 2647 ..... 14, 15

H.R. Rep. 98-857(II), 1984 U.S.C.C.A.N. 2686 ..... 14, 22

I. INTRODUCTION

Dexcel Ltd., Dexxon Ltd., and Dexcel Pharma Technologies Ltd. (collectively "Defendants") respectfully request the Court to lift the statutory 30-month stay on FDA approval at this time, because Astrazeneca AB, Aktiebolaget Hässle, KBI-E, Inc., KBI, Inc., and Astrazeneca LP (collectively "Plaintiffs") have failed to reasonably cooperate in expediting this action as required by statute. 21 U.S.C. § 355(c)(3)(C). Generally, (1) although Plaintiffs put Defendants through the task of producing thousands of pages of irrelevant documents, Plaintiffs to date have not relied upon even one of those documents and have not taken nor even noticed a single deposition on the merits, (2) Plaintiffs have failed to produce court-ordered discovery and simply refused to produce witnesses, and (3) Plaintiffs have interfered with and thereby prevented Defendants' attempts to obtain discovery from third parties.

II. NATURE AND STAGE OF THE PROCEEDINGS

This patent infringement suit arises from Dexcel Pharma Technologies Ltd.'s ("DPT Ltd.") filing of a New Drug Application ("NDA") No. 22-032 for 20 mg omeprazole delayed-release tablets ("DPT Ltd.'s Tablets") with the U.S. Food and Drug Administration ("FDA"). DPT Ltd.'s Tablets are meant to compete with Plaintiffs' blockbuster over-the-counter product, Prilosec® OTC, which has sales of $800,000,000 per year. See Exh. 1.[1]

Plaintiffs allege the filing of the NDA constituted a technical act of infringement of U.S. Patent Nos. 6,150,380 ("the '380 patent"); 4,786,505 ("the '505 patent"); and 4,853,230 ("the '230 patent"). (D.I. 1). The present motion to lift the stay on final FDA approval of DTP Ltd.'s NDA No. 22-032 details Plaintiffs' orchestrated plan to delay resolution of this lawsuit. The

[1] All exhibits referred to herein are exhibits to the Declaration of Exhibits by Saumil S. Mehta in support of Defendants' motion to lift the stay on FDA approval of Dexcel Pharma Technologies, Ltd.'s omeprazole delayed-release tablets.

Court, pursuant to the Hatch-Waxman Act[2] and its equitable powers, should now end the putative 30-month stay.

III. SUMMARY OF ARGUMENT

1. The Hatch-Waxman Act imposes an affirmative duty on all parties to patent litigation under the Act to "*reasonably cooperate in expediting the action.*" 21 U.S.C. § 355(c)(3)(C).[3] Nevertheless, at every turn Plaintiffs have engaged in dilatory tactics in breach of their statutory duty to assist in expediting resolution of this action.

2. Instead of expediting this action, Plaintiffs have orchestrated concerted delay tactics throughout the pendency of this litigation. Plaintiffs have sought irrelevant documents, taken no depositions on the merits, delayed or failed in providing discovery, and affirmatively blocked Defendants' efforts to obtain discovery from relevant third parties.

3. Plaintiffs are profiting from their obstruction of the progress of this action. Since the NDA for DPT Ltd.'s Tablets was deemed approvable by the FDA on December 8, 2006, see Ex. 2, the present litigation and the associated 30-month stay is all that stands in the way of the marketing of DPT Ltd.'s Tablets. Moreover, if the FDA does not approve DPT Ltd.'s NDA by April 20, 2007, the date two of the three patents-in-suit expire, absent court intervention, the FDA will not be able to grant such final approval until October 20, 2007. This is true because of the 6-month so-called pediatric exclusivity, the benefit of which Plaintiffs then will

---

[2] The Drug Price Competition and Patent Term Restoration Act is informally known as the "Hatch-Waxman Act." The Hatch-Waxman Act amended the Food Drug and Cosmetic Act and sets forth the process by which would-be marketers of generic drugs can file Abbreviated New Drug Applications (ANDAs) and NDAs to seek FDA approval of the generic.

[3] This case concerns a New Drug Application ("NDA") filed by DPT Ltd., rather than an Abbreviated New Drug Application ("ANDA"). Thus, this case does not fall under the specific provisions of the Hatch-Waxman Act concerning ANDA applications. However the obligation imposed by 21 U.S.C. § 355(c)(3)(C) for NDA filers is identical in language to that imposed by 21 U.S.C. § 355(j)(5)(B)(iii) for ANDA filers.

automatically obtain, regardless of whether this suit is later resolved during that six-month period. To prevent the clear prejudice to Defendants that will be caused by Plaintiffs' manifest delay of this action, the Court should use its authority under 21 U.S.C. § 355(c)(3)(C) and the Court's equitable powers to lift the stay on FDA approval of DPT Ltd.'s NDA. Plaintiffs' delay of this action then will not unfairly prevent final FDA approval of DPT Ltd.'s product.

4. A lift of the stay in this action will not deprive Plaintiffs' of their day in court regarding their infringement contentions. Even after final FDA approval of DPT Ltd's NDA, Plaintiffs will be free to pursue any extant claim of infringement of the three patents-in-suit. A lift of the stay will merely prevent Plaintiffs from unfairly benefiting from the dilatory tactics that they have employed thus far in this litigation, tactics that are in direct contravention of Plaintiffs' affirmative duty to "reasonably cooperate in expediting this action." As such, the Court's granting of the instant motion will remedy Plaintiffs' failure to cooperate in expediting this case, and will allow DPT Ltd. to obtain final FDA approval according to the timeframe it would have but for the delay orchestrated by Plaintiffs.

IV. STATEMENT OF FACTS

Defendants respectfully request that the Court lift the current stay on FDA approval at this time, because Plaintiffs have failed to cooperate in expediting this action as required by statute. 21 U.S.C. § 355(c)(3)(C). The requested relief is justified by the following facts.

A. Plaintiffs' Failure to Take Meaningful Discovery

Plaintiffs have had DPT Ltd.'s NDA No. 22-032, which describes the method of manufacture of the allegedly infringing DPT Ltd. Tablets, since May 26, 2006. See Exh. 3[4], and Plaintiffs have had samples of DPT Ltd.'s allegedly infringing omeprazole tablet (without confidentiality restrictions) since August 3, 2006. See Exh. 5.[5] Yet, to this day Plaintiffs have not tested DPT Ltd.'s Tablets for infringement.

Plaintiff's have refused to test Defendant's omeprazole active pharmaceutical ingredient ("API") to avoid taking an infringement position regarding the '380 patent.

- Plaintiffs requested that Defendants produce samples of the omeprazole active pharmaceutical ingredient ("API") and excipients used to prepare DPT Ltd.'s Tablets, indicating that such samples were needed to evaluate infringement and that they would "promptly begin our evaluation of the information" upon receipt of such samples. See Exh. 7, p. 1-2, and Exh. 8.
- Defendants offered to produce the requested samples to Plaintiffs, without any restrictions as to access, beginning in October 2006. When Plaintiffs failed to respond, Defendants again asked Plaintiffs about the samples on November 6, 2006. See Exh. 9.
- Plaintiffs then responded that they could not decide whether to accept delivery of the bulk omeprazole and excipient samples until Defendants clarified their

[4] Defendants produced the NDA subject to a May 24, 2006 agreement between AstraZeneca AB and Dexcel Pharma Technologies Ltd., which specified that such NDA would be accessible by AstraZeneca scientists Kurt Lovgren and David Noreland. See Exh. 4.

[5] Defendants produced these tablet samples without designating such samples "Confidential" in accordance with Delaware Local Rule 26.2. Accordingly, such tablets were produced without any restriction whatsoever on access. In response to Plaintiffs' alleged confusion on this point, counsel for Defendants informed Plaintiffs on November 9, 2006 that the tablets "were provided without any restriction with respect to use or access whatsoever." See Exh. 6.

"position regarding infringement of the '380 patent." See Exh. 10, p. 2, para. 2.

- After refusing to accept sample delivery, Plaintiffs in January requested "confirmation" that Defendants intended to produce the samples. See Exh. 11, p. 4, para. 9, 10. However, because of Plaintiffs' several month delay, Defendants were forced to prepare new samples for production to Plaintiffs.
- Even then, Plaintiffs resisted acceptance of the requested samples. On February 15, 2007, Defendants asked Plaintiffs to what address the courier should deliver the requested samples. See Exh. 12, para. 4. Plaintiffs failed to respond, and on March 6, 2007, with the close of fact discovery looming, Defendants resorted to essentially forcing the samples upon Plaintiffs' counsel. See Exh. 13.[6]

Plaintiffs argued for months of their need for documents relating to Defendants' unrelated omeprazole product sold in Israel. See Exh. 17, December 6, 2006 Hearing Tr. at 7:15 to 8:6. Despite the lack of relevance, Defendants produced on a rolling basis over 20,000 pages of discovery in response to Plaintiffs' requests. Plaintiffs, to date, have not relied on *a single page* of this discovery as a basis for their contention of infringement of any of the patents in suit. Plaintiffs' responses to Defendants' contention interrogatories regarding infringement rely *exclusively* on documents Plaintiffs have had in their possession since this action was filed.

[6] Again, Plaintiffs failed to respond. Accordingly, Defendants made arrangements for new samples to be shipped as indicated in the March 6, 2007 letter. On March 9, 2007 and again on March 15, 2007, Plaintiffs objected to having the samples delivered alleging problems with arranging storage conditions. See Exh. 14, p. 3, para. 6 and Exh. 15, para. 3. However such excuses were without merit, insofar as the tablet and excipient samples are harmless chemicals that, with the exception of two compounds which must be stored in a refrigerator, can be stored at room temperature in an office setting. See Exh. 16.

- Specifically, Plaintiffs' contention of infringement regarding the '505 and '230 formulation patents is entirely based on DPT Ltd.'s NDA (which Plaintiffs have had since May) and Dexcel Ltd.'s publicly available PCT application, WO 00/78284 A1, published December 28, 2000, which does not even disclose the allegedly infringing product. See Plaintiffs' Response to Dexcel Pharma Technologies Ltd.'s Third Set of Interrogatories Relating to the Merits. (D.I. 94).
- Similarly, Plaintiffs' contention of infringement regarding the '380 patent is based entirely on an alleged admission contained in DPT Ltd.'s notice of certification letters dated April 17, 2006. (D.I. 94).

During the March 12, 2007 conference, Plaintiffs indicated their desire to depose the inventors of the PCT application, WO 00/78284 A1. See Exh. 18 (March 12, 2007 Hearing Tr. at p. 33). In response, Defendants informed Plaintiffs on March 15, 2007 that one inventor was deceased, but that the other inventor, Ms. Valerie Azoulay, was available for deposition any time prior to March 30, 2007, keeping in mind the close of fact discovery on April 2, 2007. See Exh. 19. Plaintiffs have not responded to the letter nor noticed a deposition for Ms. Azoulay.

- To date, Plaintiffs have not noticed a single deposition on the merits in this action.

B. Plaintiffs' Negation of Discovery Sought by Defendants

Since October 2006, Defendants have sought from Plaintiffs various samples of omeprazole API, including potential prior art samples and representative samples of the product which is claimed by the '380 patent. See Dexcel Pharma Technologies Ltd.'s First Set of Document Requests (D.I. 45). By February, Plaintiffs had progressed to the point of stating only "We have located samples. We're -- we do not know how many we have or what samples we have." See Exh. 20, February 1, 2007 Hearing Tr. at p. 32:8-9. On March 15, 2007, Plaintiffs for the first time suggested that samples would actually be produced, but then with the caveat

that they could not verify or confirm that the samples had been stored under appropriate conditions. See Exh. 21.

- Plaintiffs have failed to produce even a single sample to Defendants to date.
- Perhaps most egregiously, Defendants in October 2006, requested a sample of the form of omeprazole covered by the '380 patent for comparative purposes. (D.I. 45). No such samples have been produced.

Since October 2006 Defendants have sought from Plaintiffs, with little success, the NDAs and DMFs detailing the method used by Plaintiffs for the manufacture of omeprazole and omeprazole-containing products. (D.I. 45).

- On January 25, 2007, Plaintiffs agreed during a meet and confer to produce an index for the NDA and DMF, which agreement was confirmed in writing. See Exh. 22, p. 1. Despite this agreement, Plaintiffs never produced these indices.
- On February 9, 2007, in response to the Court's order, Plaintiffs represented to the Court that they would produce "sections of the NDA and DMFs that contain analytical data relating to the characterization of the neutral form of omeprazole used in Prilosec." See Exh. 23. Despite this representation, Plaintiffs produced only *two pages* containing analytical testing to Defendants.
- On March 12, 2007, during a meet and confer, Plaintiffs again refused to produce the requested NDA and DMF. Then, only minutes before the hearing before this Court, Plaintiffs' counsel agreed to produce the DMF and NDA.
- On March 13, 2007, Defendants requested production of the DMF and NDA, both of which Plaintiffs likely maintain in electronic form, by March 16, 2007. See Exh. 24. Plaintiffs responded asserting that the Court had indicated they had until

April 2, 2007 to produce the DMF and NDA and that they would not produce such documents before then. See Exh. 25.

- On March 19, 2007, Defendants' counsel prepared an emergency email request for assistance from the Court, which was forwarded to Plaintiffs. See Exh. 26. On the evening of March 19, 2007, Plaintiffs mailed to Defendants a CD containing the original contents of the DMF submission from 1983.
- However, this production did not include any later amendments and FDA communications understood to be formally part of the DMF. Plaintiffs have not responded to Defendants March 20, 2007 request for production of the remaining parts of the DMF, or confirmation that none exist. See Exh. 27.
- Only on March 22, 2007, seven business days before the close of fact discovery, Plaintiffs produced over 200,000 pages from the NDA.
- The DMF and NDA documents are likely maintained by Plaintiffs in electronic form, and should have been produced to Defendants months ago, or at the very least on a rolling basis.

On March 19, 2007, Defendants properly noticed depositions of Karin Lovquist and Frans Langkilde for March 29 and 30, respectively. (D.I. 101, 102). Lovquist is the first named inventor on the '380 patent and Langkilde was substantially involved in the prosecution of the '380 patent, specifically by submitting a declaration during prosecution, which eventually led to the issuance of the '380 patent. On March 23, 2007, Plaintiffs asserted that such notice was inadequate and that, accordingly, the witnesses would not be produced on the requested dates. See Exh. 28.

On March 20, 2007, Defendants properly noticed Rule 30(b)(6) depositions of AstraZeneca. (D.I. 103, 104). In response on March 23, 2007, Plaintiffs asserted that such notice was inadequate and that, accordingly, Plaintiffs would not produce the witnesses on the requested dates. See Exh. 28. In addition, Plaintiffs indicated that the Rule 30(b)(6) categories were objectionable and that specific objections would be provided to Defendants' counsel "in due course." *Id.* Plaintiffs did not respond to Defendants' request for an immediate meet and confer to discuss the objections. See Exh. 29. The basis for Plaintiffs' objections are still unknown to Defendants.

On February 23, 2007, Plaintiffs answered Defendants' contention interrogatories directed to infringement with respect to the '505 and '230 patents related to the presence of a "subcoat." (D.I. 94). As indicated previously, Plaintiffs relied solely upon a theoretical chemistry argument, and a bad one at that. Defendants called Plaintiffs' bluff and on March 22, 2007 served Plaintiffs with an expert report of Professor Domb. See Exh. 30. The expert report clearly disproves Plaintiffs infringement theory.

- Defendants also informed Plaintiffs' counsel at the same time Professor Domb's expert report was served, that Professor Domb, an Israeli citizen, would be in the United States for a conference the week of March 26, 2007 and would be available for deposition during that time. *Id.*
- Plaintiffs refused, asserting that they had not received any of the materials considered by Dr. Domb in his report, had not consulted with their experts, and accordingly would not depose Dr. Domb at that time. See Exh. 31.

C. Plaintiffs' Interference with Discovery of Merck Documents and Samples

Defendants have since October 2006 sought from Plaintiffs documents and samples from Merck & Co. ("Merck"), which manufactured omeprazole for Plaintiffs to be sold in the original

prescription Prilosec product. See Exh. 32. Plaintiffs asserted such documents could not be produced because they were not under Plaintiffs' control. See Exh. 22, p. 2, para. 2. Plaintiffs additionally asserted that the various agreements between Plaintiffs and Merck did not obligate Merck to cooperate with discovery. *Id.*

On January 26, 2007, and again on February 21, 2007, Defendants sought discovery directly from Merck. See Exhs. 33, 34. On February 8, 2007, one day before document production was scheduled to occur, Plaintiffs' counsel telephoned to inform Defendants, for the first time, that they also represented Merck as to the subpoena. The same day, Plaintiffs' counsel objected to each and every document request, stating in some cases, that such production was not required because, among other "Merck is not a party to the captioned litigation." See Exh. 35. Defendants responded that such objections were baseless. See Exh. 36. Defendants' position was reiterated during a meet and confer on March 12, 2007. Plaintiffs' counsel last week suggested that they consider Defendants to be no longer seeking discovery from Merck. See Exh. 37.

To date, Plaintiffs' counsel has failed to produce even a single document or sample from Merck.

D. Plaintiffs' Interference with Discovery of AAIpharma Documents and Samples

Since October, Defendants have sought discovery from Plaintiffs relating to AAIpharma, Inc. and AAIpharma LLP (collectively "AAIpharma"). (D.I. 45). Plaintiffs responded that such documents would be produced to the extent they were not covered by confidentiality agreements with AAIpharma. See Plaintiffs' Responses to Dexcel Pharma Technologies Ltd.'s First Set of Document Requests (D.I. 57). During the December 6, 2006 conference, the Court indicated that such documents should be produced, or, in the alternative, a log should be provided to

Defendants of documents being withheld on the basis of a third party confidentiality agreement. See Exh. 17, Dec. 6, 2006 Hearing Tr at 27.

- On December 21, 2006, Defendants requested that Plaintiffs produce documents or provide a log in accordance with the Court's instruction. See Exh. 38, p. 1-2.
- On January 8, 2007, Defendants requested clarification, updated discovery responses, and documents related to AAIpharma, which Plaintiffs had previously claimed were subject to a third party confidentiality agreement. See Exh. 39.
- On January 11, 2007, Plaintiffs responded stating that Plaintiffs "will provide a log of any information that is withheld on the basis of this [third party confidentiality] objection." See Exh. 40, p. 3.

▪ At the discovery conference on January 12, 2007, Defendants again raised the issue of producing discovery from AAIpharma, which Plaintiffs previously indicated they would produce. See Exh. 41, Jan. 12, 2007 Hearing Tr. at p.32. At the hearing, Plaintiffs represented to the Court they were "not holding back AAI documents if they are responsive to … the requests … we're not holding back those documents. We will produce or schedule them … *See id* at p. 39.

▪ On January 25, 2007, summarized in a letter dated January 26, 2007, see Exh. 22, Plaintiffs stated during a meet and confer that they were not withholding any documents solely on the basis of third party confidentiality agreements.

On January 25, 2007, Defendants sought discovery directly from AAIpharma. See Exh. 42, 43.

▪ On January 30, 2007, Plaintiffs suddenly indicated that they were withholding documents on the basis of third party confidentiality agreements. See Exh. 44. Despite this

statement, Plaintiffs have never produced a log of documents being withheld on the basis of third party confidentiality agreements.

- On February 2, 2007, Defendants spoke with James Gumina, counsel for AAIpharma, regarding the scope of document requests. Mr. Gumina indicated that most of the documents Defendants were requesting were sitting in his office, that he needed to check with his client regarding a few requests, and that he expected he could produce documents by the end of February. See Exh. 45, Declaration of Caryn C. Borg-Breen, dated March 29, 2007. On February 14, 2007, Mr. Gumina corresponded to clarify his understanding of what documents Defendants requested. See Exh. 46. On February 22, 2007, Defendants responded stating that such understanding was correct and that the documents should be produced. See Exh. 47.

- On February 1, 2007, the Court ordered production of the requested AAIpharma documents and invited AAIpharma to appear if it had any confidentiality concerns. Exh. 20, Feb. 1, 2007 Hearing Tr. at p. 49.

- On March 12, 2007, Plaintiffs represented to the Court, for the fourth time, that they had fully cooperated in connection with discovery related to AAIpharma. See Exh. 18, Mar. 12, 2007 Hearing Tr. at p. 6.

- On March 13, 2007, Defendants' counsel telephoned Mr. Gumina to inquire as to whether the documents would be produced promptly and without need to enforce the subpoena. When no response was received, Defendants' counsel inquired again. See Exh. 48. Finally, on March 21, 2007, Mr. Gumina informed Defendants for the first time that *AstraZeneca* opposed production of documents containing AstraZeneca confidential information. See Exh. 49.

    - Specifically, Mr. Gumina stated "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 … if you want to pursue production of the documents from AAI, it will be necessary for you to have Astra withdraw its objectives. *Id.*

E. Plaintiffs' Interference with Discovery from White & Case

On March 16, 2007, Defendants noticed White & Case LLP ("White & Case") and John M. Genova, AstraZeneca's patent counsel who prosecuted the '380 patent, of a deposition scheduled for March 30, 2007. (D.I. 99, 100). When no response was received, Defendants' counsel contacted White & Case and Mr. Genova on March 23, 2007. See Exh. 50, Declaration of Saumil S. Mehta dated March 29, 2007. At that time, an attorney from White & Case notified Defendants that they had been told by Plaintiffs' counsel that the depositions of their attorneys had been postponed. *Id.* Plaintiffs' counsel never discussed this with Defendants.

* * *

The foregoing facts illustrate Plaintiffs' scheme to deliberately manipulate the discovery schedule and delay of this action such that no judgment on the merits can be had prior to the expiration date of the formulation patents in suit. The Court has the authority to prevent the imminent harm and undue prejudice to Defendants that will result from Plaintiffs' conduct. Defendants therefore seek emergency relief from the Court.

V. ARGUMENT

A. Plaintiffs Have Breached Their Affirmative Duty To Expedite This Litigation

Plaintiffs have not met their affirmative duty, imposed on them by the Hatch-Waxman Act, to expedite this action. As a result, the Court should deny them the benefit of their delay by lifting the stay that stands as the only bar to final FDA approval of DPT Ltd.'s omeprazole tablet product.

1. The Hatch-Waxman Act Imposes An Affirmative Duty For Plaintiffs To Expedite This Action

The plain language of the Hatch-Waxman Act explicitly admonishes the Plaintiffs to "reasonably cooperate in expediting the action." 21 U.S.C. § 355(c)(3)(C). Moreover, the Act's legislative history reveals that Congress intended to impose an affirmative duty on Hatch-Waxman plaintiffs to expedite litigations such as this case. For example, the reports of both House committees that issued reports (i.e., Judiciary and Energy and Commerce) illustrate the importance that Congress placed on Plaintiffs' duty to expedite litigation such as the present case:

> *Each party to the action has an **affirmative duty** to reasonably cooperate in expediting the action.* If the plaintiff breaches that duty, the court may shorten the [30][7] month period as it deems appropriate.

H.R. Rep. 98-857(I) (Energy and Commerce), 1984 U.S.C.C.A.N. 2647, 2661; H.R. Rep. 98-857(II) (Judiciary), 1984 U.S.C.C.A.N. 2686, 2704 (emphasis added).

Moreover, during the legislative debates, Rep. Sawyer sponsored an amendment to the legislation that would have provided for no expiry of the statutory stay. H.R. Rep. 98-857(I), 1984 U.S.C.C.A.N. 2686, 2720–21. This amendment, which was rejected, would have rendered it hard for generic competitors to enter the market. Yet, even Mr. Sawyer's amendment recognized the importance of the patent-holder diligently working to resolve the patent litigation and the unfair prejudice to generic manufacturers should this duty be breached. *Id.* at 2721 ("*except in those cases where the pioneer manufacturer is unduly delaying the litigation in order to keep a generic drug off the market*, no ANDA or paper NDA should be made effective...." (emphasis added)).

[7] At the time these House committee reports were drafted, the draft legislation provided for an 18-month stay, which was subsequently amended to 30 months.

In addition, many court decisions stress the affirmative nature of Plaintiffs' duty to cooperate in expediting the action. For example, the Northern District of Illinois has noted the importance of "ensur[ing] that the parties take their duty to expedite matters seriously." *Glaxo, Inc. v. Torpharm, Inc.*, 1996 WL 288524, *2 (N.D. Ill. May 30, 1996) (denying leave to amend because the delay would be contrary to the goals of the Hatch-Waxman Act and its requirement to expedite litigation under the Act) (attached as Exh. 51); *see also In re Nifedipine Capsule Patent Litig.*, 1989 WL 111112, *2 (S.D.N.Y. Sept. 20, 1989) (Hatch-Waxman "requires that 'the parties shall reasonably cooperate in expediting the action'") (attached as Exh. 52); *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 126 F.RD. 467, 474 (S.D.N.Y. 1989) (Hatch-Waxman "imposes serious obligations on the *parties* to expedite the litigation") (emphasis in original).

2. Plaintiffs' Actions In Affirmatively Delaying This Litigation Are A Violation Of Their Duty To Expedite Resolution Of This Action And Warrant Relief

Plaintiffs' conduct in this litigation falls well short of satisfying their Hatch-Waxman duty to cooperate to expedite this action. Plaintiffs have engaged in a campaign of orchestrated delay designed only to buy time to ensure that FDA will not, regardless of whether the instant litigation is resolved, grant final approval to DPT, Ltd. during the six-month period of exclusivity beginning April 20, 2007.

- **Plaintiffs' orchestrated delay of the action due to jurisdictional issues was neither cooperative nor calculated to expedite the action**

Plaintiffs' desire to delay resolution of this litigation was evident from the outset. Plaintiffs initially filed suit in two jurisdictions, Delaware and Virginia. Although the Virginia court indicated it would be able to hear the case in January 2007, Plaintiffs first moved to have the present action and the Virginia action consolidated in a Multi-District Litigation, which

motion was ultimately denied, and then moved to stay the Virginia action. At the time the Virginia action was stayed, Plaintiffs owed Defendants documents in response to discovery requests on the merits, which discovery was never produced.

In this action, Plaintiffs insisted on obtaining extensive jurisdictional discovery. Indeed, Plaintiffs did not file an answering brief in response to Defendants' motion to dismiss until nearly 6 months of jurisdictional discovery had taken place. The net effect of Plaintiffs' tactics were to delay the resolution of the substantive (i.e., patent) dispute between the parties.

- **Plaintiffs' protracted refusal to ascertain and state the basis for their infringement position was neither cooperative nor calculated to expedite the action**

Plaintiffs have to date failed to test Defendants' product for infringement, despite having possession of Defendants' NDA prior to the filing of this lawsuit, and DPT Ltd.'s Tablet samples, without any restrictions as to confidentiality, since August 2006. Plaintiffs attempt to excuse their failure to investigate infringement by asserting that (1) the tablets were not available to their experts, notwithstanding the baselessness of this assertion and Defendants clarification of this point in November, and (2) the tablets allegedly could not be tested by experts without their having access to the complete document production. Each of Plaintiffs' assertions is completely without merit. No confidential information was needed by Defendants' expert Professor Domb to totally disprove Plaintiffs' paper-chemistry argument of infringement.

In addition to their failure to test for infringement, Plaintiffs refused to provide the Defendants with any basis for their allegation of infringement until recently, and then only when required to by this Court in the form of their Responses to Defendants contention interrogatories. D.I. 94. As discussed above, Plaintiffs' theories of infringement as to all of the patents in suit are based solely on documents that have been in Plaintiffs' possession since this action was filed.

Despite not having the burden, within a week of reviewing Plaintiffs' factually unsupported theory of infringement as to the two formulation patents, Defendants' expert was able to carry out tests that completely disproved Plaintiffs' theory. Defendants communicated the results of these tests to Plaintiffs on March 22, 2007 in the form of an expert report, and indicated that the expert would be available for deposition the week of March 26, 2007. See Exh. 30. Plaintiffs have thus far declined to comment on the report, and refused Defendants offer to depose the expert.

- **Plaintiffs' stalling tactics in providing documentary and other discovery was neither cooperative nor calculated to expedite the action**

At every turn, Plaintiffs have sought to delay or refused Defendants' reasonable requests for samples of Plaintiffs' product. These samples were required to be produced in response to discovery requests filed in October 2007.

Likewise, Plaintiffs have endeavored to frustrate Defendants' attempts to obtain production of the DMF under which the Plaintiffs have manufactured or had manufactured omeprazole for use in their Prilosec® product for over two decades. Again, Court intervention was required in this regard. Even after the Court-ordered production, the DMF as produced is *limited to the DMF in existence in 1983.*

- **Plaintiffs' consistent inability to make witnesses available was neither cooperative nor calculated to expedite the action**

As discussed in more detail above, Plaintiffs have been unable (or unwilling) to make witnesses available in time to meet the Court-ordered discovery deadline. By itself, these failures are a violation of the duty that Hatch-Waxman imposes on them in this action. *In re Nifedipine Capsule Patent Litig.*, 1989 WL 111112, *2 (S.D.N.Y. 1989) (failure to timely make

witnesses available for depositions and forcing defendant to proceed through Hague Convention proceeding was a violation of the Hatch-Waxman duty).

- **Plaintiffs' repeated interference in Defendant's effort to obtain discovery from third parties was neither cooperative nor calculated to expedite the action**

Not only have Plaintiffs maintained a general attitude of obstinance regarding Defendants' attempts to obtain discovery from them, they have also actively interfered with Defendants' efforts to obtain reasonable and lawful discovery from third parties. Plaintiffs have completely stifled Defendants' attempts to obtain discovery from Merck and AAIpharma regarding relevant documents and samples in those entities' possession. The AAIpharma situation is particularly egregious since AAIpharma originally told Defendants' counsel that most of the materials sought by Defendants were located in AAipharma's counsel's office in Chicago. At some point AAIpharma was simply instructed by Plaintiffs not to produce certain documents under the guise of a confidentiality agreement. This was acknowledged by Plaintiffs' counsel in a letter dated March 22, 2007,

> AstraZeneca does not oppose the production of [responsive technical] information, provided that AstraZeneca has a chance to confirm prior to its production that it does not include irrelevant AstraZeneca confidential information.

See Exh. 53.

AstraZeneca improperly has assumed the role of judge deciding relevance under a third party subpoena.

Plaintiffs also apparently unilaterally decided to postpone the deposition of White & Case LLP, Plaintiffs' prosecution counsel.

B. The Court Should Immediately Lift The Statutory Stays To Prevent Plaintiffs From Unfairly Benefiting From Their Violation Of Their Duty To Expedite This Case

Plaintiffs' dilatory conduct has been unilateral and designed to delay rather than cooperate with Defendants to expedite this action, as Hatch-Waxman requires. Their aim has been designed to ensure that their so-called pediatric exclusivity[8] takes effect before the resolution of this case, to hopefully ensure that Defendants' application cannot be approved by FDA before October 20, 2007, regardless of whether this action is resolved before then.

1. The Appropriate Remedy For Plaintiffs' Violation Of The Hatch-Waxman Duty To Expedite Is Lifting Of The Stay

The legislative history and court decisions concerning the statutory stay reveal that this period is a privilege that Plaintiffs enjoy; it permits them to enjoin generic competition with no hearing, and without due process, merely by filing this lawsuit. However, as with many legal privileges, it can and should be taken away when, as here, Plaintiffs failed to live up to their side of the bargain. The privilege should be denied because of Plaintiffs' misconduct. The Act provides:

> (3) The approval of an application submitted under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A) of this section:
>
> ******
>
> (C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) of this section is received, an action is brought for infringement of the patent that is the subject of the certification and

[8] An NDA-holder who, upon a request from FDA, conducts studies of the drug in a pediatric population obtain from the FDA an additional six months of marketing exclusivity beyond the life of any patent covering the drug. 21 U.S.C. § 355a (2004). This exclusivity is not a patent term extension, but rather operates independently as a bar to the FDA's issuing a final approval for any ANDA during this period.

> for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) of this section before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) of this section *or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action*, except that—
>
> (i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—
>
> (I) the date on which the court enters judgment reflecting the decision; or
>
> (II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed…
>
> In such an action, *each of the parties shall reasonably cooperate in expediting the action.*

21 U.S.C. § 355(c)(3)(C) (emphasis added).

2. The Stay Should Be Lifted Immediately To Prevent Plaintiffs From Unfairly Profiting From Their Litigation Misconduct

The remedy for Plaintiffs' violation of their statutory duty to expedite this action is to lift the stay. In fact, the U.S. District Court for the Southern District of New York found that very similar—but far less extensive—misconduct as Plaintiffs have displayed in this action warranted shortening of the stay. *In re Nifedipine Capsule Patent Litigation*, 1989 WL 111112, *2 (S.D.N.Y. 1989) (failure to make witnesses available for deposition "will result in this Court exercising its aforementioned powers, thus shortening the period of [the statutory stay] which

[Plaintiff] is presently enjoying").[9]

Similarly, the District Court for the Central District of California recently held that a shortening of the statutory stay was appropriate where the plaintiff (1) refused to conduct an investigation into and take a position on a central issue in the case (inventorship of the patent-in-suit) and (2) unjustifiably failed to produce relevant discovery documents requested by the defendant (documents related to a study comparing plaintiff's product to another product predating the plaintiff's). *Dey, L.P. v. Ivax Pharms., Inc.*, 233 F.R.D. 567, 569–70 (C.D. Cal. 2005), *motion for reconsideration denied*, *Dey L.P. v. Eon Labs., Inc.*, 2005 WL 3578120 (C.D. Cal. Dec. 22, 2005) (attached as Exh. 54). In this case, Plaintiffs have similarly failed to investigate and state their position on a central issue (their infringement allegation) and unjustifiably delayed in providing discovery (i.e., by refusing to provide a supplemented DMF and samples). Additionally, Plaintiffs have also endeavored to delay the resolution of this case by refusing to take discovery from Defendants and by actively interfering with Defendants' attempts to take legitimate discovery from third parties. As such, Plaintiffs' actions here are even more pervasive and egregious than those of the plaintiff in *Dey*.

While the language of the statute does not prescribe any particular amount by which the stay should be shortened, its clear purpose is to prevent litigants from unfairly gaming the Hatch-Waxman system to the competitive disadvantage of generic competitors such as Defendants. In fact, the legislative history of reveals that Congress intended for the Courts to shorten stays so as to have the effect of preventing the exact type of unfair market-denial that Plaintiffs are seeking

[9] *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002), is inapposite. In *Andrx*, the District Court shortened a second 30-month stay based upon Biovail's behavior in obtaining a new patent, listing it in the Orange Book, changing its formulation to be covered by the new patent, initiating a second ANDA lawsuit against Andrx based on the new patent, and imposing a second 30-month stay based upon the initiation of the second lawsuit. The Federal Circuit, however, reversed the District Court's ruling, reasoning that the Court only has the power to cut short the stay based upon dilatory behavior in the patent litigation itself, not because of delays in dealings before the FDA. Defendants' present motion, however, is premised on the Plaintiffs' dilatory behavior in this litigation itself.

to inflict on Defendants. *See* H.R. Rep. 98-857(II), 1984 U.S.C.C.A.N. 2686, 2727 ("*except in those cases where the pioneer manufacturer is unduly delaying the litigation* ***in order to keep a generic drug off the market***, no ANDA or paper NDA should be made effective...." (emphasis added)). Lifting the stay in this case would also further Congress' intent in promoting drug competition. *See Mylan Pharms., Inc. v. Henney*, 94 F. Supp. 2d 36, 53 (D.D.C. 2000) (vacated on other grounds) ("[T]he general purpose of Hatch-Waxman is to 'provide incentives for drug companies to undertake research of new drugs, while enabling low-cost, *generic equivalents that are relied upon by consumers to come quickly to the market.*'" (quoting S. Rep. No. 105-36(I) at 277 (1997) (emphasis added)).

Accordingly, while the Court has equitable discretion as to how much to shorten the stay, the most appropriate remedy for this Court to impose in light of Plaintiffs' flagrant breach of their duties to cooperate in expediting this action is to immediately lift the stay. This will maximize the opportunity for Defendants to obtain FDA approval in time to enter the market before Plaintiffs' add-on exclusivity period begins. If this does not occur, Defendants may be unable to obtain FDA approval until at least October 20, 2007, regardless of whether this litigation is resolved during that time. Plaintiffs know this, which is why their main litigation strategy to this point has been to delay resolution of the parties' dispute. Thus, the most appropriate remedy for Plaintiffs' litigation misconduct is for the Court to immediately lift the statutory stay under 21 U.S.C. § 355(3)(C).

Importantly, a shortening of the stay will not limit Plaintiffs' potential remedies should the Court find that Defendants' proposed omeprazole tablets infringe any valid, in-force patent-in-suit. A shortening of the stay will not deprive Plaintiffs of their day in court regarding underlying patent dispute in this case (provided they actually desire to have such); it will simply

provide Defendants with a remedy for Plaintiffs' continued frustration of the progress of this suit and coincident breach of their duty to "reasonably cooperate in expediting the action." A shortening of the stay will therefor merely prevent Plaintiffs from unjustifiably profiting (by unfairly preventing competition) from their unlawful dilatory tactics.

VI. CONCLUSION

Plaintiffs have breached their duty to assist in expediting this case, which is imposed on them by the Hatch-Waxman Act. They should not be able to profit from the delay they have orchestrated by unfairly protracting this litigation until their pediatric exclusivity period starts, in an attempt to prevent final approval by the FDA of Dexcel's NDA for that six-month period. Accordingly, this Court should use its equitable powers and its authority to immediately lift the stay. Dexcel's motion should be granted.

March 30, 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:
Robert F. Green, Esquire
David M. Airan, Esquire
Saumil S. Mehta, Esquire
Leydig, Voit & Mayer
Two Prudential Plaza
180 N. Stetson Avenue, Suite 4900
Chicago, IL 60601
(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

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:

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 March 30, 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