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April 21, 2000

Kim E. Dettelbach, Esq.
Office of the Chief Counsel (GCF-1)
Food and Drug Administration
Room 6B20
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 99P-1589

Dear Ms. Dettelbach:

As you may be aware, at the time we submitted the above-referenced citizen petition, a patent infringement action (99 Civ. 3658 (SHS)) was filed by Purdue Pharma LP in the Southern District of New York against Roxane and related companies.

In the course of a hearing before the Court on November 18, 1999, the presiding judge, the Hon. Sidney H. Stein, at the conclusion of the evidentiary portion of the preliminary injunction hearing, stated that he wanted to make a decision on the issuance of an injunction before the actual launch date of Roxane's drug.

It is our belief that Roxane has already made submissions of data to the FDA with the objective of satisfying the conditions specified by FDA. We have no awareness as to the present status of the FDA's review of Roxane's submissions or when that review may be completed. However, we consider it appropriate to bring to your attention that counsel for Roxane, at the November 18, 1999 hearing referred to above, committed to the Court and to Purdue's counsel that notification of the launch date by Roxane would be provided to the Court and to Purdue's counsel, Herbert F. Schwartz. Enclosed are copies of relevant pages from the transcript of the November 18 hearing that speak to the points stated above. The pertinent comments of Judge Stein and of John Sweeney, Roxane's counsel, are contained on page 595 (lines 15-25) and page 596 (line 1).

99P-1589

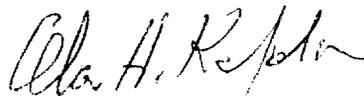
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We will be providing the Court a copy of this letter and enclosure. We request that the stay of Roxane's application not be lifted by FDA until after it is clear that Roxane has fulfilled its commitment to inform the Court and Purdue's counsel of the date of its launch.

Your cooperation in this endeavor will be appreciated.

Sincerely,

A handwritten signature in cursive script, appearing to read "Alan H. Kaplan".

Alan H. Kaplan
Richard S. Morey
Peter R. Mathers

AHK:sdj

Enclosure

cc: Donald O. Beers, Esquire

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF NEW YORK

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3 PURDUE PHARMA L.P., et al.,

4 Plaintiffs,

5 v.

99 Civ. 3658 (SHS)

6 BOEHRINGER INGELHEIM, GMBH,
7 et al.,

8 Defendants.

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9
10 New York, NY
11 November 18, 1999
12 9:30 a.m.

13 Before:

14 HON. SIDNEY H. STEIN

15 District Judge

16 APPEARANCES

17 FISH & NEAVE
18 Attorneys for Plaintiffs
19 HERBERT F. SCHWARTZ
20 ROBERT J. GOLDMAN
21 RICHARD A. INZ
22 KELSEY I. NIX
23 AVINASH S. LELE
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25 MORGAN & FINNEGAN
Attorneys for Defendants
JOHN F. SWEENEY
BRUCE D. RADIN
JOSEPH A. DeGIROLOMO
TONY V. PEZZANO
ISRAEL BLUM

Rapp - recross

1 THE COURT: Is there any objection?

2 MR. NIX: If it is a deposition exhibit, it is
3 already in, your Honor.

4 THE COURT: Again I will put it in.

5 MR. SWEENEY: I think that concludes our witnesses,
6 your Honor.

7 THE COURT: And you rest?

8 MR. SWEENEY: Yes.

9 THE COURT: All right.

10 Thank you. That concludes, then, the evidentiary
11 portion of this preliminary injunction hearing. We will have
12 the briefs on whatever date I set. It was post-Thanksgiving I
13 know, and I will try to get you a decision as soon as
14 possible.

15 If there is any change in the proposed launch date of
16 the Roxane product, I would appreciate knowing it since it
17 will give me a little more breathing room in terms of a
18 decision, but I want everybody to have a decision one way or
19 the other before that actual launch date.

20 MR. SCHWARTZ: I think we are working on December 10
21 at the moment.

22 MR. SWEENEY: Yes, your Honor.

23 THE COURT: That is what you had said the other day.

24 MR. SWEENEY: Yes, your Honor. If there's any
25 change, I will let you know promptly and with a copy to

1 Mr. Schwartz.

2 THE COURT: If after you all look at the transcripts
3 there is any additional cleanup in terms of things that have
4 not been admitted into evidence, just talk to each other and
5 then submit me a letter, and I assume it will be fairly easy.
6 I'll keep the record open solely for those purposes in the
7 event that it arises. I just want to thank counsel for the
8 orderly presentation of the evidence. I think it was very
9 professionally done on both sides.

10 Thank you very much.

11 MR. SCHWARTZ: Thank you, your Honor.

12 MR. SWEENEY: Thank you, your Honor.

13 (Adjourned)

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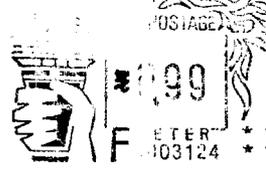
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