MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347
(302) 658-9200
(302) 658-3989 FAX

ANTHONY RAUCCI
(302) 351-9392
(302) 498-6201 FAX
araucci@mnat.com

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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:

Apotex admits that it cannot currently present any evidence on its new non-enablement theory in its case-in-chief—and, thus, could not survive a Rule 52(c) motion. Undeterred, Apotex appears to suggest—for the first time, thirteen months after it served expert reports and two months before trial during a global pandemic—that the solution to its failure of proof is to re-open discovery and allow its expert to address the issue, the burdens of which would fall disproportionally on Bayer. D.I. 159 at 3. *Pennypack* does not countenance such an approach. And Apotex's regret that it focused on a now-discredited obviousness theory during discovery does not permit it to treat Dr. Myerson's deposition as a pretext for raising a new defense. Bayer's motion should be granted.

Apotex makes no attempt to explain how its new theory could survive a Rule 52(c) motion without re-starting fact and expert discovery. Indeed, Apotex acknowledges that *Pfizer* and *Kirk* preclude its reliance on Dr. Myerson's testimony in its case-in-chief. D.I. 159 at 2. Apotex's solution to this conundrum—that it will establish the theory "through cross-examination," *id.*—misses the crucial point that Dr. Myerson cannot testify in Apotex's case-in-chief, entitling Bayer to judgment before he is cross-examined. *See, e.g.*, *Cosmo Techs. Ltd. v. Actavis Labs. FL, Inc.*, C.A. No. 15-164-LPS, 2017 WL 7185967 (D. Del. Oct. 27, 2017) (granting Rule 52(c) motion).[1]

Clearly recognizing this fatal inability to carry its burden, Apotex reverses course: it no longer intends to abide by its promise not to "submit any of its own expert evidence," D.I. 158-1 at 4, but instead asserts that the short delay of trial somehow allows it to "cure any perceived prejudice by conducting limited fact and expert discovery." D.I. 159 at 3. Any suggestion that Apotex now be permitted to submit additional expert evidence only further compounds the prejudice to Bayer. Apotex's experts had over two years to develop their opinions, and its new theory relates to the patent's disclosures, not some heretofore unknown fact. If Apotex wished to pursue the theory, the time to do so was long ago—not now, as the parties furiously prepare for a nearly unprecedented remote trial in the face of extremely challenging circumstances. Instead, Apotex effectively asks to serve a new expert report, following document and deposition fact discovery, requiring Bayer to depose Apotex's expert and prepare a response on the eve of trial. Apotex is solely responsible for

[1] In *Pfizer*, the court denied a motion *in limine* to preclude Pfizer from relying on Ranbaxy's experts' testimony. However, in contrast to this case, Pfizer had other evidence it could present to support its theory. *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 405 F. Supp. 2d 495, 510 (D. Del 2005). *Pfizer* also held that *Kirk* is not limited to prior litigations. 2005 WL 2296613, at *2.

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disclosing its theory long after the deadline, but Bayer would bear the burdens. D.I. 158 at 3.[2] That should not be permitted.

To justify its approach, Apotex uses Dr. Myerson's deposition as a pretext. Although Apotex professes innocence, its own arguments demonstrate its willfulness under *Pennypack*. Had Apotex intended to limit its examination of Dr. Myerson to its existing non-obviousness theory, it would have had no reason to question him about the lower limit of the claimed range because—as Apotex itself argues—its obviousness defense is based on the "upper limit." D.I. 159 at 1 n.1. Instead—to inject a non-enablement theory it had not presented or preserved—Apotex questioned Dr. Myerson about the *lower limit*, intentionally trying to elicit testimony about the patent's teachings that had nothing to do with obviousness (since, of course, the patent is not prior art). *Id.* at 3.

In any event, Dr. Myerson's testimony does not support non-enablement, and Apotex is left to mischaracterize it. Apotex confuses (a) whether the patent expressly states how to achieve 1 ppm versus 100 ppm, with (b) whether the POSA, based on the patent and the POSA's own knowledge and skill, would be able to reasonably practice the full scope of the range without undue experimentation. D.I. 159 at 4. What Dr. Myerson actually testified—in response to questions framed in terms of whether there is "anything in the patent"—was that the disclosed method could be used to achieve values within the claimed range, but did not expressly state how to obtain one value versus another. Ex. A at 84:10-86:10. Recognizing this, Apotex points to Dr. Myerson's testimony about non-obviousness, which explained that the POSA, ***without the patent's teachings***, could only achieve the claimed impurity levels, if at all, through "extensive experimentation." *Id*. How this is an "extreme position" or inconsistent with the method in the patent enabling the full scope of the range, D.I. 159 at 1, 3, is baffling. While Apotex asserts that Dr. Myerson admitted that undue experimentation is required "*even with the benefit of the patent's disclosures*," *id*. at 4, 5 n.6, it provides no supportive citation. The reason is simple: Dr. Myerson said no such thing.

None of the cases Apotex cites advances its position. In *Alcon*, the patentee conceded that the claims were not enabled for a significant portion of the range. Bayer, however, has not conceded non-enablement. Nor has Apotex—which has the burden—presented any evidence that the POSA, following the methods in the patent, would be unable to achieve the lower limit of the range (or any other value) without undue experimentation. Dr. Myerson's testimony regarding what is "in the patent," Ex. A at 84:10-86:10, comes nowhere close to admitting that the POSA would not achieve the lower limit without undue experimentation. *Magsil* and *Fisher* are even further afield, as they addressed claims without *any* limit on the range. *Idenix* and *MorphoSys*, which addressed vast chemical and biological genera, are also inapposite. In those cases, the POSA could not determine the scope of the claims without testing potentially billions of compounds. There is no such question about the scope of the claim here. Nor is there evidence that anywhere near that level of experimentation—if any at all—is required here. Moreover, Dr. Myerson explained that while the patent did not expressly state whether the lower limit was obtained, the POSA could find out simply by performing the method. *Id.* at 82:9-21. And of course, Dr. Myerson had no reason to analyze what exact purity the method achieves, because Apotex *had not raised the issue*.

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[2] Apotex takes Bayer's draft status report out of context. Unlike Apotex's proposal, Bayer's initial proposal sharply limited fact discovery and did not permit Apotex to submit new expert reports. D.I. 159-1 at 9-10. Instead, it simply permitted Dr. Myerson to respond to Apotex's theory.

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Respectfully,

/s/ Anthony D. Raucci

Anthony D. Raucci (#5948)

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

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