IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC AND BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 16-1221 (LPS)
TEVA PHARMACEUTICALS USA, INC., APOTEX CORP. and APOTEX, INC.	)	**PUBLIC - REDACTED VERSION**
Defendants.	)	

LETTER TO THE HONORABLE LEONARD P. STARK
FROM KENNETH DORSNEY REGARDING DISCOVERY DISPUTE

Dated: April 25, 2019

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Attorneys for Defendants Apotex Corp. and Apotex, Inc.

Dear Chief Judge Stark:

I write on behalf of Defendants Apotex Corp. and Apotex Inc., (collectively, "Apotex") in opposition to Plaintiff Bayer Healthcare LLC et al.'s (collectively, "Bayer") letter to Your Honor regarding discovery relating to U.S. Patent No. 8,957,232 (the "'232 patent"). Apotex respectfully asks the Court to (1) deny Bayer's request that the Court compel Apotex to produce unexpired samples of its ANDA product, and (2) deny Bayer's request that the Court sever C.A. No. 18-1465 (the "'232 Patent Case") from C.A. No. 16-1221 (the "Main Case") and stay the '232 Patent Case until Apotex manufactures and produces to Bayer additional samples of its ANDA Product.

A. Apotex Never Agreed to Produce Unexpired Samples of Its ANDA Product

Apotex does not dispute Bayer's recitation of the procedural history relating to the Main Case and portions of the '232 Patent Case. Apotex, however, disagrees with Bayer's understanding that "Apotex had 'represented that Apotex can produce the samples requested in [Dov Grossman's] August 29, 2018 letter to Ian Scott, with the caveat that Apotex no longer has unexpired samples of the regorafenib API." D.I. 122 (Raucci letter at 2).

Apotex informed Bayer at least as early as November 19, 2019 that its sample API was expired. *See* D.I. 122 (Ex. A at 5). As an accommodation to Bayer, Apotex agreed to purchase new unexpired API from its supplier and produced it to Bayer. *See* Ex. 1 at 1. When counsel for Apotex became aware that Apotex's ANDA product expired in March, 2018 under the FDA's Guidance for Industry ANDAs (two months before the '232 patent issued) (*see* Ex. 2 at 3-4), we immediately informed counsel for Bayer. *See* D.I. 122 (Ex. A at 5). During a meet-and-confer on March 26, 2019, Apotex informed Bayer that it would send its ANDA product to Bayer's experts, after which they were free to use the product in any way they saw fit. *See* Ex. 1 at 2 (confirming the March 26, 2019 meet-and-confer). Counsel for Bayer subsequently informed Apotex that it would not be testing the expired product. After Bayer finally provided Apotex with proper addresses, Apotex shipped both the unexpired API and expired ANDA product to Bayer's respective experts. *See* Ex. 1 at 1. On April 12, 2019, Apotex again sought to accommodate Bayer by offering additional time to allow Bayer to test Apotex's API and ANDA product. *Id.* at 1. Bayer responded by reiterating its unfounded understanding that Apotex would supply unexpired tablets and indicated that the "schedule for the '232 patent depends on the resolution of that dispute." *Id.* at 1.

Apotex has never indicated, either implicitly or explicitly, that it would provide unexpired ANDA product to Bayer. Apotex has consistently maintained that it would provide Bayer with sample API and ANDA product "[t]o the extent possible," and has diligently worked toward that end. *See* D.I. 122 (Ex. A at 5; *see also id.* at 7 ("To the extent possible and such information is under Apotex's custody and control, Apotex will produce the samples requested by Bayer in your August 29, 2018 letter to Ian Scott, as well as the material data safety sheets and any handling and storage instructions, as well as the XRPDs requested in your August 29, 2018 letter to Ian Scott.")). Bayer fails to provide any evidence to support its "understanding" that Apotex would produce unexpired ANDA product. This is because there is none.[1]

[1] In its letter to the Court, Bayer omitted Apotex's response to Dov Grossman's email of March 25, 2019 to Philip Kouyoumdjian, in which Mr. Kouyoumdjian requested that Bayer

B. There is No Precedent to Compel Apotex to Make New ANDA Product

Bayer does not cite, and Apotex is not aware of any case in which a court compelled a generic drug manufacturer to make new samples solely for purposes of litigation. Indeed, at least two courts have denied such a request, including this one. The Eastern District of Pennsylvania ruled that Fed. R. Civ. P. 34(a) does not compel production of items that are not "in the responding party's possession, custody or control," including products not currently manufactured, and thus not currently in the defendant's possession. *Apotex, Inc. v. Cephalon, Inc.*, Civ. No. 2:06-cv-2768, 2010 WL 11463178 at *2 (E.D. Pa. April 9, 2010). More recently, this Court also held that it would not compel a generic drug company to produce unexpired ANDA product. *See* Ex. 4 (*Wyeth LLC, et al. v. Alembic Pharmaceuticals, Ltd., et al.*, D. Del., C.A. No. 16-1305-RGA, Andrews, J. (Nov. 29, 2018) (Transcript). In *Wyeth, et al. v. Alembic et al.*, Judge Andrews stated the following:

> So as I understand it, plaintiff wants some 100-milligram tablets, maybe some 500, too, and Sun doesn't have any anymore, or any that are other than the expired ones that they gave. ***So they've got nothing to produce here, and I'm not going to make them make some more.*** And I'm also not going to make them stipulate that the expired tablets are representative of their ANDA product (emphasis added).

Id. at 4:3-9.

Similarly, Apotex has no unexpired sample tablets to produce. And, Apotex is not required to stipulate that its expired tablets are representative of its ANDA product. Accordingly, the Court should deny Bayer's request that, unless Apotex agrees not to contest infringement, the Court should order Apotex to produce unexpired samples of its ANDA product.

C. The '232 Patent Case Should Not Be Severed from the Main Case

Bayer fails to cite any authority to support its argument that the Court should sever the '232 Patent Case from the Main Case. This is because there is no precedent for such an order. In fact, the contrary is true. In one case where a defendant already had plans to manufacture new, unexpired samples, the court denied the production of those samples immediately after their planned manufacture, holding that the federal rules do not require production of responsive information immediately after it becomes available. *Shionogi Pharma Inc. v. Mylan Inc.*, CA No. 10-135 (D. Del. Aug. 13, 2012), *slip op.* at 2 (Ex. 5).

The '232 Patent Case and the Main Case, which were consolidated on December 28, 2018 should not now be severed.

D. Expired Samples May Be Used to Determine Noninfringement

An expert may conclude that a defendant's unexpired ANDA product may or may not infringe based on his or her testing of expired ANDA product. In *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, TWi challenged plaintiff's expert, Dr. David Bugay, conclusion because he "'tested expired samples of TWi's product,' which 'calls the testing into question as it was not conducted on the actual product TWi will sell, because FDA regulations do not permit the sale of expired product.'" *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, 265 F. Supp. 3d 490, 509 (D.N.J. Sep.

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produce any evidence that Apotex had represented that it had unexpired samples of its ANDA product. Mr. Grossman did not provide any. *See* Ex. 3 at 1.

21, 2017). However, the Court ruled that since the TWi Tablets were only subject to a proposed expiration date—like Apotex's in this case—there was no evidence that the TWi Tablet tested by Dr. Bugay was not representative of the TWi Tablets that TWi submitted to the FDA for approval and that TWi intended to market. The Court also held that there was no evidence that Dr. Bugay's analysis was impaired, altered, or otherwise inaccurate because he tested a sample tablet beyond its proposed expiration date. *See id.* Dr. Bugay is acting as Bayer's expert in the instant case, and is free to test the samples produced to him by Apotex.

This Court has followed a similar procedure in determining whether expired samples are representative of unexpired samples. In *Wyeth, et al. v. Alembic et al.*, *supra,* Judge Andrews allowed the plaintiff to test defendant's expired product to determine infringement. He noted that if plaintiff's and defendant's experts differ in their conclusions, it then becomes "a fact question" for the Court. *See* Ex. 5 at 8:4-9:20. Judge Andrews then reiterated that plaintiff's "got expired tablets. I'm not going to get you unexpired tablets, so you need to do what you need to do in order to make your best argument down the road." *Id.* at 9:21-24. Bayer, therefore, is free to conduct its own testing on Apotex's sample tablets, just as Apotex is free to challenge Bayer's testing methods during expert discovery and at trial.

E. [redacted]

F. Apotex Does Not Oppose Modifying the Scheduling Order

Apotex will not object to pushing back the scheduling order to allow Bayer to conduct testing on Apotex's API and ANDA product. However, after conducting fact discovery relating to the '232 patent, Apotex has determined that many documents produced in connection with the '232 patent are related to both the '553 and '107 patents. Thus, if this Court agrees to modify the schedule for the '232 Patent Case, Apotex requests that the remaining deadlines for the Main Case be similarly adjusted in order to give it the opportunity to take further discovery on the '553 and '107 patents based on 2 new discovery in connection with the '232 patent.

Respectfully,

/s/ Kenneth L. Dorsney

Kenneth L. Dorsney (#3726)

cc: all counsel of record via efiling and email service

Exhibit 1

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