IN THE 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)

PLAINTIFF ASTRAZENECA'S
ANSWERING BRIEF IN OPPOSITION TO
DEFENDANTS' MOTION TO LIFT STAY

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I. INTRODUCTION

Dexcel's motion should never have been brought. AstraZeneca has consistently cooperated in expediting this complex action even as Dexcel and Cipla have routinely failed to reciprocate. AstraZeneca asked the Court for an early Rule 16 scheduling conference so it could get discovery started. Dexcel responded by moving for a 30-day extension to respond. AstraZeneca has met every deadline under the Federal Rules and has responded fully and timely to every discovery request served by defendants. In addition, AstraZeneca has consistently sought to obtain relevant discovery from defendants but has been hampered at every turn. As recently as April 2, Defendants refused to even discuss coordinated scheduling of the depositions noticed by all parties.

As will be detailed below, since the inception of this lawsuit, Dexcel has repeatedly delayed and denied AstraZeneca access to the discovery it needs to prosecute this action. For example, although AstraZeneca timely produced documents in response to Dexcel's requests, Dexcel did not start producing documents until December 1, 2006, more than three months after AstraZeneca served its document requests. Dexcel delayed the commencement of discovery on the merits by several months by filing a motion to dismiss or transfer. Then, after jurisdictional discovery and extensive briefing, it dropped the motion. Even then Dexcel refused to produce key development documents, requiring AstraZeneca to seek court intervention. Dexcel delayed entry of a protective order for over four months, and still continues to impede AstraZeneca's preparation by refusing to properly designate documents under the Protective Order.

AstraZeneca has been seeking for months critical information regarding the infringing omeprazole that Dexcel says is uniquely in the possession of its supplier,

defendant Cipla. But Cipla has refused to accept service of process and will not fully participate in discovery. All Cipla has produced is selected parts of its submissions to the FDA and self-serving communications with third parties. Cipla has steadfastly refused to produce other, highly relevant documents like a party, or otherwise subject itself to the jurisdiction of the Court.

II. NATURE AND STAGE OF THE PROCEEDINGS

This is an infringement action regarding AstraZeneca's[1] patents relating to Prilosec®. Prilosec® was the first in a new class of medicines called proton pump inhibitors which revolutionized gastrointestinal therapy. Defendants[2] seek to manufacture and sell generic versions of the Prilosec OTC® product before the expiration of AstraZeneca's patents.

The patents-in-suit are United States Patents No. 4,786,505 ("the '505 patent"), No. 4,853,230 ("the '230 patent") and No. 6,150,380 ("the '380 patent"). The '505 and '230 patents are directed to a formulation of omeprazole, and will expire later this month, on April 20, 2007. The '380 patent is directed to a polymorph of omeprazole called "Form A", and will expire on November 10, 2018.

AstraZeneca filed this action less than a year ago, on May 30, 2006. Because AstraZeneca filed the action within 45 days of receiving defendants' Notices of Certification under Paragraph IV of the Hatch-Waxman Act, AstraZeneca received a 30-

[1] Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, KBI-E, Inc., KBI, Inc. and AstraZeneca LP are referred to herein as "AstraZeneca."

[2] Defendants Dexcel, Ltd., Dexxon, Ltd. and Dexcel Pharma Technologies, Ltd. are referred to herein as "Dexcel." Defendant Cipla, Ltd. is referred to herein as "Cipla."

month stay of an effective date of approval defendants' NDA.[3] 21 U.S.C. §355 (b)(3)(C). That stay will expire on October 17, 2008[4] unless defendants obtain a dispositive judgment earlier. *Id*. In addition, AstraZeneca has received a separate six-month exclusivity period that will begin when the formulation patents expire on April 20, 2007. During that "pediatric exclusivity" period, the FDA will not finally approve Dexcel's NDA. The expiration of the formulation patents will not change the status of the 30-month stay, because the '380 patent will not expire until long after the 30-month stay.

Trial is set to begin on November 5, 2007, almost a year before the expiration of the 30-month stay. Discovery was set to close April 2, 2007, but the parties have continued to produce documents beyond the close of discovery. Fact depositions have been noticed in the last few weeks, but have not been taken. According to the schedule entered on August 10, 2006, expert discovery is scheduled to begin May 1, 2007.

III. SUMMARY OF THE ARGUMENT

1. AstraZeneca has complied fully with its statutory duty to reasonably cooperate to expedite the action. AstraZeneca has taken affirmative steps to overcome defendants' efforts to prevent AstraZeneca from obtaining discovery.

2. Contrary to defendants' incorrect accusations, AstraZeneca has sought relevant documents, noticed merits depositions and timely provided all requested

[3] Dexcel does not have FDA approval for its NDA, so there is nothing to stay in this case.

[4] The 30 months begins on the date of receipt of a paragraph IV notice. AstraZeneca received notice of paragraph IV certification of the '380 patent on April 17, 2006 and the '505 and '230 patents on May 4, 2006.

relevant discovery. And AstraZeneca has not blocked defendants' efforts to obtain discovery from third parties.

3. There is no basis for Dexcel to get the drastic and extraordinary remedy of lifting the 30-month stay. Congress carefully crafted a balance between innovators and generics, determining that most cases would take about that long to be resolved.[5] This case is more complex than most, and it is scheduled to go to trial more than a year before the end of the 30-month stay. Reported decisions show that only two courts have lifted the 30-month stay since the Hatch-Waxman Act was passed in 1984 -- one of which was reversed on appeal. Nothing in the record justifies lifting the 30-month stay.

4. Dexcel has no one but itself to blame for any delay in its NDA approval caused by AstraZeneca's six-month pediatric exclusivity that will follow the April 20, 2007 expiration of the formulation patents. If Dexcel had wanted to be sure it would reach trial before the formulation patents expired, it could have sought FDA approval years ago.

5. Dexcel has known since the Scheduling Order was entered in August, 2006 that the formulation patents would expire long before trial. Dexcel urged this Court to adopt an abbreviated discovery schedule at the Rule 16 conference due to the impending expiration of the '505 and '230 patents. (D.I. 31). In response, this Court set trial for November 5, 2007. *See id.* If Dexcel had a problem with the Court's schedule, it should have asked for reconsideration with a concrete proposal that would allow the parties to fairly try the formulation patents before they expired. Dexcel was

[5] The 18-month stay in early legislation was subsequently extended to 30 months. H.R. Rep. 98-857 (I) (1984), *reprinted in* 1984 U.S.C.A. 2647, 2661; s*ee* D.I. 116 at n.7.

invited to do so by the Court, but instead chose to file this motion days before the formulation patents expire.

6. Dexcel's stated reason for now seeking the extraordinary relief of lifting the 30-month stay is wrong. Dexcel points to an "approvable" letter from the FDA as evidence that "only the present litigation and the associated 30-month stay is all that stands in the way of the marketing of DPT Ltd.'s Tablets." *See* D.I. 116 at 2. But that "approvable" letter identifies numerous things that third parties and Dexcel have to do before its application actually can be approved.[6] Dexcel has provided no evidence that any of those things have been done, let alone that the FDA has accepted that these deficiencies have been corrected and that Dexcel's application is approved but for the pendency of this action.[7]

AstraZeneca respectfully asks this Court to deny defendants' Motion to Lift Stay. The facts simply do not warrant such extreme relief.

IV. STATEMENT OF THE FACTS

As the following facts demonstrate, AstraZeneca has met its obligation to expedite this action. AstraZeneca has (1) quickly moved to set a discovery schedule; (2) quickly moved to enter the Protective Order; (3) immediately sought discovery; and (4)

[6] Dexcel's approvable letter requires that a MDS Pharma Services Bioequivalence facility satisfactorily resolve certain deficiencies noted in a 483 Notice of Findings. In addition, one of the manufacturing facilities involved in Dexcel's application must revise its specifications and analytical procedures. Also, Dexcel must submit revised draft labeling deleting any statements that suggest that its product is a generic version of Prilosec OTC, or stating that its active ingredient (omeprazole base) is comparable to the active ingredient in Prilosec OTC, omeprazole magnesium. *See* D.I. 119, Exh. 2.

[7] In addition, Dexcel has provided no evidence, by declaration or otherwise, that it is actually ready to launch its product, even if it had tentative approval. Any evidence of commercial scale-up should have been provided in document discovery long ago, but Dexcel has not provided any such evidence.

promptly responded to discovery requests. Any delay is due to Dexcel but, in any event, this case is on track for trial only nineteen months into the thirty-month period.

A. AstraZeneca Diligently Sought and Provided Discovery

1. **AstraZeneca Moved Quickly to Set a Discovery Schedule**

One week after filing its complaint, AstraZeneca moved for a scheduling order to try to jump start discovery. (D.I. 8). Rather than pushing this action forward, Dexcel moved for an extension of time to answer. (D.I. 13). A month later, Dexcel moved to dismiss or transfer to the Eastern District of Virginia. (D.I. 21). The Scheduling Order set a date to resolve the defendants' motion to dismiss or transfer (D.I. 31), which required separate discovery and extensive briefing -- after which Dexcel simply dropped the matter. The Scheduling Order also set an early trial date for November 5, 2007 -- eleven months before the 30-month stay expires.

Dexcel's new sense of urgency comes too late. Dexcel knew from the beginning that this action would not go to trial until after the formulation patents expire. Dexcel could have challenged the discovery or trial dates last August. Instead, Dexcel maneuvered to get to the Eastern District of Virginia from June to late October and did not pursue this action with any sense of urgency.

2. **AstraZeneca Moved Quickly to Enter a Protective Order**

Dexcel single-handedly delayed entry of a protective order for months. This prevented AstraZeneca from showing critical documents to its in-house experts.

On November 1, 2006 AstraZeneca provided Dexcel with a draft protective order. *See* Exh. 1.[8] More than a month later, at a meet and confer on December 6, 2006, Dexcel objected to the proposed order. AstraZeneca responded six days later with a revised draft so that AstraZeneca could proceed with in-house experts, but Dexcel did not respond. S*ee* Exh. 2 AstraZeneca again urged Dexcel to sign the order or provide objections in early January (s*ee* D.I. 119, Exh. 40 at p. 2) and then again in late January. *See* Exh. 3 at p. 1.

A protective order was finally entered on March 9, 2007 -- four months after AstraZeneca had proposed such an order and three weeks before the close of fact discovery. (D.I. 95). Immediately upon entry of the protective order, AstraZeneca requested that Dexcel reclassify certain material as "Confidential" under the Protective Order. *See* Exhs. 4; 6 at p. 2. Once again, Dexcel did not respond. Nor did Dexcel respond to AstraZeneca's March 19 and March 29 follow up requests for reclassification. *See* Exhs. 5 and 6.

Dexcel's failure to agree to a protective order, and failure to timely reclassify its documents, has delayed AstraZeneca's efforts to move this case forward.

3. **AstraZeneca Immediately Sought Discovery**

AstraZeneca first served document requests and interrogatories on August 17, 2006, just one week after the Rule 16 conference. (D.I. 34). Since then, AstraZeneca has served additional interrogatories and two sets of documents requests and requests for admission on Dexcel. (D.I. 48, 50, 96, 105). AstraZeneca has also served

[8] Unless otherwise indicated, all exhibits referred to herein are exhibits to the Declaration. (continued) of Allison Fulton in Support of Plaintiff AstraZeneca's Answering Brief in Opposition to Defendants' Motion to Lift Stay.

interrogatories, document requests and requests for admission on Cipla (D.I. 94, 121), and has served a subpoena for documents and deposition on Byron Chemical Co., Inc., Cipla's U.S. agent. (D.I. 125). In contrast, Dexcel did not serve document requests until October 24, 2006 -- two months after fact discovery commenced and two months after AstraZeneca had served its requests. (D.I. 45).

AstraZeneca has also promptly noticed depositions relating to the NDAs and DMFs. AstraZeneca asked Cipla to identify persons involved with the development of DMF 12827. *See* Exh. 7 at p. 19. Cipla responded with the names of five persons on March 26. Four days later, AstraZeneca noticed their depositions. (D.I. 108, 109, 111-113).

4. **AstraZeneca Promptly Responded to Discovery**

- **AstraZeneca produced documents and samples relating to Merck**

On March 29, 2007, AstraZeneca shipped twenty-five samples of omeprazole API, twenty of which had been manufactured by Merck. Exhs. 8, 9. These samples include the pre-critical date samples that Dexcel seeks. *See* D.I. 116 at 10.

Dexcel's assertion that AstraZeneca "for the first time" suggested it would produce samples on March 15, 2007 is incorrect. *See* D.I. 116 at 6. Dexcel did not request any samples until October 24, 2006. S*ee* Exh. 10. AstraZeneca responded that it would produce responsive samples to the extent they existed. *See* Exh. 11. During the February 1 discovery conference, AstraZeneca said it would produce the samples once the parties reached an agreement on delivery protocol. *See* Exh. 12, Feb. 1, 2007 Hearing Tr. at 32:6-14. Dexcel's argument that AstraZeneca has not cooperated because it has not tested defendants' samples (D.I. 116 at 4-5, 16-17) makes no sense -- sample testing is

usually handled during expert discovery. Dexcel has just recently produced its bulk omeprazole.

Merck timely objected to the discovery requests served by Dexcel. Counsel for AstraZeneca (also acting as counsel for Merck on the subpoena) offered to negotiate the scope of the requests (*See* Exh. 13, Jan. 12, 2007 Hearing Tr. at 5:23-6:13), but Dexcel flat out rejected any compromise on scope. *See Id*. at 22:14-19. Dexcel again refused to compromise in a meet and confer on April 2. AstraZeneca's objections to Dexcel's overbroad requests are proper and were not a tactic to unreasonably delay this action.

- **AstraZeneca produced documents relating to aaiPharma**

Despite AstraZeneca's repeated assurances, Dexcel accuses AstraZeneca of withholding critical aaiPharma documents. In fact, AstraZeneca has fully cooperated with Dexcel's requests.

Dexcel first complained about AstraZeneca's response to Dexcel's overbroad document request relating to aaiPharma documents at the December 6, 2006 discovery conference. *See* Exh. 14, Dec. 6, 2006 Hearing Tr. at 26:12-22.[9] In response to a letter from Dexcel (s*ee* D.I. 119, Exh. 38), AstraZeneca stated that it would provide a log of any material withheld. *See* D.I. 119, Exh. 40 at 3. In the letter, however, AstraZeneca also clearly stated that it was not aware of any responsive information being

[9] Contrary to what Dexcel states (*See* D.I. 116 at 11), the Court did not make any determination with respect to production of aaiPharma documents. Instead, the Court briefly recessed while the parties conferred on the issue. *See* Exh. 14, Dec. 6, 2006 Hearing Tr. at 30:10-13; 31:10-14.

withheld. *Id*. And only two days after counsel reached an agreement on the scope of Dexcel's request,[10] AstraZeneca produced responsive documents. *See* Exhs. 15 and 16.

AstraZeneca did not deliberately withhold documents responsive to Dexcel's request relating to aaiPharma (*i.e*. document request no. 27). *See* D.I. 116 at 11. To the contrary, during AstraZeneca's review of documents, it realized that certain potentially responsive documents were in fact subject to a third party confidentiality agreement and so informed Dexcel. *See* D.I. 119, Exh. 44. AstraZeneca promptly sent the documents scheduled for production to aaiPharma, whose permission was necessary for their production under the terms of the confidentiality agreement. *See* Exh. 12, Feb. 1, 2007 Hearing Tr. at 52:4-8. In the February 1 discovery conference, AstraZeneca assured the Court that AstraZeneca had produced all responsive documents within the scope of the parties' agreement that relate to Dexcel's request involving aaiPharma. *See Id*. at 51:25-52:8.

Dexcel subpoenaed documents directly from aaiPharma, in an attempt to circumvent the Court's supervision of discovery in this action. *See* D.I. 119, Exhs. 42 and 43. In a letter to Dexcel, aaiPharma counsel indicated that for aaiPharma to produce documents containing AstraZeneca confidential information, it was first necessary that AstraZeneca withdraw its objections to producing AstraZeneca confidential information. *See* D.I. 119, Exh. 49. In a follow up letter, aaiPharma also stated that it would provide documents and samples to Dexcel once Dexcel prepared a confidentiality agreement for review by aaiPharma. *See* Exh. 17. As far as AstraZeneca is aware, Dexcel has not

[10] AstraZeneca agreed to produce all scientific data and technical information relating to Form A, Form B, and the tautomerization of omeprazole. *See* D.I. 119, Exh. 22 at 2.

provided aaiPharma with a confidentiality agreement necessary to expedite production and protect all parties' confidential information.

- **AstraZeneca promptly responded to Dexcel's unreasonable deposition notices**

The following chart sets forth Dexcel's proposed deposition schedule:

Date of Notice	Witness	Proposed Date of Deposition
March 16, 2007	Non-party John M. Genova	March 30, 2007
March 16, 2007	30(b)(6) of non-party White & Case	March 30, 2007
March 19, 2007	Karin Lövqvist	March 29, 2007
March 19, 2007	Frans W. Langkilde	March 30, 2007
March 20, 2007	30(b)(6) of AstraZeneca AB	March 29, 2007
March 20, 2007	30(b)(6) of AstraZeneca LP	March 29, 2007

Even a glance at Dexcels's proposed schedule shows that it was not workable.[11] *See* D.I. 116 at 8-9. Dexcel's proposed deposition dates were simply unrealistic.

Immediately after receiving Dexcel's deposition notices, on March 23, 2007, AstraZeneca informed Dexcel that its notices were unreasonable and objectionable, and requested a meet and confer to schedule the noticed depositions and depositions of certain Dexcel and Cipla witnesses at a *mutually agreeable time*. *See* D.I. 119, Exh. 28 at p. 2. Dexcel responded to this request by suggesting a meet and confer at 9:00 a.m. the following day. *See* D.I. 116 at 9; D.I. 119, Exh. 29. Counsel for AstraZeneca explained that the suggested time was not possible based on AstraZeneca's counsel's schedule. *See*

[11] Dexcel stated that its notices were sufficient under the local rules, which states that "reasonable notice" is "not less than 5 days." *See* D.I. 119, Exh. 29. AstraZeneca does not dispute the reading of the local rules. Rather, AstraZeneca disputes the reasonableness of noticing six 30(b)(6) depositions, two of which were directed to witnesses who live in Sweden, within *the same* 10 days.

Exh. 18. AstraZeneca tried to discuss deposition scheduling at a meet and confer on April 2, 2007, but Dexcel/Cipla refused to discuss scheduling the depositions of their employees in a cooperative and coordinated fashion.

- **Dexcel's premature demands for expert discovery are unreasonable**

Dexcel demands that AstraZeneca rush to commence, and presumably finish, expert discovery before fact discovery closes.[12] *See* D.I. 116 at 9.

Certainly Dexcel did not "call AstraZeneca's bluff" by offering an expert report from Dr. Domb. *See* D.I. 116 at 9. Dexcel served the expert report on Thursday, March 22 and offered the deposition of Dr. Domb the following Monday. *See* D.I. 119, Exh. 30. Moreover, Dexcel failed to produce any documents to support Dr. Domb's expert report. Dexcel then feigned surprise when AstraZeneca stated that it would not depose Dr. Domb on the unreasonable date Dexcel offered. Dexcel could not realistically expect AstraZeneca to agree to take expert deposition with only one business day's notice, and without any data at all to review.

Dexcel's insistence on expert discovery before AstraZeneca has been provided the necessary facts makes no sense. The testing performed by AstraZeneca's experts has to be specifically adapted to the specific structure and composition of Dexcel's NDA Product. Full fact discovery is needed to permit AstraZeneca to determine critical facts such as, for example, the nature and qualities of Dexcel's enteric coating, and the conditions under which Dexcel's product is made.

[12] In every other action involving infringement of AstraZeneca's formulation patents by ANDA holders, fact discovery was completed before expert discovery commenced. That is also the practice of this Court.

- **AstraZeneca has not interfered with any third party depositions**

AstraZeneca has not "interfered" with depositions of White & Case or John Genova, the attorney who prosecuted the '380 patent. AstraZeneca spoke with White & Case counsel on March 20, just four days after service of Dexcel's notice of deposition. White & Case counsel indicated that Mr. Genova would be unavailable on March 30, the proposed date of deposition. *See* Exh. 19. AstraZeneca told Dexcel that the depositions of White & Case and Mr. Genova would have to be rescheduled. *See* Exh. 20. Dexcel has misconstrued Mr. Genova's unavailability as evidence of improper interference by AstraZeneca.

B. Although Any Delay is Due to Dexcel, This Case is Still on Track For Trial Only 19 Months Into the 30-Month Period

Both parties have an obligation to reasonably cooperate to expedite this action (s*ee* D.I. 116 at 14), and AstraZeneca's responses should be gauged in light of how quickly Dexcel has provided discovery.

Dexcel delayed this action from the start and only recently has been clamoring to get before this Court. Dexcel has stalled AstraZeneca's infringement investigation by (1) refusing to secure Cipla's participation or provide documents relating to bulk omeprazole and (2) unreasonably refusing to provide critical documents.

1. Dexcel Refuses to Secure Cipla's Cooperation or Provide Requested Documents

Cipla insists on producing documents as a non-party. By doing so, Cipla and Dexcel have delayed AstraZeneca's efforts to reasonably expedite this action.

Dexcel contends that Cipla sold omeprazole in the United States, through its U.S. agent, Byron, prior to the critical date of the '380 patent. Cipla also supplies the

active pharmaceutical ingredient, omeprazole, covered in DMF 12827 ("Cipla DMF") and used in Dexcel's NDA 22-032. Yet, counsel for Dexcel indicated that it was either unwilling or unable to produce relevant information from Cipla. *See* Exh. 14 Dec. 6, 2006 Hearing Tr. at 6:22-25; 15:3-9. Dexcel, however, likely has indemnified Cipla with regard to infringement arising from Cipla's omeprazole, and should be in a position to demand this information. Cipla also has submitted to the jurisdiction of this Court in another pending action,[13] but has refused to do so here.

In order for AstraZeneca to be sure it has received all of the discovery it needs, Cipla's discovery should be subject to Court supervision and the Federal Rules. AstraZeneca has asked repeatedly for Cipla to acknowledge its role as a party in this action and to provide discovery like a party. *See* Exhs. 21 and 22. At the April 2, 2007 meet and confer, Dexcel refused to agree that Cipla would provide document discovery as if it were a party pursuant to Rule 34 of the Federal Rules of Civil Procedure, and also refused to agree that Cipla would be subject to the Court's jurisdiction for discovery purposes. Dexcel further refused to produce Cipla documents under the Protective Order, because Cipla did not want its documents to be accessible to in-house lawyers otherwise entitled to see Confidential – Attorney's Eyes Only material. Cipla should join and abide by the Protective Order in this case.

AstraZeneca has also unsuccessfully requested that Dexcel and Cipla produce agreements and communications concerning omeprazole[14] and for omeprazole

[13] *Forest Laboratories v. Ivax Pharm.*, C.A. No. 03-891-JJF.

[14] *See* Exhs. 7 at pp. 9-11; 23 at p. 19; 25 at p. 2; 26 at p. 4. AstraZeneca has also requested that Cipla produce communications with Byron and Andrx. *See* Exhs. 21 at p. 2; 27 at p. 10.

batch records and certificates of analysis used in the research and development of NDA 22-032 and/or DMF 12827. [15]

2. AstraZeneca Has Unsuccessfully Sought Research and Development Surrounding Dexcel's Drug Reformulation

AstraZeneca has made repeated efforts to obtain documents relating to Dexcel's design-around of the patents-in-suit. *See* Exhs. 23, 24, 25. After being ordered by the Court to do so, Dexcel produced a list of allegedly relevant tests on January 10, 2007. *See* Exh. 14, Dec. 6, 2006 Hearing Tr. at 31:22-32:16. This list, however, only includes tests performed on the API and finished omeprazole product and does not appear to include any tests that would have been performed during the development of the formulation. *See* Exh. 26.

After almost eight months of requests, including AstraZeneca's recent March 29 and April 5 letters, Dexcel agreed to take AstraZeneca's request for production of all design around and development documents under advisement at the April 2, 2007 meet and confer. *See* Exhs. 21, 22.

By refusing to produce these critical docs, Dexcel has prevented AstraZeneca from preparing and conducting fact depositions necessary to advance this case.

[15] AstraZeneca has identified the following batches in its documents requests to Dexcel and Cipla: F10035, F11132, F20412, F20789, F20976, F21201, F40615, F40618, F50071, F50440, F61332, FX0323, FX1043, FX1066, FX1231, FX1232, FX1233, FX6107, FX6157, FX6311, FX7061, FX7246, FX7268, FX8128, FX9012, FX9311, FX9329, FX9566, FX9593, , F20897, F20453, F40624, F40615, F40618, F90165, F80453, F80463, F90105, F90443, FX9274, FX0323, FX90458, FX9566, FX1066, FX7341, FX8212, FX8213, FX9329, FX6346, FX31213, FX31214, FX31215. *See* Exhs. 7 at p. 11; 23 at pp. 16-17, 18.; 21 at p. 3; 22 at p. 2.

V. ARGUMENT

A. Courts Have Lifted The 30-Month Stay Only In Extreme Circumstances Nothing Like This Case

In crafting the 30-month stay, Congress struck a careful balance between providing the public with cheaper drugs and providing incentive to pioneer manufacturers to make investments necessary to develop the life-saving drug products.[16] Congress believed that thirty months was adequate time to resolve patent disputes between the pioneer drug manufacturer and generic drug makers who merely develop a copycat drug.[17] AstraZeneca received the 30-month stay because it invested years of research and development to obtain the patents covering the form of omeprazole and the formulations which are listed for the Prilosec® and Prilosec OTC® NDAs, and filed this action within 45 days of receiving Dexcel's Paragraph IV Notices.

AstraZeneca has complied fully with its statutory duty to reasonably cooperate, doing everything possible to comply with Dexcel's discovery requests, and facilitating third-party discovery where possible. *See supra* pp. 6-15. AstraZeneca has, among other things:

- Initiated discovery by filing a motion for a scheduling order (*supra* p. 6);
- Sought a protective order in order to consult with in-house experts (*supra* pp. 6-7);
- Served discovery requests and fully responded to Dexcel's requests (*supra* pp. 8-12);
- Noticed seven depositions of persons familiar either with the NDA Product or Cipla's DMF (*supra* p.8);

[16] *See Dey L.P. v. Eon Labs*., 2005 WL 3578120, *9 (C.D. Cal. Dec. 22, 2005).

[17] *See supra* n. 5.

- Produced documents relating to aaiPharma (*supra* pp. 9-10);
- Collected and produced samples relating to Merck (*supra* pp. 8-9); and
- Requested meet and confers to schedule depositions at a mutually agreeable time (*supra* p. 11).

On its face, Dexcel's suggestion that AstraZeneca has failed to reasonably cooperate with expediting this action is ludicrous.

The cases Dexcel relies on demonstrate that its motion should be denied. In *In re Nifedipine Capsule Lit*., 1989 WL 111112 (S.D.N.Y. Sept. 20, 1989), the court did not disturb the stay. It merely ordered the plaintiff to produce witnesses. Defendants have issued notices of depositions to the inventors of the patent-in-suit. *In re Nifedipine Capsule Lit*., 1989 WL 111112 at *1. Three weeks later, plaintiffs notified defendants that they refused to exert control over the inventors who were located in Germany and no longer employed by the plaintiffs. *Id*.

Here, AstraZeneca is not refusing to produce Ms. Lövqvist, the first-named inventor of the '380 patent or Mr. Langkilde, a scientist consulted during prosecution of the '380 patent. Nor does AstraZeneca argue that Dexcel should issue letters rogatory to compel testimony of these scientists, as in *In re Nifedipine*. AstraZeneca merely informed Dexcel, four days after receiving Dexcel's notice, that the dates proposed -- only eight business days after service -- were unrealistic for the scientists, who are located in Sweden, to adequately prepare for and schedule attendance. Unlike plaintiffs in *In re Nifedipine*, AstraZeneca assured Dexcel that the depositions of Mr. Langkilde and Ms. Lövqvist could be scheduled at a mutually agreeable time.

Similarly unavailing is Dexcel's attempt to compare this case to *Dey, L.P. v Eon Labs., Inc.* 2005 WL 3578120 (C.D. Cal. Dec. 22, 2005). In *Dey*, the court found that the plaintiff purposefully failed to produce crucial studies that went directly to the

merits of defendants' invalidity case. *Dey*, 2005 WL 3578120 at *7. The court also found that the plaintiff repeatedly changed its position on inventorship and that the failure to resolve issues of inventorship before initiating the litigation was unreasonable and would likely delay the action. *Dey*, 2005 WL 3578120 at *3. Dey's "unreasonable delay" was not merely a failure to reveal critical facts in discovery, but a failure to commence the litigation with a solid idea as to the true identity of the inventors. *Dey*, 2005 WL 3578120 at *6.

AstraZeneca has done nothing like the deliberate and inconsistent acts in *Dey*. AstraZeneca has not concealed critical studies. AstraZeneca has not refused to produce responsive documents. AstraZeneca has fully cooperated with Dexcel's requests and has set forth justified objections where appropriate. AstraZeneca had forty-five days to file an infringement action against Dexcel. In those forty-five days, it formed an opinion that the NDA Product infringes the three patents-in-suit. Dexcel cannot reasonably argue that AstraZeneca's position will cause "unreasonable delay" merely because Dexcel does not agree with AstraZeneca's position. *See* D.I. 116 at 21.

Contrary to Dexcel's arguments, AstraZeneca was well within its rights to challenge Dexcel's attempt to manipulate jurisdiction to Virginia and to seek full discovery on jurisdictional issues. *See* D.I. 116 at 15-16. In any event, legitimate challenges to jurisdiction are not considered in determining whether to modify the statutory stay. *See Zeneca Ltd. v. Pharmachemie B.V.*, 16 F. Supp. 2d 112 (D. Mass. 1998). In *Zeneca*, the plaintiff contended that by contesting personal jurisdiction in Maryland, the defendant "failed to reasonably cooperate in expediting the action" such that the plaintiff should be entitled to an extension of the 30-month stay. *Id.* at 114. The

Magistrate did not agree, stating that "it is manifest that the phrase [failed to reasonably cooperate in expediting prosecution] will not be construed so as to encompass non-frivolous assertions of legal rights." *Id.* at 116. The Magistrate noted that the phrase "failed to reasonably cooperate in expediting prosecution" Congress could not have meant that a party, in order to "reasonably cooperate in expediting prosecution" must give up the right to challenge the jurisdiction of the Court over it. *Id*.

B. The Expiration Of The Formulation Patents Was Entirely Foreseeable

The Court should not relieve Dexcel of the foreseeable consequence of its decision to seek FDA approval less than a year before the formulation patents expire. Dexcel did not apply to the FDA for approval to market its drug in the United States until February 2006, even though Dexcel admits that it has been selling a substantially similar product in Europe for at least five years. *See* Exhs. 28 at n. 2; Exh. 14, Dec. 6, 2006 Hearing Tr. at 21:21-25. Dexcel could have applied for FDA approval in the United States years earlier, thus setting the stage for a fair resolution of the formulation patent disputes before they expired. The fact that Dexcel may have to wait for FDA approval until AstraZeneca's pediatric exclusivity period expires is not a consequence of any delay by AstraZeneca. Rather, it is a direct consequence of the timing of Dexcel's certification letters.

Dexcel claims that a stay will cause prejudice because failure to conduct a trial before the expiration of two of the three patents-in-suit will deprive the public of the benefits of generic omeprazole. *See* D.I. 116 at 1. This is incorrect. Even setting aside Dexcel's overblown rhetoric as to the merits of AstraZeneca's infringement case, as well as AstraZeneca's motivations (*see* D.I. 116 at 2-3), the FDA will not approve an NDA

until it has made a thorough evaluation of the safety and efficacy of the new drug being proposed. Dexcel provides no evidence that the FDA would be ready to approve its NDA before AstraZeneca's pediatric exclusivity begins April 20, 2007, or even before it runs out in October 2007.[18]

No facts in this case warrant shortening, much less lifting, the 30-month stay.

VI. CONCLUSION

AstraZeneca has more than complied with its obligation to "reasonably cooperate" to expedite this action. In fact, AstraZeneca has advanced this action since its inception. AstraZeneca respectfully asks this Court to deny defendants' motion.

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[18] AstraZeneca also earned the six-month pediatric exclusivity periods that follow expiration of the formulation patents. As with the 30-month stay, Congress considered ways to promote the testing of pioneer drugs on children, whose tolerance for certain substances is lower than adults . . . (continued) and whose reactions to such drugs can be far more severe. *See, e.g.* 143 Cong. Rec. S4281-02 (daily ed. May 9, 1997, statement of Sen. DeWine). After careful deliberation, Congress determined that awarding pioneer manufacturers with six months of marketing exclusivity would promote the research and development of drugs that are safe for child consumption. H.R. Rep. No. 107-277 at 53-54 (2001). AstraZeneca performed the pediatric studies requested by the FDA, and so was properly awarded 6 months of exclusivity beyond the expiration of the formulation patents. *See* 21 U.S.C. §355a (c)(2)(A) and (B).

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Dated: April 11, 2007

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 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 11, 2007 upon the following in the manner indicated:

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