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***VIA ELECTRONIC FILING***

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

Re: *Bayer HealthCare LLC, et al. v. Apotex Inc. et al.*,
C.A. No. 16-1221-LPS (Consolidated)

Dear Chief Judge Stark:

Plaintiff Bayer respectfully moves to strike Defendant Apotex's belated non-enablement defense regarding U.S. Patent No. 9,458,107, which Apotex first raised just three days before the close of expert discovery. Apotex's untimely disclosure fails to satisfy any of the *Pennypack* factors, including because (1) as an invalidity theory for which Apotex cannot adduce any evidence in its case-in-chief, it cannot survive a Rule 52(c) motion for judgment, and (2) the alleged new "evidence" Apotex cites does not come close to supporting its theory, rendering it futile. Even if Apotex could overcome such defects, Bayer would be substantially prejudiced—both because it would need to take further discovery at this late juncture and because it would need to devote valuable trial time to respond. Apotex's late-raised theory should be stricken.

Apotex's Untimely Non-Enablement Defense. On October 22, 2019, after watching its existing defenses crumble during expert discovery, Apotex announced for the first time that it wished to advance a non-enablement theory that the "asserted claims of the '107 patent are invalid for lack of enablement because the specification fails to enable the full scope of the claims." Haché E-Mail (Oct. 22, 2019) (Ex. A). At the time, the parties' chemistry experts for the '107 patent had already been deposed, and fact discovery had long since been closed.

Apotex does not—and cannot—contend that its new non-enablement defense is based on any theory that Apotex disclosed in its expert reports, invalidity contentions, or interrogatory responses. Indeed, Apotex has represented that it does "not intend to submit any of its own expert evidence" on the issue. Soderstrom E-mail (Oct. 25, 2019) (Ex. B). Rather, Apotex asserts that its belated defense "is borne directly from, and because of" the deposition testimony of Dr. Allan Myerson, Bayer's expert chemist for the '107 patent. D.I. 153, at 2. According to Apotex, Dr. Myerson purportedly admitted at his deposition that the asserted claims were invalid for lack of enablement because he testified that (1) the specification did not expressly state whether the synthesis method described in the patent could be used to make regorafenib comprising "1 ppm versus 100 ppm's [sic]" (0.0001% to 0.01%) of the claimed impurities; and

(2) the POSA would not have "reasonably expected" to reduce the amount of the claimed impurities in regorafenib from 1,000 ppm—ten times the upper limit of the claim—to 100 ppm—the upper limit of the claim (*i.e.*, from 0.1% to 0.01%). Apotex Stmt. of Fact ¶¶ 179-80 (Ex. C); Myerson Dep. Tr. 80:13-18, 81:17-82:6, 82:13-20, 83:2-17, 83:22-85:14. (Ex. D).[1]

Here, the factors set forth in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977), warrant that Apotex's non-enablement defense be stricken.

Importance of the Excluded Evidence. The only factor that could in theory justify permitting Apotex to proceed with its new non-enablement defense—the importance of the excluded evidence—does not support that result. By Apotex's own admission, Apotex's defense "is borne directly from, and because of" Dr. Myerson's deposition testimony. D.I. 153, at 2. However, under Third Circuit law, which applies here, Apotex cannot rely on Dr. Myerson's testimony in its case-in-chief, because it is inadmissible hearsay. *See Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 2005 WL 2296613, at *2 (D. Del. Sept. 20, 2005) (citing *Kirk v. Raymark Indus., Inc.*, 61 F.3d 147 (3d Cir. 1995)); Fed. R. Civ. P. 32. Absent any admissible affirmative evidence in its case-in-chief, Apotex's defense is doomed to failure. *See* Fed. R. Civ. P. 52(c).

Moreover, even if Apotex could rely on Dr. Myerson's deposition testimony, it is plainly insufficient to prevail on non-enablement—*i.e.*, the defense is futile. The asserted claims require that the compound or composition contain 0.0001% (1 ppm) to 0.01% (100 ppm) of certain impurities. To prove non-enablement, Apotex must do more than allege that the '107 patent fails to disclose expressly how to achieve impurity levels of 100 ppm versus 1 ppm. It must prove that the patent fails to provide a "reasonable enablement of the scope of the range." *See AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). In the testimony Apotex cites, Dr. Myerson merely acknowledged that because the patent's experimental examples did not report the final impurity amount, Ex. D, at 81:14-82:21, the patent did not expressly state what changes, if any, the POSA would need to make to the disclosed synthesis method to achieve impurity levels of "1 ppm versus 100 ppm." Ex. C ¶ 179; Ex. D, at 81:17-82:6; 82:13-20.

That testimony comes nowhere close to establishing that the POSA would need to make ***any*** changes to the disclosed synthesis method for the claims to be enabled—much less to proving that the POSA, ***armed with both the benefit of the patent and the POSA's own "knowledge and skill***," ***could not*** practice the full scope of the claimed range without undue experimentation. *N. Telecom Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). Indeed, Dr. Myerson could not have conceded—and plainly did not concede—that any experimentation was needed or that, if needed, such experimentation would have been undue. Because Apotex did not timely raised this non-enablement defense, Dr. Myerson had neither performed experiments, Ex. D, at 130:8-11, nor reviewed documents—such as materials from Bayer reflecting impurity levels achieved with the patent's method—pertinent to the questions of whether and how much experimentation would be required to practice the claims using that method. Without such evidence, Apotex's defense fails. *See Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188-92 (Fed. Cir. 2014) (reversing non-enablement finding where the court compared only the claims to the relevant disclosures rather than determining whether

[1]For consistency with Defendants' proposed statement, Plaintiffs' cite Dr. Myerson's rough transcript. The final version is not materially different, and Plaintiffs will provide it, if needed.

experimentation would be "undue").

Apparently recognizing this deficiency, Apotex relies on Dr. Myerson's non-obviousness opinions that the POSA, at the priority date, would not have "reasonably expected" to reduce the impurities from 1,000 ppm (above the claimed range) to 100 ppm (the upper bound of the range). Ex. C ¶ 180. However, as Dr. Myerson's testimony and report demonstrate, those opinions addressed whether the POSA, in light of the prior art, ***and without the benefit of the patent's teachings***, would have "reasonably expected" to achieve the claimed inventions. Ex. D, at 83:2-17 (citing Myerson Rep. ¶ 85); Myerson Rep. ¶ 85 (Ex. E). That the POSA would consider the claims to be nonobvious says nothing about whether they are enabled—the latter, but not the former, concerns what the POSA could do with ***both*** the patent ***and*** the POSA's own knowledge and skill. *See Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) (rejecting argument that "if the asserted claims are non-obvious, they cannot possibly be enabled").

Prejudice and Surprise. Bayer would be prejudiced if Apotex can pursue its theory. Although Apotex lacks any affirmative evidence to support its defense, Bayer would be required to respond—out of an abundance of caution. That would require Bayer to conduct further fact discovery that it had no reason to pursue before Apotex belatedly raised its defense. Given the pandemic and the impending trial date, that would impose a great burden on Bayer, as discussed below. Bayer also would need to devote a portion of its already-limited trial time to the issue if Apotex somehow survived a Rule 52 motion—including offering fact and expert testimony—thereby reducing Bayer's time to address issues that actually were litigated during discovery.

Ability to Cure and Extent of Trial Disruption. Permitting Apotex's new theory requires Bayer to collect, review, and produce additional documents and make additional witnesses available for deposition in response. While accomplishing these tasks on an expedited schedule would be burdensome even in normal circumstances, they are especially challenging given the ongoing pandemic. For example, Bayer's potential fact witnesses reside in Germany and are not native English speakers. Bayer's counsel—who has never met some of these potential witnesses in person—would need to conduct any meetings or depositions with these witnesses remotely and may need to rely on interpreters to interview them and to facilitate their testimony. Those burdens are wholly disproportionate to any benefit Apotex might obtain from maintaining this baseless defense. *See Intellectual Ventures I LLC v. AT&T Mobility LLC*, C.A. No. 13-1668-LPS, 2017 WL 658469, at *3 (D. Del. Feb. 14, 2017) (striking infringement contentions that failed to conform to claim construction, citing opposing party's inability to receive notice).

Bad Faith and Willfulness. Apotex cannot argue credibly that it discovered its new defense at Dr. Myerson's deposition unexpectedly. To the contrary, Apotex appears to have entered the deposition with the theory in mind, failed to disclose it, and intentionally elicited the inadequate testimony on which it now relies to assert an argument it knew was not in the case. The alternative explanation—that Apotex fortuitously happened to ask questions at an expert deposition directed to enablement and adduce statements that it now claims provide the only support for an invalidity theory it chose not to advance for the first 34 months of the litigation—strains credulity. Apotex had every opportunity to develop that enablement theory during the first two years of this litigation. The defense involves the disclosures of the patent, not some heretofore unknown fact. Apotex opted for litigation by ambush, rather than adhering to the Federal and Local Rules. Its gambit should not be countenanced.

Respectfully,

*/s/ Anthony D. Raucci*

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cc: All Counsel of Record (by e-mail)