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The Honorable Leonard P. Stark
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Bayer HealthCare LLC v. Teva Pharmaceuticals USA, Inc.*,
C.A. No. 16-1221-LPS (D. Del.) (Consolidated)

Dear Chief Judge Stark:

I write on behalf of Plaintiffs Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") regarding discovery relating to Defendants Apotex Inc. and Apotex Corp.'s (collectively, "Apotex") infringement of U.S. Patent No. 8,957,232 (the "'232 patent"). Bayer respectfully requests that the Court order Apotex to produce unexpired samples of the ANDA Product at issue. Alternatively, Bayer requests 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.

I. Bayer Agreed to Consolidation and an Expedited Schedule Based in Part on the Understanding that Apotex Would Produce Unexpired Samples of Its ANDA Product.

This is a consolidated Hatch-Waxman case relating to Bayer's Stivarga® product. In December 2016 and March 2017, Bayer sued Apotex for infringement of two Orange Book patents listed in connection with Stivarga®. In December 2017, those cases were consolidated with the Main Case, which at the time involved Teva Pharmaceuticals USA, Inc ("Teva"). C.A. No. 16-1221, D.I. 26. Trial in the consolidated action was set for June 2019. *Id.*, D.I. 20, at 13. Bayer and Teva have since settled their dispute. Bayer's claims against Apotex remain at issue.

The '232 patent issued in May 2018 and claims the monohydrate form of regorafenib, the active pharmaceutical ingredient in Stivarga®. After Bayer listed the '232 patent in the Orange Book in connection with Stivarga®, Bayer received a Notice Letter from Apotex and filed suit on September 21, 2018. *See* C.A. No. 18-1465, D.I. 1. Apotex denies that it infringes the '232 patent, allegedly, because its ANDA Product does not contain the monohydrate form of

regorafenib. In light of the existing action, the parties held discussions as to how the '232 Patent Case should proceed. During those discussions, Bayer requested that Apotex produce unexpired samples of various substances—including Apotex's ANDA Product and regorafenib active pharmaceutical ingredient ("API")—to permit Bayer's experts to test them to determine whether Apotex's ANDA Product contained regorafenib monohydrate. *See* Ex. A, at 5–7; Ex. B, at 1. Based on conversations between counsel, as memorialized in a November 19, 2018 email, Bayer understood 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." *See* Ex. A, at 2. That letter specifically requested samples of Apotex's ANDA Product itself and specified that all references to samples "should be understood to refer to unexpired samples." Ex. B, at 1. In responding, Apotex did not contradict Bayer's understanding.[1] Ex. A, at 5. Bayer ultimately agreed to consolidation and an expedited schedule in reliance on its expressly stated understanding that Apotex would produce unexpired samples of its ANDA Product in time to permit expert discovery. The parties then requested that the Court consolidate the actions and re-schedule the trial. C.A. 16-1221, D.I. 105. The Court did so in December 2018. Trial is now scheduled for November 2019. C.A. 16-1221, D.I. 106, at 11.

In March 2019, in the midst of fact discovery for the '232 patent, Apotex revealed that it did not, in fact, possess the unexpired samples of its ANDA Product. Ex. A, at 5. Instead, Apotex stated that its samples of its ANDA Product had expired in March 2018, months before the parties began the discussions referenced above. Ex. A, at 1, 3. Bayer asked when Apotex intended to manufacture additional batches of its ANDA Product. Ex. A, at 1. Apotex did not provide a clear answer. Ex. A, at 1. Bayer inquired whether Apotex would make additional samples for production in the '232 Patent Case. Ex. A, at 1. Apotex declined to do so. Ex. A, at 1. Bayer asked whether Apotex would agree to treat expired samples of its ANDA Product as representative (even though that was an imperfect solution). Ex. A, at 1. Apotex again declined. Ex. A, at 1. Bayer now seeks relief from the Court.

II. If Apotex Wishes to Contest Infringement, the Court Should Order It To Produce Samples of Its ANDA Product.

This is not a case in which a party is simply refusing to produce documents or materials that it does not have in its possession, custody, or control. Bayer agreed to consolidation and amendment of the case schedule, including an expedited trial date for the '232 patent, based in part on its understanding that Apotex had agreed to and would produce unexpired samples of its ANDA Product. Apotex's subsequent revelation that it does not actually possess those samples has unfairly prejudiced Bayer. Bayer understood that it would be able to assess infringement by analyzing Apotex's ANDA Product itself. Having obtained Bayer's agreement to consolidation and an expedited schedule for the '232 patent based on the prospect of Bayer's obtaining

[1] During the meet-and-confer process regarding this dispute, Apotex asserted that it had never represented that it would produce unexpired samples of its ANDA Product. Although Bayer has a different recollection, the parties' correspondence clearly demonstrates Bayer's understanding that Apotex would produce unexpired samples of its ANDA Product.

unexpired samples of its ANDA Product, Apotex should not now be permitted to deny infringement, but not provide the unexpired samples that to Bayer's documented understanding Apotex had agreed to produce. Thus, unless Apotex agrees not to contest infringement, the Court should order Apotex to produce unexpired samples of its ANDA Product.

III. Alternatively, the Court Should Sever the '232 Patent Case from the Main Case.

In the alternative, Bayer requests that the Court sever the '232 Patent Case from the Main Case under Fed. R. Civ. P. 21 and stay the '232 Patent Case until such time as Apotex manufactures new samples of its ANDA Product. The question for the '232 Patent Case is whether Apotex's ANDA Product—which is not commercially available—infringes. Under the circumstances, if the Court decides not to grant the relief requested above, an alternative approach is to wait until Apotex actually has unexpired samples of its ANDA Product so that infringement can be analyzed using the product that Apotex proposes to market. There is no thirty-month stay applicable to the '232 patent, and in any event Apotex cannot enter the market until at least June 28, 2022, in light of another Orange Book patent (U.S. Patent No. 7,351,834) that Apotex has not challenged. Should Bayer prevail in the Main Case on the other two patents, Apotex will not be able to enter the market until even later than June 2022. There is no reason why Bayer's claims regarding the '232 patent must be tried in November 2019, and under the circumstances, there is good reason not to do so. Apotex will need to manufacture its ANDA Product before it can enter the market. When it does, Apotex should provide samples to Bayer so that they can be tested for infringement, as the Hatch-Waxman regime contemplates. The parties can then discuss how to proceed in light of the results of that analysis.

[redacted]

Respectfully,

/s/ Anthony D. Raucci

Anthony D. Raucci (#5948)

Enclosure

cc: Clerk of Court (Via Hand Delivery)
All Counsel of Record (Via Electronic Mail)