Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and BAYER HEALTHCARE PHARMACEUTICALS INC. Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. 16-1221-LPS (Consolidated) **CONFIDENTIAL – FILED UNDER SEAL**

EXHIBIT 12

PLAINTIFFS' MOTION IN LIMINE NO. 1
TO PRECLUDE APOTEX'S UNTIMELY NON-ENABLEMENT THEORY

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") should be precluded from arguing at trial that asserted claims 11, 14, and 20 of U.S. Patent No. 9,458,107 (the "'107 Patent") are invalid for lack of enablement based on the theory that the specification fails to enable the full scope of the claims— a theory first raised three days prior to the close of expert discovery.

I. Apotex's Effort to Raise a New Theory is Untimely

On October 22, 2019—three days from the close of expert discovery, after Apotex and Bayer's experts on the '107 patent were deposed, and after Apotex had served its initial pretrial disclosures—Apotex notified Bayer of its intention "to assert that all of 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." E-Mail from Haché (Oct. 22, 2019) (Ex. 12A). The asserted claims require certain impurities be present "from 0.0001% to a maximum of 0.01%." There is no dispute that Apotex's ANDA Product in fact contains levels below 0.01% and above 0.0001%, which is all that is required. The purported basis for Apotex's new theory appears to be that the exemplary methods disclosed in the '107 patent do not enable making regorafenib having anilinic impurity levels at 0.0001% or 1 ppm, and that section 112 somehow requires that the '107 patent expressly disclose a method to achieve all impurity levels between 0.0001% and 0.01%.

To be clear, Apotex's new non-enablement theory is completely different from any theory advanced by Apotex's experts during discovery or in Apotex's previous pretrial disclosures. Apotex's only expert on the '107 patent, Dr. Marvin Hansen, opined that claims 11 and 14—but not claim 20—were invalid for lack of enablement because those claims express the amount of impurities in terms of percentage "by weight, based on the weight," a phrase that does not literally appear in the specification. Dr. Hansen's report discussed enablement only in passing, in a section spanning three paragraphs. Hansen Rep. ¶¶ 125-27 (Ex. 12B).

At his deposition, Dr. Hansen reiterated that the "weight based on the weight of the

compound" language was "the key point for enablement." *See* Hansen Tr. at 234:13-15 ("So the key point for the enablement is the lack of the weight, based on the weight language in the specification."), 235:12-15 ("So the key point for the enablement, as I said, is the weight, based on the weight.") (Ex. 12C). He has never offered the opinion that claim 20 is non-enabled for any reason or that any claim is non-enabled based on the lower bound of the claimed range.

To justify its untimely theory, Apotex relies on Apotex's examination of Bayer's expert on the '107 patent, Dr. Allan Myerson. Ex. 12A ("In light of Dr. Myerson's testimony yesterday, Apotex is amending its contested facts . . . ."). While Dr. Myerson's testimony does not actually support Apotex's theory,[1] that is beside the point. Apotex had every opportunity to explore the theory (which purports to rely on the adequacy of the '107 patent's examples) during fact discovery and to disclose expert opinion regarding the issue. It chose not to do so. To allow Apotex to change course now would deprive Bayer of the opportunity to meaningfully respond.

II. Preclusion is the Appropriate Remedy

The appropriateness of preclusion turns on the factors recited in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977). *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 298 (3d Cir. 2012). Those factors require preclusion here.

A. Prejudice or Surprise to the Party Against Whom the Evidence Is Offered

Apotex's attempt to pursue a new enablement theory would severely prejudice Bayer. Bayer did not have the opportunity to take any fact or expert discovery on the new theory. Nor

[1] Apotex cobbles together its new non-enablement theory based on Dr. Myerson's (1) opinion that the claims were non-obvious because the POSA, ***without the benefit of the patent's disclosures***, would not be able to make the claimed inventions without undue experimentation; and (2) purported acknowledgment that the specification does not expressly disclose how to make regorafenib with "1 ppm versus 100 ppm's [sic]" of the recited impurities. Myerson Tr. at 85:7-18 (Ex. 12D). Because Apotex presents no evidence that the POSA, ***with the benefit of the patent***, would be unable to make and use the claimed inventions without ***undue experimentation***, its theory fails as a matter of law.

did Bayer's experts have the opportunity to rebut Apotex's new theory during expert discovery.

B. Ability to Cure and Extent of Trial Disruption

To the extent Bayer's prejudice could be cured, Bayer would need to take additional fact and expert discovery, including an opportunity to submit supplemental expert reports, and if necessary, perform testing regarding the exemplary methods. Such remedies are impossible without reopening both fact and expert discovery. *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) (granting motion to strike infringement contentions that failed to conform to claim construction, citing opposing party's inability to receive notice).

C. Bad Faith or Willfulness in Not Disclosing the Evidence

Even though Apotex disclosed its new non-enablement theory following the deposition of Dr. Myerson, three days from the close of expert discovery, Apotex's theory appears to rest entirely on the '107 patent's disclosures. Given that, Apotex cannot plausibly argue that it unexpectedly discovered the theory at Dr. Myerson's deposition. Indeed, Apotex's questioning of Dr. Myerson makes clear that Apotex entered his deposition with the theory in mind.

D. Importance of the Excluded Evidence

Apotex has had more than three years to prepare its defense at trial. That Apotex has only now somehow stumbled its way into a case-winning argument beggars belief. 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. 12E). Were Apotex's new non-enablement theory actually important, it is unlikely that Apotex's experts would have failed to address it (unlike Apotex's other obviousness, written description, non-enablement, and indefiniteness theories). Apotex should be precluded from presenting at trial its new and untimely non-enablement theory.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Anthony D. Raucci

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November 20, 2019

CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2019, copies of the foregoing were caused to be served upon the following in the manner indicated:

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Seth Bowers

Exhibit 12A

Subject: Bayer HealthCare LLC v. Apotex

From: Hache, Guylaine [mailto:guylaine.hache@katten.com]
Sent: Tuesday, October 22, 2019 5:34 PM
To: Bowers, Seth <SBowers@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Genderson, Bruce <BGenderson@wc.com>; Perlman, Adam <APerlman@wc.com>; Grossman, Dov <DGrossman@wc.com>; jblumenfeld@mnat.com; dfahnestock@mnat.com; araucci@mnat.com
Cc: Kouyoumdjian, Philip Y. <pkouyoumdjian@taftlaw.com>; Skinner, Patricia <PSkinner@taftlaw.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Soderstrom, Lance A. <lance.soderstrom@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Janusz, Joe <joe.janusz@katten.com>; Kenneth Dorsney <kdorsney@morrisjames.com>; elarson@morrisjames.com
Subject: Bayer HealthCare LLC v. Apotex

Counsel –

In light of Dr. Myerson's testimony yesterday, Apotex is amending its contested facts to assert that all of 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. A redline of Apotex's amendments is attached.

Regards,

Guylaine Haché, Ph.D.
Associate

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Exhibit 12B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and , BAYER HEALTHCARE , PHARMACEUTICALS INC., ,	)	
Plaintiff,	)	C.A. No. 16-cv-1221-LPS (CONSOLIDATED)
v.	)	
APOTEX INC. and APOTEX CORP.,	)	Contains Material Designated as HIGHLY CONFIDENTIAL Pursuant to Protective Order
Defendants.	)	

EXPERT REPORT OF MARVIN M. HANSEN, PH.D.

Date: May 31, 2019

M. M. Hansen

Marvin M. Hansen, Ph.D.

Table of Contents

IX. CLAIMS 1, 2, AND 9-14 OF THE '107 PATENT ARE INVALID FOR LACK OF ENABLEMENT

125. As discussed above, I have been informed by counsel that to meet the enablement requirement, a patent's specification must set forth and describe the invention in terms such that a POSA would be able to carry out or practice the claimed invention without undue or unreasonable experimentation. However, detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit a POSA to make and use the invention. In my opinion, this requirement has not been met.

126. As discussed above with regard to the written description requirement, there is no description in the specification of the claimed language "weight based on the weight of the compound," such that a POSA would be able to prepare regorafenib with the claimed impurity profile without undue experimentation.

127. Accordingly, based on the understanding of the enablement requirement provided to me by counsel, in my opinion, claims 1, 2, and 9-14 are invalid for lack of enablement.

X. ALL ASSERTED CLAIMS OF THE '107 PATENT ARE INVALID AS INDEFINITE

128. As discussed above, I have been informed by counsel that to meet the definiteness requirement, a claimed invention must inform the POSA about the scope of the invention with reasonable clarity.

129. As previously discussed, the specification of the '107 patent does not provide adequate written support or enablement for the claimed impurity profiles with respect to the claim term "weight based on weight."

Exhibit 12C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

- - - - - - - - - - - - - - -x

BAYER HEALTHCARE LLC	:	
and BAYER HEALTHCARE	:	
PHARMACEUTICALS	:	C.A. No. 16-1221 (LPS)
INC.,	:	CONSOLIDATED
Plaintiffs, v.	:	
APOTEX INC. and	:	
APOTEX	:	
CORP.,	:	
	:	
Defendants.	:	
	:	

- - - - - - - - - - - - - - -x

CONFIDENTIAL PURSUANT TO THE PROTECTIVE ORDER

Deposition of

MARVIN M. HANSEN, PH.D.

New York, New York

Thursday, October 3, 2019

8:07 a.m.

Job No.: 264818

Pages: 1 - 317

Reported By: Nancy Mahoney, CCR/RPR

Deposition of MARVIN M. HANSEN, PH.D., held at the offices of:

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Pursuant to agreement, before Nancy Mahoney, Notary Public in and for the state of New York.

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ALSO PRESENT:

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Head of Patents & Licensing Radiology
Bayer U.S.

Shaye Lankford, Videographer

C O N T E N T S

E X H I B I T S

(Attached to transcript)

A. Okay. 15:27:32
Q. Have you reviewed this report? 15:27:32
A. Yes. 15:27:37
Q. If you look at Paragraphs 21 and 22, 15:27:37
he talks about the definition of the POSA and 15:27:40
compares it to your definition of a POSA. 15:27:45
A. Yes, I have. 15:27:52
Q. And would you regard your definition 15:27:54
of the POSA and Dr. Myerson's definition of the POSA 15:28:08
to be substantively similar? 15:28:12
A. Yes. 15:28:14
Q. If you can -- what is ppm? 15:28:24
A. Parts per million. 15:28:31
Q. How do you calculate ppm? 15:28:34
A. It's a weight of an impurity divided 15:28:36
by the weight of what you're measuring it relative 15:28:40
to. 15:28:45
Q. And if you take a look at page 48 of 15:28:47
your report. Sorry, not Dr. Myerson's report. Your 15:31:17
expert report. 15:31:20
A. Okay. 15:31:32
Q. Section IX you talk about your 15:31:33
opinions concerning non-enablement. 15:31:39
A. Correct. 15:31:43
Q. I'm trying to -- did you perform any 15:31:45

experiments in connection with your non-enablement opinions? 15:31:58 15:32:06

A. No. The key conclusion there is captured in 126, "weight by based on weight of the compound is not described in the specification." 15:32:07 15:32:11 15:32:16

Q. So your non-enablement opinions are based on your written description opinions? 15:32:19 15:32:21

MR. SCOTT: Objection. 15:32:28

A. I'm looking at 126 which is in the lack of enablement. 15:32:30 15:32:34

Q. Right. And that refers to your written description opinions? 15:32:40 15:32:43

A. So those are separate. So the key point for the enablement is the lack of the weight, based on the weight language in the specification. 15:32:51 15:33:00 15:33:06

Would you like a summary of the written description opinion as well? 15:33:11 15:33:12

Q. If I understand -- so if the court determines as a matter of law that the specification does provide support for the claim language "weight, based on the weight of the compound," would you agree that the -- that Claims 11 and 14 are enabled? 15:33:17 15:33:35 15:33:43 15:33:49 15:33:55

MR. SCOTT: Objection. 15:34:05

A. I wouldn't want to give a legal opinion based on a court decision. 15:34:05 15:34:07

Q. I'm not asking for a legal opinion. 15:34:16
I'm asking you to assume that the court concludes as 15:34:18
a matter of law that the specification does contain 15:34:20
a written description of weight, based on the weight 15:34:27
of the compound. 15:34:30
Do you understand my hypothetical? 15:34:32
A. Yes. 15:34:34
Q. With that understanding, under that 15:34:36
scenario, would you agree that Claims 11 and 14 are 15:34:40
enabled? 15:34:43
MR. SCOTT: Objection. 15:34:43
A. So the key point for the enablement, 15:34:51
as I said, is the weight, based on the weight, but I 15:34:53
look at it in the full context of the indefiniteness 15:34:56
as well and the lack of written description. 15:35:01
Q. Well, you don't refer to 15:35:06
indefiniteness in the discussion here, 15:35:09
non-enablement; you as I think you identified 15:35:13
referred to your written description. Do you see 15:35:15
that? 15:35:16
A. Correct. 15:35:17
Q. And so if the court rejects your 15:35:18
written description opinion, would you agree that 15:35:20
Claims 11 and 14 are enabled? 15:35:24
MR. SCOTT: Same objection. 15:35:26

Exhibit 12D

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and BAYER HEALTHCARE PHARMACEUTICALS, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., APOTEX, CORP. AND APOTEX INC., Defendants.	Case No. 16-1221(LPS) - USDC-DDE

C O N F I D E N T I A L

DEPOSITION OF ALLAN MYERSON, Ph.D.

Washington, D.C.

October 21, 2019

REPORTED BY: Tina Alfaro, RPR, CRR, RMR

Videotaped deposition of ALLAN MYERSON, Ph.D., held at the offices of:

Williams & Connolly
725 12th Street, NW
Washington, D.C. 20005

Taken pursuant to notice before Tina M. Alfaro, a Notary Public within and for the District of Columbia.

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ALSO PRESENT: Ian Scott (Taft Stettinius)
David Schramm (Bayer)
T.J. O'Toole (videographer)

I N D E X

EXAMINATION

****

E X H I B I T S

11:06:28 check. Yeah, mine is off.
11:06:28 THE VIDEOGRAPHER: The time is 11:06:45.
11:06:33 Off the record.
11:08:22 (A short break was had.)
11:08:48 THE VIDEOGRAPHER: On the record. The
11:08:49 time is 11:09:03.
11:08:50 BY MR. MALIK:
11:08:50 Q. Let me restate the question so it's
11:08:54 crystal clear because I think I made an error when
11:08:57 it came to the decimal points.
11:09:00 Claim 11 of the '107 Patent requires the
11:09:03 impurity levels be between 0.0001 percent to a
11:09:08 maximum of 0.1 percent by weight, correct?
11:09:12 A. Correct.
11:09:13 Q. And the other claims -- asserted claims 14
11:09:15 and --
11:09:17 MR. BOWERS: I'm sorry to interrupt. Did
11:09:18 you say 0.1 percent by weight or 0.01 percent by
11:09:21 weight?
11:09:23 MR. MALIK: I hope I said 0.01 percent.
11:09:25 Let me start over. Third time lucky.
11:09:29 BY MR. MALIK:

11:09:29 Q. Claim 11, the recited amounts of the
11:09:32 impurities are 0.0001 percent to a maximum of
11:09:39 0.01 percent by weight, correct?
11:09:44 A. Correct.
11:09:45 Q. And the same is true for the other
11:09:47 asserted claims, correct?
11:10:00 A. Correct.
11:10:01 Q. Does the '107 Patent exemplify a
11:10:05 regorafenib composition having impurities in an
11:10:10 amount of 0.0001 percent to a maximum of
11:10:16 0.1 percent -- 0.01 percent?
11:10:24 A. I'm sorry. I don't think I understand the
11:10:25 question.
11:10:26 Q. Sure. Is there any example in the
11:10:30 '107 Patent that has the impurity levels within the
11:10:35 recited limits?
11:10:39 A. Ah, okay. I gotcha.
11:10:52 They don't actually report the impurity
11:10:56 limits in the example. So if you did stage 4,
11:11:03 practiced it and did the HPLC analysis, I would
11:11:06 think you would get that level, both levels, but
11:11:10 it's not -- it's not shown. I would agree with

11:11:14 that.

11:11:18 Q. Well, let's just kind of break that up.

11:11:20 So there are four stages in the example, correct?

11:11:24 A. Correct.

11:11:28 Q. And looking at stage 3, which is on

11:11:32 column 14, what amount of impurities do you

11:11:37 achieve?

11:11:39 A. It doesn't say.

11:11:45 Q. Certainly doesn't tell you whether

11:11:47 0.0001 percent was ever achieved, correct?

11:11:53 A. It doesn't say, but, of course, a POSA

11:11:56 could perform this example and do the analysis and

11:11:58 they would know.

11:12:03 Q. Stage 4 also measures the amount of

11:12:05 impurities, correct?

11:12:06 A. Correct.

11:12:09 Q. And it does not tell you whether

11:12:11 0.0001 percent was ever achieved, correct?

11:12:17 A. The data's not in there, that's correct.

11:12:21 The POSA would have to perform example 4 and

11:12:23 determine if it was achieved.

11:12:25 Q. To achieve 0.001 percent can you show me

11:12:34 in the patent where it says what changes need to be
11:12:37 made to the basic synthetic pathway?
11:12:41 A. I think you mean 0.0001 percent. You left
11:12:45 a zero out again.
11:12:47 Q. Yes.
11:12:48 A. Yeah. If you want to make this simple for
11:12:51 yourself, you could just say 1 PPM and a hundred
11:12:54 PPM if that's easier to do.
11:12:57 Q. Let's do that. 1 PPM, just so we're
11:13:01 clear, is -- let's try this again --
11:13:05 0.0001 percent. Fair enough?
11:13:10 A. I think you left a zero out again.
11:13:13 THE REPORTER: No, he didn't.
11:13:15 THE WITNESS: He didn't that time? Good.
11:13:16 Okay.
11:13:17 BY MR. MALIK:
11:13:17 Q. 1 PPM, I actually do like that much
11:13:20 better.
11:13:21 The patent doesn't show you what specific
11:13:23 changes need to be made to achieve 1 PPM versus a
11:13:26 hundred PPM, does it, to the basic synthetic
11:13:28 pathway?

11:13:29 A. Say that again at the end. I'm sorry.
11:13:32 Q. Sure. Is there any -- strike that. Let
11:13:37 me see if I can lay some foundation.
11:13:40 In paragraph 87 of your report you say
11:13:43 that to achieve the levels would require
11:13:46 optimization involving a variety of variables,
11:13:48 including the basic synthetic pathway, reaction
11:13:52 conditions, and you go on, correct?
11:13:54 A. Right.
11:13:54 Q. Okay. So that's the foundation for my
11:13:56 question. The patent doesn't show what specific
11:14:06 changes need to be made to the basic synthetic
11:14:09 pathway to achieve 1 PPM versus 100 PPM's, correct?
11:14:15 MR. BOWERS: Object to the form of the
11:14:16 question.
11:14:18 A. Okay. I think I understand. The patent
11:14:22 itself teaches the optimized synthetic procedure to
11:14:29 make regorafenib with the desired levels of
11:14:33 impurities. Practicing the examples should allow
11:14:37 you to do so, but if you're asking me it doesn't --
11:14:43 it doesn't say if I do it one way I'll get a
11:14:46 hundred PPM and if I do it this way I'll make 1

PPM. I would agree it doesn't say that anywhere.

Q. Do you have an opinion as to which would be more challenging, reaching a composition with 1 PPM's or 100 PPM's?

A. 1 PPM is certainly more difficult than a hundred PPM.

Q. Is there anything in the patent, the '107 Patent that teaches what changes need to be made to the reaction conditions at each stage of the synthesis to achieve 1 PPM versus 100 PPM's?

MR. BOWERS: Object to the form of the question.

A. No, it does not. Certainly a POSA could practice the invention and see what purity levels they did achieve, but it doesn't tell you -- and it would -- it would be, in my opinion, within the claimed range, but it doesn't tell you how to achieve 1 versus 100.

Q. Is there anything in the patent that you're aware of that would teach what changes to the intermediate work -- sorry -- to the intermediate purification that needs to be made to

11:15:57 achieve 1 PPM versus 100 PPM's?

11:16:02 A. Same answer as I just gave.

11:16:05 Q. Is there anything in the patent that

11:16:06 teaches what specific changes need to be made to

11:16:10 the final isolation to achieve 1 PPM versus

11:16:13 100 PPM's?

11:16:16 A. No. Again, if you practice the invention,

11:16:19 it's my opinion you would get a result in the

11:16:21 range, but you wouldn't know how to do 1 PPM versus

11:16:24 100 PPM.

11:16:51 Q. In paragraph -- turn to paragraph 85 of

11:16:53 your report.

11:17:04 A. Yes.

11:17:04 Q. Paragraph 85 of your report you state that

11:17:08 "Dr. Hansen has not provided any opinion or

11:17:11 analysis explaining how the POSA would have

11:17:14 reasonably expected a ten-fold reduction from

11:17:17 1,000 PPM to 100 PPM (i.e. the highest level

11:17:25 allowed in the asserted claims of the '107 Patent)

11:17:28 to be successful"; do you see that sentence?

11:17:32 A. Yes.

11:17:32 Q. You're saying in that paragraph that even

11:17:33 a ten-fold reduction would be difficult to achieve,
11:17:36 correct?
11:17:37 A. Yes.
11:17:37 Q. And a 100-fold reduction would be even
11:17:41 harder, correct?
11:17:42 A. To go from a thousand to one, certainly
11:17:44 that's correct.
11:18:03 Q. Turn to paragraph 83 of your report. I'm
11:18:14 sorry. Paragraph -- strike that -- 80 of your
11:18:21 report. Let me know when you're there.
11:18:32 A. Yes.
11:18:32 Q. Paragraph 80 there's a sentence "To the
11:18:35 contrary, the POSA would have recognized that
11:18:37 reducing regorafenib anilinic impurities and in
11:18:43 particular the impurity AF-PMA to the levels
11:18:48 required by the asserted claims would be especially
11:18:50 challenging"; do you see that?
11:18:53 A. Yes.
11:18:53 Q. Do you have an understanding -- strike
11:18:57 that.
11:18:57 Now, in that paragraph you use the term
11:18:59 "especially challenging," correct?

Exhibit 12E

Subject: Bayer HealthCare LLC v. Apotex

From: Soderstrom, Lance A. <lance.soderstrom@katten.com>
Sent: Friday, October 25, 2019 5:28 PM
To: Picozzi, Ben <BPicozzi@wc.com>; Hache, Guylaine <guylaine.hache@katten.com>; Bowers, Seth <SBowers@wc.com>; Genderson, Bruce <BGenderson@wc.com>; Perlman, Adam <APerlman@wc.com>; Grossman, Dov <DGrossman@wc.com>; jblumenfeld@mnat.com; dfahnestock@mnat.com; araucci@mnat.com
Cc: Kouyoumdjian, Philip Y. <pkouyoumdjian@taftlaw.com>; Skinner, Patricia <PSkinner@taftlaw.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Janusz, Joe <joe.janusz@katten.com>; Kenneth Dorsney <kdorsney@morrisjames.com>; elarson@morrisjames.com
Subject: RE: Bayer HealthCare LLC v. Apotex

Counsel -

I'm not sure we understand your email. Dr. Myerson's testimony was clear. According to him, the specification does not enable a POSA to practice the full scope of the asserted claims. That defense is from Dr. Myerson's deposition testimony on Monday. Contrary to the email below, Apotex, not Bayer, would be unfairly prejudiced if Dr. Myerson's testimony may not be used to challenge the asserted claims. Apotex does not intend to submit any of its own expert evidence in furthering Dr. Myerson's concession. We can raise this with the Court next week or during the pretrial conference.

Lance A. Soderstrom
Partner

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From: Picozzi, Ben <BPicozzi@wc.com>
Sent: Wednesday, October 23, 2019 7:52 PM
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Cc: Kouyoumdjian, Philip Y. <pkouyoumdjian@taftlaw.com>; Skinner, Patricia <PSkinner@taftlaw.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Soderstrom, Lance A. <lance.soderstrom@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Janusz, Joe <joe.janusz@katten.com>; Kenneth Dorsney <kdorsney@morrisjames.com>; elarson@morrisjames.com
Subject: RE: Bayer HealthCare LLC v. Apotex

EXTERNAL EMAIL – EXERCISE CAUTION
Counsel,

Apotex's attempt to introduce a new non-enablement defense on the eve of trial is inconsistent with Apotex's disclosure obligations and unfairly prejudices Bayer. Please confirm that Apotex will not attempt to advance the defenses referenced in your email at trial. If Apotex refuses, we intend to raise the issue with the Court.

Regards,

Ben Picozzi
Associate | Williams & Connolly LLP
725 Twelfth Street, N.W., Washington, DC 20005
(P) 202-434-5266 | (F) 202-434-5029
bpicozzi@wc.com | www.wc.com

From: Hache, Guylaine [mailto:guylaine.hache@katten.com]
Sent: Tuesday, October 22, 2019 5:34 PM
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Cc: Kouyoumdjian, Philip Y. <pkouyoumdjian@taftlaw.com>; Skinner, Patricia <PSkinner@taftlaw.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Soderstrom, Lance A. <lance.soderstrom@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Janusz, Joe <joe.janusz@katten.com>; Kenneth Dorsney <kdorsney@morrisjames.com>; elarson@morrisjames.com
Subject: Bayer HealthCare LLC v. Apotex

Counsel –

In light of Dr. Myerson's testimony yesterday, Apotex is amending its contested facts to assert that all of 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. A redline of Apotex's amendments is attached.

Regards,

Guylaine Haché, Ph.D.
Associate

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. 16-cv-1221-LPS (CONSOLIDATED)
v.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION IN LIMINE NO. 1

Plaintiffs' MIL misses the mark. The predicate of its Motion is Plaintiffs' misguided allegation that Apotex is somehow trying to shoehorn a new defense to the patent-in-suit. Not so. Apotex's invalidity argument is, and has been, that the asserted claims of the '107 patent are obvious—a POSA would have lowered the identified impurities to the claimed ranges without undue experimentation. In attempting to rebut that position, however, Plaintiffs went too far. Plaintiffs' expert, Dr. Myerson, testified at his deposition that the specification supports removal of the impurities to a certain level, but a POSA would *not* be able to practice the full scope of the claims without undue experimentation. Not once did Dr. Meyerson contradict his foregoing testimony. Plaintiffs would have this Court believe that Apotex is now springing a surprise. In truth, Plaintiffs' own expert conceded that the full scope of the asserted claims is not enabled. And, Apotex wants to present that evidence at trial. Contrary to what Plaintiffs imply, Apotex will not be offering any new expert opinions in connection with Dr. Meyerson's concession. Dr. Meyerson's testimony stands on its own. And the prejudice to Apotex in precluding it from presenting its case based on Dr. Meyerson's new testimony would be manifest.

I. Exclusion Is Not the Appropriate Remedy

The balance of the *Pennypack* factors weighs in favor of admissibility. As this Court has noted, "[i]t bears emphasis that exclusion of 'critical evidence,' . . . is an extreme sanction." *E.g.*, *B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 221 (D. Del. 2010) (Stark. J.). Here, invalidity of the '107 patent is critical to Apotex's defense as Apotex stipulated to infringement. The other *Pennypack* factors also largely favor admissibility. Plaintiffs claim they were "severely prejudice[d]" because "Bayer's experts were given no opportunity to rebut Apotex's new theory." MIL 3-4. But, as noted above, Apotex's theory stems *directly* from Dr. Myerson's deposition testimony. Plaintiffs even had an opportunity to do a redirect on that testimony during the deposition. They will have that opportunity at trial. Regardless, that Dr.

Myerson could now somehow rebut his own testimony is nonsensical. Nor can Plaintiffs show that Apotex had any bad faith or willfulness in not disclosing its defense until the day immediately after Dr. Myerson's deposition.[1]

II. Dr. Myerson's Testimony Forms the Basis of Apotex's Non-Enablement Theory

Each asserted claim requires "from 0.0001% to a maximum of 0.01%" impurities. Dr. Myerson testified that the examples disclose only "*typically*" achieving "less than 0.01%." Tr. 240:2-242:13. He conceded that the examples *do not* disclose levels as low as 0.0001%: "The data's not in there . . . The POSA would have to perform example 4 and determine if it was achieved." Tr. 82:19-21; 82:11-13. But, directing one of skill in the art to simply "perform the example" and "do the analysis" is not an enabling disclosure. *See, e.g.*, *Idenix Pharm.*, 2019 WL 5583543, at *8 (affirming JMOL (Stark, J.) that claims were not enabled because, *inter alia*, plaintiff's witness testified "you don't know whether or not a nucleoside will have activity against HCV until you make it and test it"); *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 372-74 (D. Del. 2019) (Stark, J.). Further, according to Dr. Myerson, reducing impurity levels *10-fold*, "from 1000 ppm to 100 ppm (*i.e.*, the highest level allowed in the asserted claims of the '107 patent) . . . would be difficult to achieve even with extensive experimentation." Rpt. ¶ 85. "Extensive experimentation," according to Dr. Myerson, "would require optimization involving a *wide variety of variables*." Rpt. ¶ 87; Tr. 77:10-17.

There is more. When asked whether the '107 patent taught the POSA what variables needed to be optimized to reduce the impurity levels *100-fold*, from 100 ppm (i.e., 0.01%, the upper limit

[1] Further, Plaintiffs' argument that it may be necessary for their experts to "perform testing regarding the exemplary methods" (MIL at 4) supports Apotex's non-enablement theory. *See In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009) ("Enablement is determined as of the effective filing date of the patent's application.") Regardless, Plaintiffs' experts will have the opportunity to do so now with trial having been postponed.

in the claims) to 1 ppm (i.e., 0.0001%, the lower limit in the claims), Dr. Myerson testified: "No, it does not. . . . [I]t doesn't tell you how to achieve one [ppm] versus 100 [ppm]." Tr. 85:7-18; 86:3-10 (same); 86:14–87:7 (100-fold reduction would be harder to achieve than 10-fold). Thus, Dr. Myerson confirmed that the POSA would not have been able to practice the full scope of the claims, ***even with the benefit of the patent's disclosures***, without undue experimentation.

Contrary to Plaintiffs' assertion, the basis for Apotex's non-enablement theory is not that "section 112 somehow requires that the '107 patent expressly disclose a method to achieve all impurity levels between 0.0001% and 0.01%." MIL at 2. Rather, as this Court stated in *MorphoSys*:

> The "full scope" requirement does not require the specification to "provide a detailed recipe for preparing every conceivable permutation" of a claimed embodiment. . . . *However, it is not always sufficient if a specification merely enables a POSA to practice an embodiment of the claimed invention*. . . . In *MagSil*, 687 F.3d at 1379-84, claims to a semiconductor device that could change in resistance by "at least 10%" were not enabled, even though the specification enabled a device that changed resistance by 11.8%, because the specification did not enable devices that changed resistance by 100% or 1000% percent.

358 F. Supp. 3d at 368 (emphasis added). Here, as in *MagSil*, the specification purportedly enables impurity levels of 0.01% but it does not enable reducing them to 0.0001%, at least according to Dr. Myerson. "[W]hen there is an embodiment within the claim's scope that a person of ordinary skill, reading the specification, would be unable to practice without undue experimentation . . . the full scope of the claims is not enabled." *MorphoSys*, 358 F. Supp. 3d at 368.

Plaintiffs created their own enablement problem. "In cases involving unpredictable factors, such as most chemical reactions . . ., the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). Here, by relying on the purported unpredictability of the art to establish non-obviousness, Plaintiffs brought upon themselves "the peril of losing any claim that cannot be enabled across the full scope of its coverage." *MagSil Corp.*, 687 F.3d at 1381. Plaintiffs' MIL should be denied.

/s/ Guylaine Haché

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CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2019, copies of the foregoing were caused to be served upon the following in the manner indicated:

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/s/ Guylaine Haché
Guylaine Haché

Ex. A

To Defendants' Opposition to Plaintiffs' MIL

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and BAYER HEALTHCARE PHARMACEUTICALS, INC., Plaintiff,	)	Case No.
v.	)	16-1221(LPS) - USDC-DDE
TEVA PHARMACEUTICALS USA, INC., APOTEX, CORP. AND APOTEX INC., Defendants.	)	

C O N F I D E N T I A L

DEPOSITION OF ALLAN MYERSON, Ph.D.

Washington, D.C.

October 21, 2019

REPORTED BY: Tina Alfaro, RPR, CRR, RMR

11:02:11 stipulate to infringement that says you're
11:02:13 infringing the claims, and if you say you infringe
11:02:16 something that implies you understand what the
11:02:17 claims mean. If you tell me that Apotex wanted to
11:02:20 stipulate to infringement but they don't understand
11:02:22 the claims, you can tell me that, but a reasonable
11:02:26 person would agree to what I just said. Why would
11:02:29 you stipulate to infringement of something you
11:02:30 didn't understand?
11:02:42 Q. Let's go to paragraph 87 of your report.
11:02:52 There you say "A POSA would understand reducing the
11:02:55 levels of AF-PMA and 4-amino-3-fluorophenol to
11:03:01 within the ranges required by the '107 Patent would
11:03:04 require optimization of a wide variety of
11:03:08 variables," and you go ahead and list some
11:03:11 variables, correct?
11:03:11 A. Right.
11:03:12 Q. Let's go back -- bear with me. Let's go
11:03:33 back to Myerson Exhibit 3, which is the file
11:03:36 history excerpt that I directed your attention to,
11:03:45 going to Bayer-361.
11:03:49 A. Yes.

11:11:14 that.

11:11:18 Q. Well, let's just kind of break that up.

11:11:20 So there are four stages in the example, correct?

11:11:24 A. Correct.

11:11:28 Q. And looking at stage 3, which is on

11:11:32 column 14, what amount of impurities do you

11:11:37 achieve?

11:11:39 A. It doesn't say.

11:11:45 Q. Certainly doesn't tell you whether

11:11:47 0.0001 percent was ever achieved, correct?

11:11:53 A. It doesn't say, but, of course, a POSA

11:11:56 could perform this example and do the analysis and

11:11:58 they would know.

11:12:03 Q. Stage 4 also measures the amount of

11:12:05 impurities, correct?

11:12:06 A. Correct.

11:12:09 Q. And it does not tell you whether

11:12:11 0.0001 percent was ever achieved, correct?

11:12:17 A. The data's not in there, that's correct.

11:12:21 The POSA would have to perform example 4 and

11:12:23 determine if it was achieved.

11:12:25 Q. To achieve 0.001 percent can you show me

11:14:48 PPM. I would agree it doesn't say that anywhere.
11:14:51 Q. Do you have an opinion as to which would
11:14:53 be more challenging, reaching a composition with
11:14:55 1 PPM's or 100 PPM's?
11:14:59 A. 1 PPM is certainly more difficult than a
11:15:01 hundred PPM.
11:15:05 Q. Is there anything in the patent, the
11:15:08 '107 Patent that teaches what changes need to be
11:15:11 made to the reaction conditions at each stage of
11:15:15 the synthesis to achieve 1 PPM versus 100 PPM's?
11:15:19 MR. BOWERS: Object to the form of the
11:15:24 question.
11:15:25 A. No, it does not. Certainly a POSA could
11:15:28 practice the invention and see what purity levels
11:15:31 they did achieve, but it doesn't tell you -- and it
11:15:37 would -- it would be, in my opinion, within the
11:15:40 claimed range, but it doesn't tell you how to
11:15:42 achieve 1 versus 100.
11:15:45 Q. Is there anything in the patent that
11:15:47 you're aware of that would teach what changes to
11:15:52 the intermediate work -- sorry -- to the
11:15:54 intermediate purification that needs to be made to

11:15:57 achieve 1 PPM versus 100 PPM's?
11:16:02 A. Same answer as I just gave.
11:16:05 Q. Is there anything in the patent that
11:16:06 teaches what specific changes need to be made to
11:16:10 the final isolation to achieve 1 PPM versus
11:16:13 100 PPM's?
11:16:16 A. No. Again, if you practice the invention,
11:16:19 it's my opinion you would get a result in the
11:16:21 range, but you wouldn't know how to do 1 PPM versus
11:16:24 100 PPM.
11:16:51 Q. In paragraph -- turn to paragraph 85 of
11:16:53 your report.
11:17:04 A. Yes.
11:17:04 Q. Paragraph 85 of your report you state that
11:17:08 "Dr. Hansen has not provided any opinion or
11:17:11 analysis explaining how the POSA would have
11:17:14 reasonably expected a ten-fold reduction from
11:17:17 1,000 PPM to 100 PPM (i.e. the highest level
11:17:25 allowed in the asserted claims of the '107 Patent)
11:17:28 to be successful"; do you see that sentence?
11:17:32 A. Yes.
11:17:32 Q. You're saying in that paragraph that even

11:17:33 a ten-fold reduction would be difficult to achieve,
11:17:36 correct?
11:17:37 A. Yes.
11:17:37 Q. And a 100-fold reduction would be even
11:17:41 harder, correct?
11:17:42 A. To go from a thousand to one, certainly
11:17:44 that's correct.
11:18:03 Q. Turn to paragraph 83 of your report. I'm
11:18:14 sorry. Paragraph -- strike that -- 80 of your
11:18:21 report. Let me know when you're there.
11:18:32 A. Yes.
11:18:32 Q. Paragraph 80 there's a sentence "To the
11:18:35 contrary, the POSA would have recognized that
11:18:37 reducing regorafenib anilinic impurities and in
11:18:43 particular the impurity AF-PMA to the levels
11:18:48 required by the asserted claims would be especially
11:18:50 challenging"; do you see that?
11:18:53 A. Yes.
11:18:53 Q. Do you have an understanding -- strike
11:18:57 that.
11:18:57 Now, in that paragraph you use the term
11:18:59 "especially challenging," correct?

17:16:57 BY MR. BOWERS:

17:16:57 Q. Is there information in the HPLC method disclosed in lines 44 to 62 of column 14 of the '107 Patent that would provide information to the POSA regarding the level of impurities that might be expected if following the method of the '107 Patent to make regorafenib?

17:17:26 A. Yes.

17:17:28 Q. And what is that information?

17:17:31 A. Well, if we start on, let's see, line 52 approximately, starting with the term "relevant potential byproducts," then it says "4-amino-3-fluorophenol at RO -- RRT (relative retention time) of 0.1, typically less than 0.01 percent (2.6 minutes), 4-(4-Amino-3-flourophenoxy)-N-methylpyridine-2-carboxamide RRT 0.37, typically less than 0.01 percent (9.5 minutes), RRT 0.46 of 4(3-fluoro-4{[2-(methylcarbamoyl)pyridine-4-[amino}-phenoxy)-N-methylpyridine-2-carboxamide), typically less than 0.15 percent (11.7 minutes) RRT .69," and then there's another one -- another impurity listed as

well.

Q. Okay. The impurity listed beginning at line 52 --

A. Yes.

Q. -- 4-amino-3-fluorophenol --

A. Yes.

Q. -- is that one of the two impurities specified in the asserted claims?

A. Yes.

Q. And the statement "typically less than 0.01 percent" --

A. Yes.

MR. MALIK: Object to form. Go ahead.

MR. BOWERS: I'd appreciate if you'd let me finish my question before you state your objection.

BY MR. BOWERS:

Q. The statement "typically less than 0.01 percent," how does that amount relate to the level of fluoroamino-3-fluorophenol permitted by the asserted claims?

A. It's certainly within the permitted claim

17:20:02 because it's between -- that's upper limit and it's
17:20:06 less than the upper limit.
17:20:08 Q. And beginning in line 54, is the impurity
17:20:16 specified 4-(4-amino-3-flourophenoxy) and so on the
17:20:29 impurity that we discussed today as AFP-PMA?
17:20:36 A. Yes.
17:20:36 Q. And same question with respect to AFP-PMA
17:20:38 as disclosed in this passage. What does the
17:20:42 reference to less than -- "typically less than
17:20:46 0.01 percent" indicate?
17:20:48 A. It indicated it would be within the
17:20:51 claimed range, which is between -- is where 0.01 is
17:20:57 the upper limit, it's less than that.
17:20:59 Q. Thank you.
17:21:09 Dr. Myerson, do you recall testifying
17:21:10 today regarding the asserted claims recitation of
17:21:15 the phrase "and/or"?
17:21:17 A. Yes.
17:21:18 Q. All right. I have a hypothetical question
17:21:21 regarding "and/or" in the context of the asserted
17:21:25 claims. Suppose you have 4-amino-3-fluorophenol
17:21:32 present at a level of 0.005 percent or 50 PPM and

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 (Consolidated)
TEVA PHARMACEUTICALS USA, INC., ET AL.,	)	**HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**
Defendants.	)	

EXPERT REPORT OF ALLAN S. MYERSON, PH.D.

3. The POSA would expect the risk of hydrolytic degradation to complicate further the process of producing a pharmaceutical composition comprising regorafenib having the required low levels of the specified impurities. For example, the POSA would recognize that processing regorafenib with other excipients could increase the risk of hydrolytic degradation (and resulting formation of AFP-PMA as a product of that degradation).

85. *Fourth*, the POSA would understand that the challenge of eliminating impurities significantly increases as the target impurity level decreases. This is especially true at the low levels required by the asserted claims of the '107 patent. For example, suppose one were to assume that the POSA could obtain regorafenib with the specified impurities each in an amount below 1000 ppm (0.1 %). Dr. Hansen has not provided any opinion or analysis explaining how the POSA would have reasonably expected the ten-fold reduction from 1000 ppm to 100 ppm (*i.e.*, the highest level allowed in the asserted claims of the '107 patent) to be successful. Indeed, for an impurity such as AFP-PMA that, as noted above, shares several common structural features with the target compound (regorafenib)—and is both a reaction intermediate and a degradation production—the POSA would have expected that reducing the impurity level to 100 ppm or below would be difficult to achieve even with extensive experimentation.

86. The final form of separated regorafenib is a crystalline solid. Impurities in crystalline solids can be present due to two main mechanisms. The first mechanism involves the adsorption of the impurities on the surface of the crystals where they can be chemically or physically bonded. The second mechanism is lattice incorporation. Crystals are made up of three-dimensional structures where the molecules are in an ordered repeating arrangement. When an impurity is structurally similar to the crystallization molecule it often can substitute into the crystalline lattice. When that occurs, repeated recrystallization of the material often will not

necessarily result in significant improvements in purity, making the reduction of the impurities to very low levels particularly difficult. *See generally* Meenan et al., The Influence of Impurities and Solvents on Crystallization, *in Handbook of Industrial Crystallization* ch. 3 (Myerson ed., 2d ed. 2002); *see above* ¶ 33.

87. As the POSA would understand, reducing the levels of AFP-PMA and 4-amino-3-fluorophenol to within the ranges required by the '107 patent would require optimization involving a wide variety of variables, including the basic synthetic pathway, the reaction conditions at each stage of the synthesis (*e.g.*, solvents, catalysts, temperatures, reaction times, intermediate workup steps, and so on), intermediate purification steps (each with a host of possibilities), and the final isolation.

88. I note that Müller, discussed above, ¶¶ 75, 78, recognizes the challenge inherent in reducing impurities to the levels required by the patent:

> Detection, quantitation, and control of potentially genotoxic impurities to very low levels below the above mentioned identification threshold presents considerable challenges for the synthetic and analytical chemist for the development, manufacture, and control of API, impurities in the API and the drug product. . . . Structural identification and characterization as well as robust control of impurities at low levels are generally not achieved until the efficacy of the drug is established, a commercial route of synthesis is selected and a high level of process understanding is obtained. In particular, for control of an impurity to a very low level, an understanding of the functional relationship between process parameters and quality attributes learned through the synthesis of multiple lots is essential.

Müller at 203. I agree. Müller is consistent with my opinion that, even if the POSA were—contrary to my opinion—motivated to make regorafenib having the levels of specified impurities required by the asserted claims of the '107 patent, the POSA would not have had a reasonable expectation of success in doing so.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and BAYER HEALTHCARE PHARMACEUTICALS INC. Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. 16-1221-LPS (Consolidated) **CONFIDENTIAL – FILED UNDER SEAL**

EXHIBIT 12C

PLAINTIFFS' REPLY IN SUPPORT OF MOTION IN LIMINE NO. 1 TO PRECLUDE APOTEX'S UNTIMELY NON-ENABLEMENT THEORY

There is not enough space here to rebut fully Defendants' mischaracterization of Dr. Myerson's testimony. Suffice it to say, Dr. Myerson did not come close to testifying that "the POSA would not have been able to practice the full scope of the claims, even with the benefit of the patent's disclosures, without undue experimentation." Opp. 3. Defendants conflate the distinct legal issues of whether the POSA would have a reasonable expectation of success *without the benefit of the patent* (non-obviousness, the subject of Dr. Myerson's testimony) with whether the POSA could practice the invention without undue experimentation *with knowledge of the method in the patent* (enablement). *Allergan, Inc. v. Sandoz Inc.*, 769 F.3d 1293, 1310 (Fed. Cir. 2015). Dr. Myerson's supposed "admission" that the specification only provides that its method results in less than 100 ppm of the impurity, but not how much less, is not an admission that the full scope of the claim cannot be practiced. And there is no evidence whatsoever, and certainly no testimony from Dr. Myerson, that the impurity level reached by the disclosed method is not near the bottom of the range or that routine experimentation could not take it there. Moreover, Apotex miscites *Idenix*, which stands for the unremarkable proposition that it would require undue experimentation to test potentially billions of compounds to determine the full scope of a genus claim. Here, Dr. Myerson merely said that the POSA would have to run a single experiment disclosed in the patent.

Defendants claim that their "theory stems *directly* from Dr. Myerson's deposition testimony," Opp. 1, and confirm that they will not be offering any expert testimony on the issue, *id.* Importantly, Dr. Myerson's deposition testimony—even if misread as Defendants suggest—is not itself admissible evidence and cannot be presented in Defendants' case-in-chief. *Kirk v. Raymark Indus., Inc.*, 61 F.3d 147 (3d Cir. 1995); *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 2005 WL 2296613, at *2 (D. Del. Sept. 20, 2005); Fed. R. Civ. P. 32. Defendants' new theory is therefore futile because Defendants have no affirmative evidence to offer. *See* Fed. R. Civ. P. 52(c).

Exhibit B

Hache, Guylaine

From: Soderstrom, Lance A.
Sent: Monday, June 8, 2020 2:45 PM
To: Picozzi, Ben; Bowers, Seth; Grossman, Dov; Mukerjee, Deepro R.; Malik, Jitty; Hache, Guylaine; Scott, Ian; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce; Berl, David; Farha, Griffin; Jack B. Blumenfeld
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order
Attachments: 2020.06.08 Joint Status Report Apotex REDLINE.docx

Ben –

We are disappointed in the lack of cooperation given Plaintiffs' wholesale new position. But we obviously cannot agree to Plaintiffs' proposal. As we noted in our prior draft, we are not trying to keep discovery open-ended, but simply stated that we do not know what discovery Plaintiffs are contemplating and therefore cannot agree to restrictions related thereto at this time. Plaintiffs advised that document production would conclude by July 10th and Apotex noted that it was willing to meet and confer thereafter to discuss any limitations on further discovery (as opposed to determining those now). Attached is a revised version with Apotex's position in light of Plaintiffs' deletion of their prior position. Once again, we have not modified Plaintiffs' position other than to note that it is Plaintiffs' position and not the parties' position.

Thanks,

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From: Picozzi, Ben <BPicozzi@wc.com>
Sent: Monday, June 8, 2020 2:27 PM
To: Soderstrom, Lance A. <lance.soderstrom@katten.com>; Bowers, Seth <SBowers@wc.com>; Grossman, Dov <DGrossman@wc.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

EXTERNAL EMAIL – EXERCISE CAUTION

Lance,

We disagree with your characterization of events. Moreover, the Court asked the parties to submit a joint status report regarding the discovery Bayer is proposing to provide relating to Apotex's late-raised non-enablement theory, and further noted that if the parties did not agree, it would entertain a motion to strike. We provided you with a draft status report concerning the scope of discovery. Apotex, however, wants to keep the scope of discovery open-ended, as if this were an issue that Apotex had timely raised and litigated. Given that disagreement, and in accordance with the Court's

guidance, we believe we need to proceed with a motion to strike. Accordingly, we do not see a reason for the proposed extension. Please confirm that the briefing schedule we have proposed is acceptable to Apotex so we can get the status report on file.

Best,

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Sent: Monday, June 8, 2020 1:55 PM
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Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

Ben –

We are at a loss with respect to this attachment. It is not overstating it when we say that Plaintiffs keep moving the mark. Last Monday, Plaintiffs raised the scepter of an early adjudication of their MIL (which is fully briefed). When Apotex agreed to that, Plaintiffs notified us that they would no longer be raising the issue with the Court during last Thursday's call. We of course said that in light of Plaintiffs' reversed course, that Apotex intended to raise it as it made sense to have an early adjudication on the parties' respective MILs. Then without forewarning, during the Court conference, Plaintiffs offered making discovery available with respect to Plaintiffs' Motion in Limine. Next, Plaintiffs' provided a Status Report related to the MIL and scheduled discovery. In response, Apotex added a position that it would meet and confer after documents were produced, but noted that early adjudication (in line with Plaintiffs' proposal last Monday) seemed proper. Now, in a rewrite of the parties' discussions—even before the Court—Plaintiffs are abandoning the motion in limine opting instead for a renewed bite at the apple under the moniker of a motion to strike. Given that there are only four hours left for the parties to file this, we believe a modest 48 hour extension is warranted. Please let us know by 3pm whether the parties agree on the extension.

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Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B.

Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

EXTERNAL EMAIL – EXERCISE CAUTION

Thanks Lance,

Given the parties' positions, it appears we will need to proceed with the motion to strike. Can you confirm whether the attached briefing schedule works for your side? Unless you have further edits, we can get this on file.

Best,

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Sent: Monday, June 8, 2020 9:39 AM
To: Bowers, Seth <SBowers@wc.com>; Grossman, Dov <DGrossman@wc.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

All –

Attached provides Apotex's position. We did not modify Plaintiffs' position. Absent any additional edits from Plaintiffs, we are fine with this being filed today.

Thanks,

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Sent: Friday, June 5, 2020 1:35 PM
To: Soderstrom, Lance A. <lance.soderstrom@katten.com>; Grossman, Dov <DGrossman@wc.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

EXTERNAL EMAIL – EXERCISE CAUTION

All,

I have attached a draft Joint Status Report regarding Apotex's non-enablement theory. Please let us know promptly if you have proposed changes or would like to discuss so that we can get this on file on Monday.

Best,
Seth

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To: Grossman, Dov <DGrossman@wc.com>; Bowers, Seth <SBowers@wc.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

Dov –

Just to close the loop below, we do plan to raise the parties' discussion from Monday related to Plaintiffs' MIL. We obviously will defer to the Court's preferences, but do note the points you and Bruce raised and think it worthwhile to raise it and leave it to the Court.

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Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

Thanks Dov. As I understand it, Plaintiffs' proposal was that Plaintiffs' MIL be adjudicated early and Plaintiffs would raise it with the Court. I understand now Plaintiffs will not be raising that on their own. As I noted on the call, we're not

interested in any sort of ambush tomorrow and will do our best to get back to you on whether we will separately raise it. But we are in depositions today and tomorrow, so please bear with us.

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Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

EXTERNAL EMAIL – EXERCISE CAUTION

Lance – as we discussed earlier today, that wasn't what we proposed, but in any event we do not intend to raise early adjudication of any motion in limine with the Court tomorrow.

Regards,
Dov

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From: Soderstrom, Lance A. <lance.soderstrom@katten.com>
Sent: Wednesday, June 03, 2020 10:48 AM
To: Bowers, Seth <SBowers@wc.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Grossman, Dov <DGrossman@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

Dov –

To follow up on our call, we do not oppose Plaintiffs raising earlier adjudication of the MILs with the Court tomorrow, but will of course defer to whatever the Court deems fit.

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From: Bowers, Seth <SBowers@wc.com>
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To: Soderstrom, Lance A. <lance.soderstrom@katten.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Grossman, Dov <DGrossman@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

EXTERNAL EMAIL – EXERCISE CAUTION
Thanks, Lance. We can use the dial-in below.

Dial-in: 8887596037
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From: Soderstrom, Lance A. <lance.soderstrom@katten.com>
Sent: Wednesday, May 27, 2020 11:35 AM
To: Bowers, Seth <SBowers@wc.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Grossman, Dov <DGrossman@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

Yes, that's fine. Thank you.

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Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Grossman, Dov <DGrossman@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

EXTERNAL EMAIL – EXERCISE CAUTION

Lance,

Would 2:30pm on Monday work?

Best,
Seth

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To: Bowers, Seth <SBowers@wc.com>; Mukerjee, Deepro R. <deepro.mukerjee@katten.com>; Malik, Jitty <jitty.malik@katten.com>; Hache, Guylaine <guylaine.hache@katten.com>; Scott, Ian <iscott@taftlaw.com>; pkouyoumdjian@taftlaw.com; kdorsney@morrisjames.com
Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Grossman, Dov <DGrossman@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: RE: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

Seth –

Does 2pm EST on Monday work? If so, please circulate a calendar invite.

Thanks,

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Cc: Genderson, Bruce <BGenderson@wc.com>; Berl, David <DBerl@wc.com>; Grossman, Dov <DGrossman@wc.com>; Picozzi, Ben <BPicozzi@wc.com>; Farha, Griffin <GFarha@wc.com>; Jack B. Blumenfeld <jblumenfeld@mnat.com>
Subject: FW: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

EXTERNAL EMAIL – EXERCISE CAUTION

Lance,

In light of the Court's order, we should find a time in the next couple of days to discuss trial logistics in advance of our June 4 conference with the court.

With respect to the software platform, our current view is that Zoom for Business provides the best functionality. We can discuss on our call whether that platform will work for your team and, if so, can propose it to the Court. We expect that our respective trial techs will coordinate to ensure everything runs smoothly.

Let's also discuss the timing for exchanging documents. We don't anticipate any issue with exchanging documents among counsel, but should discuss how best to handle providing cross-examination materials to remote witnesses. Relatedly, we will need to determine the Court's preferences for receiving demonstrative and callouts.

Finally, we should consider whether to ask the Court to adjust start times for trial days to accommodate witnesses in different time zones.

We are of course happy to discuss any other issues you have identified.

Best,
Seth

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Subject: Activity in Case 1:16-cv-01221-LPS Bayer Healthcare LLC et al v. Apotex Inc. et al. Order

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U.S. District Court

District of Delaware

Notice of Electronic Filing

The following transaction was entered on 5/21/2020 at 5:45 PM EDT and filed on 5/21/2020
Case Name: Bayer Healthcare LLC et al v. Apotex Inc. et al.
Case Number: 1:16-cv-01221-LPS
Filer:
Document Number: 150(No document attached)

Docket Text:
ORAL ORDER: Having reviewed the parties' May 15, 2020 joint status report (D.I. 148), IT IS HEREBY ORDERED that trial will be held on September 8-11, 2020. At this time, the Court believes that because not all counsel and witnesses are likely to be able to attend trial in person, it is likely that the entire trial will proceed remotely by video. The parties shall be prepared to discuss how the trial will proceed during a teleconference which will be held on June 4, 2020 at 3:45 p.m. The parties shall provide to the Court the dial-in information for the call. IT IS FURTHER ORDERED that the final pretrial order shall be submitted by no later than August 19, 2020 and the pretrial conference will be held on August 26, 2020 at 4:30 p.m. (in whatever format trial will proceed in). ORDERED by Judge Leonard P. Stark on 5/21/20. (ntl)

1:16-cv-01221-LPS Notice has been electronically mailed to:

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1:16-cv-01221-LPS Filer will deliver document by other means to:
