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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

HSINGCHING HSU, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

PUMA BIOTECHNOLOGY, INC., et al.,

Defendants.

Case No. 8:15-cv-00865-AG-SHK

CLASS ACTION

PLAINTIFF'S STATEMENT OF UNCONTROVERTED FACTS IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

DATE: September 24, 2018
TIME: 10:00 a.m.
CTRM: 10D
JUDGE: Hon Andrew J. Guilford

APPENDIX OF ACRONYMS AND DEFINED TERMS

Acronym/Defined Term	Meaning/Reference
AE	Adverse event
ASCO	American Society of Clinical Oncology
DFS	Disease-free survival
ESMO	European Society for Medical Oncology
ITT	Intent to treat
KM curves	Kaplan-Meier curves

NO.	UNCONTROVERTED FACT	EVIDENCE
1.	On July 22, 2014, Puma hosted a conference call that was open to analysts and investors.	Ex. 33[1] (Thomas Reuters StreetEvents Edited Transcript of July 22, 2014 conference call) [Depo. Ex. 103]. Ex. 66 (audio recording of July 22, 2014 conference call). Ex. 65, ¶50 (Defendants' Answer).
2.	A transcript of Puma's July 22, 2014 conference call was available to the public on Puma's website.	Ex. 67 at PUMA00015512 (conference call archived for 30 days on Puma website following the conference call) [Depo. Ex. 102].
3.	During the July 22, 2014 conference call, Alan Auerbach engaged in the following exchange with Yaron Werber, a Citi Research equity analyst: "[WERBER:] Congrats on this fantastically and, in many ways, unexpected data. So I have a ton of	Ex. 33 at 5-6 (Thomas Reuters StreetEvents Edited Transcript of July 22, 2014 conference call) [Depo. Ex. 103]. Ex. 66 (audio recording of July 22, 2014 conference call).

[1] All exhibit references herein are to the Declaration of Trig R. Smith in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment, filed concurrently herewith.

NO.	UNCONTROVERTED FACT	EVIDENCE
	questions. Maybe I'll just take two, if you don't mind. One is, give us a little bit of a sense, what was the DFS on the control arm, first. And then second, help us understand, what do you know about the safety profile? [AUERBACH:] Okay. So in terms of the DFS of the placebo arm of the trial, it was in line with other reported trials. So it's in line with the Herceptin adjuvant studies. And then in terms of the safety profile, we haven't yet fully validated the safety database. * * * [WERBER:] You're thinking that, if I'm correct, the DFS is probably around mid to high 80s, around 86% or so in the control arm? [AUERBACH:] I would be comfortable with that number. [WERBER:] And one would imagine you probably had to show around 90% or 91% [in the treatment	Ex. 65, ¶50 (Defendants' Answer).

NO.	UNCONTROVERTED FACT	EVIDENCE
	arm]? Is that reasonable? [AUERBACH:] Yes. I think you can do a 33% improvement in DFS and come up with that calculation, given the numbers we gave."	
4.	Given a placebo DFS rate of 86% and drug with a 33% relative improvement in DFS, the drug DFS rate would be expected to be approximately 90.62%: (86% + (14% * .33) = 90.62%).	Ex. 22, ¶50 [Depo. Ex. 608]. Ex. 36 at CGMI000471 (physician notes that 86%-88% placebo performance with 33% DFS benefit results in a 4%-5% DFS range) [Depo. Ex. 420].
5.	Given a drug with a DFS rate of 90% or 91% and a 33% relative improvement in DFS, the placebo DFS rate would be expected to be approximately 85% or 86.5%: (85% + (15% * .33) = 90%); (86.5% + (13.5% * .33) = 91%).	Ex. 22, ¶50 [Depo. Ex. 608]. Ex. 36 at CGMI000471 (physician notes that 86%-88% placebo performance with 33% DFS benefit results in a 4%-5% DFS range) [Depo. Ex. 420].
6.	The DFS rate at 2 years ± 28 days for the neratinib arm of the ITT population in the ExteNET trial was 93.9%.	Ex. 28 at PUMA00014632, 35 [Depo. Ex. 123]. Ex. 31 (ASCO Abstract)

NO.	UNCONTROVERTED FACT	EVIDENCE
		[Depo. Ex. 158]. Ex. 68 at No. 5 (Defendants' Responses to Plaintiff's Second Set of Interrogatories to All Defendants, dated January 17, 2017). Ex. 65, ¶¶12, 66 (Defendants' Answer).
7.	The DFS rate at 2 years ± 28 days for the placebo arm of the ITT population in the ExteNET trial was 91.6%.	Ex. 28 at PUMA00014632, 35 [Depo. Ex. 123]. Ex. 31 (ASCO Abstract) [Depo. Ex. 158]. Ex. 68 at No. 5 (Defendants' Responses to Plaintiff's Second Set of Interrogatories to All Defendants, dated January 17, 2017). Ex. 65, ¶¶12, 66 (Defendants' Answer).
8.	The absolute difference in DFS rates at 2 years ± 28 days for the neratinib and	Ex. 28 at PUMA00014632, 35 [Depo. Ex. 123].

NO.	UNCONTROVERTED FACT	EVIDENCE
	placebo arms of the ExteNET trial ITT population was 2.3%.	Ex. 31 (ASCO Abstract) [Depo. Ex. 158]. Ex. 68 at No. 5 (Defendants' Responses to Plaintiff's Second Set of Interrogatories to All Defendants, dated January 17, 2017). Ex. 65, ¶¶12, 66 (Defendants' Answer). Ex. 1 at 138:11-140:4 [Adelson Depo.].
9.	Capital International Limited was one of the Norfolk Pension Fund's investment managers and Philip May was the investment advisor at Capital International Limited for the Norfolk Pension Fund during the period July 2014 to June 2015.	Ex. 18 at 63:21-64:8 (Phillip May was the Capital Information Limited contact during class period) [Younger Depo.]. *Id*. at 65:12-17 [Younger Depo.]. Ex. 69 (Investment Management Agreement)

NO.	UNCONTROVERTED FACT	EVIDENCE
		[Depo. Ex. 10].
10.	Skye Drynan was one of multiple individuals at Capital International Limited who would have analyzed Puma during the period July 2014 to June 2015.	Ex. 5 at 41:15-44:11 [Drynan Depo.].
11.	Skye Drynan had no communications with representatives of the Norfolk Pension Fund during the period July 2014 to June 2015.	Ex. 5 at 146:9-147:6 [Drynan Depo.].
12.	During the period July 2014 to June 2015, Skye Drynan had no knowledge of any of Norfolk Pension Fund's transactions in Puma common stock.	Ex. 5 at 29:7-12, 147:22-148:6 [Drynan Depo.].
13.	Between July 22, 2014 and May 12, 2015, analysts covering Puma estimated that the absolute difference in the DFS rates in the ExteNET trial was at least 4%-6%.	Ex. 70 at STIFEL0005146 (Stifel analyst report: "Puma proves us wrong with overwhelming adjuvant success") [Depo. Ex. 239]. Ex. 71 at STIFEL0002878 (Stifel analyst report: "Resuming Coverage of Puma Biotechnology with a Hold Rating") [Depo. Ex. 241].

NO.	UNCONTROVERTED FACT	EVIDENCE
		Ex. 72 at CW000025 (Cowen analyst report: "The Cat With Nerat(inib) Strikes Back") [Depo. Ex. 299]. Ex. 73 at CGMI000415 (Citi analyst report: "Always Expect the Unexpected-ExteNET Trial Hits – Game Changer for the Stock – Raising TP to $292- Expecting a Takeout") [Depo. Ex. 417]. Ex. 74 at CGMI002227 (Yaron Werber email stating that DFS was 86% on placebo and 90%-91% on neratinib) [Depo. Ex. 418]. Ex.75 at CGMI000443 (Citi analyst report: "Raw Transcript: Always Expect the Unexpected ExteNET Trial Hits – Game Changer – TP of $292 – Expecting a Takeout") [Depo. Ex. 419].

NO.	UNCONTROVERTED FACT	EVIDENCE
		Ex. 36 at CGMI000471 (Citi analyst report: "Even the Skeptics May Get on Board: Key Takeaways + Transcript from our Recent ExteNET Physician Call") [Depo. Ex. 420]. Ex. 76 at CGMI000654 (Citi analyst report: "Alert: Takeaways from our Management Dinner at ESMO") [Depo. Ex. 426]. Ex. 77 at PUMA00015841 (email from Mariann Ohanesian to Alan Auerbach re: Cowen and Leerink Reports with attachments) [Depo. Ex. 301]. Ex. 65, ¶31 (Defendants' Answer).
14.	Between July 22, 2014 and May 12, 2015, no analyst report identified an	Ex. 73 (Citi analyst report: "Always Expect the

NO.	UNCONTROVERTED FACT	EVIDENCE
	estimated absolute difference in the DFS rates in the ExteNET trial of 2%-8%.	Unexpected- ExteNET Trial Hits – Game Changer for the Stock – Raising TP to $292- Expecting a Takeout") [Depo. Ex. 417]. Ex. 75 (Citi analyst report: "Raw Transcript: Always Expect the Unexpected ExteNET Trial Hits – Game Changer – TP of $292 – Expecting a Takeout") [Depo. Ex. 419]. Ex. 36 (Citi analyst report: "Even the Skeptics May Get on Board: Key Takeaways + Transcript from our Recent ExteNET Physician Call") [Depo. Ex. 420]. Ex. 76 at CGMI000654 (Citi analyst report: "Alert: Takeaways from our Management Dinner at ESMO") [Depo. Ex. 426].

NO.	UNCONTROVERTED FACT	EVIDENCE
15.	Between July 22, 2014 and May 12, 2015, no analyst report identified an estimated absolute difference in the DFS rates in the ExteNET trial of less than 3%.	Ex. 73 (Citi analyst report: "Always Expect the Unexpected- ExteNET Trial Hits – Game Changer for the Stock – Raising TP to $292- Expecting a Takeout") [Depo. Ex. 417]. Ex. 75 (Citi analyst report: "Raw Transcript: Always Expect the Unexpected ExteNET Trial Hits – Game Changer – TP of $292 – Expecting a Takeout") [Depo. Ex. 419]. Ex. 36 (Citi analyst report: "Even the Skeptics May Get on Board: Key Takeaways + Transcript from our Recent ExteNET Physician Call") [Depo. Ex. 420]. Ex. 76 at CGMI000654 (Citi analyst report: "Alert: Takeaways from our

NO.	UNCONTROVERTED FACT	EVIDENCE
		Management Dinner at ESMO") [Depo. Ex. 426].
16.	On September 29, 2014 at a dinner hosted by Yaron Werber, a Citi Research equity analyst, at the ESMO meeting in Madrid, Spain, Alan Auerbach confirmed that the DFS rate for the placebo arm of the ExteNET trial was approximately 86% and the DFS rate for the neratinib arm was approximately 90%.	Ex. 18-A at 181:17-183:18 [Werber Depo.]. Ex. 76 at CGMI000654 (Citi analyst report: "Alert: Takeaways from our Management Dinner at ESMO") [Depo. Ex. 426].
17.	During the July 22, 2014 conference call, Alan Auerbach engaged in the following exchange regarding KM curves with Howard Liang, a Leerink Partners equity analyst: "[LIANG:] Congratulations, Alan, and your team. So can you – I assume you have seen the curves for the two arms. Can you give us a sense as to whether the separation is widening over time? Or how would you describe the curve separation? [AUERBACH:] Yes, Thanks for	Ex. 33 at 7 (Thomas Reuters StreetEvents Edited Transcript of July 22, 2014 conference call) [Depo. Ex. 103]. Ex. 66 (audio recording of July 22, 2014 conference call). Ex. 65, ¶52 (Defendants' Answer).

NO.	UNCONTROVERTED FACT	EVIDENCE
	that question, Howard. Okay, so the [ExteNET] trial started in April of 2009, and this data cut is as of October 2013. So that's essentially the last patient was followed for 2 years. So from those numbers, you can see we have a lot of patients who have been in for much more than that 2-year cutoff. If we look at the curves going out beyond that, it looks like the curves are continuing to separate. And to give a little more detail on that, if you look at the curves in the Herceptin adjuvant trials – so the HERA study, the BCIRG study, et cetera – the absolute difference in disease-free survival increases as you go out year over year. So, for instance, in the BCIRG trial, the DFS difference was 6% at 2 years and 7% at 3 years, then 8% at 4 years . . . . We're seeing the same preliminary trend in the ExteNET trial, where the curves appear to be continuing to	

NO.	UNCONTROVERTED FACT	EVIDENCE
	separate as you go out year over year, and the absolute DFS difference is increasing year over year as well."	
18.	On July 17, 2014 at 11:35 AM, Alvin Wong sent Alan Auerbach an email with the subject line "Topline Efficacy Results" with an attachment titled "Neratinib Protocol 3144A2-3004-WW Top-line Efficacy Analyses Part A (2 years + 28 days)" (the "Top-line Efficacy Analyses").	Ex. 28 at PUMA00014636 (email from Alvin Wong to Alan Auerbach, Richard Phillips, and Richard Bryce, and cc'd to Claire Sherman re: Topline Efficacy Results with attachments) [Depo. Ex. 123]. Ex. 3 at 215:14-20 [Auerbach Depo.]. Ex. 17 at 30:4-31:5 [Wong Depo.].
19.	The KM curves for the ITT population in the ExteNET trial that were included in the July 17, 2014 Top-line Efficacy Analyses were narrowing at the end of 2 years ± 28 days.	Ex. 28 at PUMA00014636 (email from Alvin Wong to Alan Auerbach, Richard Phillips, and Richard Bryce, and cc'd to Claire Sherman re: Topline Efficacy Results with attachments) [Depo. Ex. 123]. Ex. 37, ¶¶11, 24 (Expert Report of Philip T. Lavin,

NO.	UNCONTROVERTED FACT	EVIDENCE
		Ph.D.) [Depo. Ex. 594].
20.	The Top-line Efficacy Analyses that was provided to Alan Auerbach prior to July 22, 2014 did not include any KM curves including results for the period beyond 2 years ± 28 days.	Ex. 28 (email from Alvin Wong to Alan Auerbach, Richard Phillips, and Richard Bryce, and cc'd to Claire Sherman re: Topline Efficacy Results with attachments) [Depo. Ex. 123].
21.	There is no evidence that any assessment was done of the KM curves for any period after 2 years ± 28 days.	Ex. 37, ¶12 (Expert Report of Philip T. Lavin, Ph.D.) [Depo. Ex. 594]. Ex. 84 at Nos. 43-44, 46 (Alan Auerbach's Supplemental Responses to Plaintiff's Third Set of Requests for Admission Nos. 43, 44 & 46, dated November 16, 2017).
22.	On October 6, 2014, Pfizer Assistant General Counsel Katherine Yang sent a letter to Alan Auerbach and Latham & Watkins attorney Judith Hasko and requested data related to the ExteNET trial, including: "3 Year (and beyond) DFS Data. • During the July 22 Puma investor	Ex. 78 at PUMA00241584.

NO.	UNCONTROVERTED FACT	EVIDENCE
	call, and more recently at a dinner at ESMO hosted by Citi (as reported by Citi on October 1, 2014), you alluded to 3-year DFS data (and beyond for some early enrolled patients), yet in your most recent disclosure to us on September 28, you only included the 2-year DFS rate."	
23.	In response to requests by Pfizer for KM curves demonstrating that the DFS curves were continuing to separate after 2 years ± 28 days, Alan Auerbach had Puma's Senior Director of Biostatistics, Bin Yao, prepare simulated KM curves that went through 36 months.	Ex. 79 (email from Alan Auerbach to Bin Yao re: DFS and DFS-DCIS simulation results; simulation of DFS and DFS-DCIS beyond two years) [Depo. Ex. 473]. Ex. 78 at PUMA00241584, 87 (letter from Katherine Yang to Auerbach and Judith Hasko with revised information request).
24.	On October 12, 2014, Alan Auerbach requested that Bin Yao provide him with a print out of the simulated "KM curve for the 3 years DFS and DFS-DCIS analysis using the optimistic scenario" from the KM curve simulations.	Ex. 79 (email from Alan Auerbach to Bin Yao re: DFS and DFS-DCIS simulation results; simulation of DFS and DFS-DCIS beyond two years) [Depo. Ex. 473].
25.	On October 29, 2014, Alan Auerbach	Ex. 81 at PUMA00022378

NO.	UNCONTROVERTED FACT	EVIDENCE
	requested that Bin Yao provide him with a revised print out of the simulated "optimistic scenario" KM curves that did "not show the number of patients at risk at the bottom of the graph."	[Depo. Ex. 474].
26.	On November 5, 2014, Alan Auerbach sent representatives of Pfizer the print out of the simulated "optimistic scenario" KM curves, but identified them as "the Kaplan-Meier curves for the ExteNET trial."	Ex. 39 [Depo. Ex. 475].
27.	In response to an interrogatory in this litigation requesting the identification of documents reviewed prior to July 22, 2014 that supported Alan Auerbach's July 22, 2014 statement that the ExteNET trial KM curves "'appear to be continuing to separate,'" Defendants responded that "[t]he Kaplan-Meier curves Mr. Auerbach recalls reviewing or discussing were substantially similar to those reflected in PUMA00242055."	Ex. 82 at No. 13 [Defendants' Puma Biotechnology, Inc. and Alan Auerbach's Responses to Plaintiff's Fifth Set of Interrogatories to All Defendants, dated September 18, 2017]. Ex. 81 [Depo. Ex. 474]. Ex. 39 [Depo. Ex. 475].
28.	PUMA20042055 is a copy of the "optimistic scenario" simulated DFS curves that were not generated until October 30, 2014 and that Alan	Ex. 39 [Depo. Ex. 475].

NO.	UNCONTROVERTED FACT	EVIDENCE
	Auerbach sent to Pfizer on November 5, 2014.	
29.	In response to a request for admission in this litigation requesting Alan Auerbach "[a]dmit that defendants have not produced any document in this litigation identifying your receipt on or prior to July 22, 2014 of any Kaplan-Meier curves that reflected data for ExteNET trial participants for the period beyond two years (+/- 28 days)," Alan Auerbach denied the request, identified PUMA00242055-56 and responded "Mr. Auerbach saw these three-year curves before July 22, 2014 . . . ."	Ex. 83 at No. 44 [Alan Auerbach's Responses to Plaintiff's Third Set of Requests for Admission, dated October 20, 2017]. Ex. 81 [Depo. Ex. 474]. Ex. 39 [Depo. Ex. 475].
30.	PUMA00242055-56 is a copy of the "optimistic scenario" simulated DFS and DFS-DCIS curves that were not generated until October 30, 2014 and that Alan Auerbach sent to Pfizer on November 5, 2014.	Ex. 39 [Depo. Ex. 475].
31.	On the morning of Bin Yao's deposition in this litigation, Defendants' counsel acknowledged that the KM curves identified at PUMA00242055-56 did not exist prior to July 22, 2014.	Ex. 84 at No. 46 [Alan Auerbach's Supplemental Responses to Plaintiff's Third Set of Requests for Admission Nos. 43, 44 & 46, dated

NO.	UNCONTROVERTED FACT	EVIDENCE
		November 16, 2017].
	Subsequently, in response to a request for admission in this litigation, Alan Auerbach "admit[ed] that the particular Kaplan-Meier curves produced at PUMA00242055-56 were created after July 22, 2014."	
32.	On July 18, 2014, Alvin Wong sent Alan Auerbach an email with a "slide deck of the safety results" and safety tables and confirmed that "[t]hey are now validated."	Ex. 25 at PUMA00014833 [Depo. Ex. 124].
33.	The slide deck and safety tables Alan Auerbach received on July 18, 2014 identified that the Grade 3+ diarrhea rate for neratinib users in the ExteNET trial was 39.9%.	Ex. 25 at PUMA00014834.00005-.00006, PUMA00014838, 46 [Depo. Ex. 124].
34.	The slide deck and safety tables Alan Auerbach received on July 18, 2014 identified that the rate of treatment discontinuation due to diarrhea for neratinib users was 16.8%.	Ex. 25 at PUMA00014834.00007, PUMA00014837 [Depo. Ex. 124].
35.	The safety tables Alan Auerbach received on July 18, 2014 identified that the AE leading to discontinuation rate for neratinib users was 27.6%.	Ex. 25 at PUMA00015081 [Depo. Ex. 124].

NO.	UNCONTROVERTED FACT	EVIDENCE
36.	During the July 22, 2014 conference call, Alan Auerbach made the following statement in his opening remarks: "From a safety perspective, the Company has not yet seen the safety results from the ExteNET trial for neratinib, as the data is still being validated. . . . Prior to Puma licensing the drug, neratinib monotherapy was previously tested in two Phase II trials in patients with HER2-positive metastatic breast cancer, the results of which were published in European Journal of Cancer in December 2013 and the Journal of Clinical Oncology in 2010. In those studies, grade 3 or higher diarrhea was seen in 29% and 30% of the patients, respectively. The ExteNET trial was started in April of 2009, prior to Puma licensing the drug in 2011. Neratinib was given as a monotherapy, and no prophylaxis to	Ex. 33 at 3-4 (Thomas Reuters StreetEvents Edited Transcript of July 22, 2014 conference call) [Depo. Ex. 103]. Ex. 66 (audio recording of July 22, 2014 conference call). Ex. 65, ¶53 (Defendants' Answer).

NO.	UNCONTROVERTED FACT	EVIDENCE
	prevent neratinib-related diarrhea was used. Therefore, the Company anticipates that the grade 3 diarrhea rates in the ExteNET trial are likely to be in line with what was previously published in the prior Phase II trials that were published in the European Journal of Cancer and the Journal of Clinical Oncology."	
37.	During the July 22, 2014 conference call, Alan Auerbach engaged in the following exchange with Yaron Werber, a Citi Research equity analyst: "[WERBER:] Congrats on this fantastically and, in many ways, unexpected data. So I have a ton of questions. Maybe I'll just take two, if you don't mind. One is, give us a little bit of a sense, what was the DFS on the control arm, first. And then second, help us understand, what do you know about the safety profile? [AUERBACH:] Okay. So in terms of the DFS of the placebo arm of	Ex. 33 at 5 (Thomas Reuters StreetEvents Edited Transcript of July 22, 2014 conference call) [Depo. Ex. 103]. Ex. 66 (audio recording of July 22, 2014 conference call). Ex. 65, ¶54 (Defendants' Answer).

NO.	UNCONTROVERTED FACT	EVIDENCE
	the trial, it was in line with other reported trials. So it's in line with the Herceptin adjuvant studies. And then in terms of the safety profile, we haven't yet fully validated the safety database. Our anticipation is the main AE we're going to see is what we've historically seen with neratinib, which is the diarrhea. And again, we would anticipate that the diarrhea rate, the grade 3 diarrhea rate, would be in line with the 29% to 30% that's been seen in the prior studies of neratinib as a monotherapy."	
38.	During the July 22, 2014 conference call, Alan Auerbach engaged in the following exchange with Eric Schmidt, a Cowen and Co. equity analyst: "[SCHMIDT:] Thanks. And lastly, I think you probably do know the dropout rate from the trial. Could you remind us of that? [AUERBACH:] Dropout rate[s] due to side effects?	Ex. 33 at 9-10 (Thomas Reuters StreetEvents Edited Transcript of July 22, 2014 conference call) [Depo. Ex. 103]. Ex. 66 (audio recording of July 22, 2014 conference call). Ex. 65, ¶54 (Defendants' Answer).

NO.	UNCONTROVERTED FACT	EVIDENCE
	[SCHMIDT:] Sure, or anything, if you have it. [AUERBACH:] I don't have that. I apologize. That's part of the stuff being validated, but we anticipate, typically in the neratinib studies – the legacy ones that were done before, when Pfizer was running it without any prophylaxis – it was usually in the 5% to 10% range was the dropout rate due to AEs. So we'd anticipate it's in that same vein."	
39.	During the July 22, 2014 conference call, Alan Auerbach engaged in the following exchange with Matt Roden, a UBS Securities equity analyst: "[RODEN:] I just wanted to clarify an earlier answer to a question. So you were asked about the dropout rate, and I think you wanted to defer to dropouts due to – discontinuations due to adverse events. But can you just mention, or maybe I missed it, how many patients actually completed the	Ex. 33 at 14 (Thomas Reuters StreetEvents Edited Transcript of July 22, 2014 conference call) [Depo. Ex. 103]. Ex. 66 (audio recording of July 22, 2014 conference call). Ex. 65, ¶54 (Defendants' Answer).

NO.	UNCONTROVERTED FACT	EVIDENCE
	year of therapy? Or another way of saying it is how much missing data is there from the DFS analysis? [AUERBACH:] Yes, so in terms of patients who dropped out due to AEs, like I said, historically with neratinib, that should be somewhere in the 5% to 10% range. [RODEN:] Okay, but do you have a sense for dropouts for any reason across the study? [AUERBACH:] No, the main one we would expect is due to AEs. And obviously, if they progressed or died."	
40.	On May 13, 2015 ASCO Abstract #508, titled "Neratinib after adjuvant chemotherapy and trastuzumab in HER2-positive early breast cancer: Primary analysis at 2 years of a phase 3, randomized, placebo-controlled trial (ExteNET)," was publicly released.	Ex. 31 (ASCO Abstract) [Depo. Ex. 158]. Ex. 2 at 36:11-14 [ASCO 30(b)(6) Depo.].
41.	ASCO Abstract #508 identified that "[d]iarrhea was the most common	Ex. 31 (ASCO Abstract) [Depo. Ex. 158].

NO.	UNCONTROVERTED FACT	EVIDENCE
	adverse event (AE) for N patients with 40% G3 (1pt G4)".	
42.	On June 1, 2015, Dr. Arlene Chan presented results of the ExteNET trial at the ASCO conference.	Ex. 32 (ASCO 2015 Conference slides) [Depo. Ex. 176]. Ex. 4 at 12:2-7 [Chan Depo.].
43.	During her June 1, 2015 presentation, Dr. Arlene Chan presented a slide deck that identified that the Grade 3-4 diarrhea rate for neratinib users in the ExteNET trial was 39.9%.	Ex. 32 at 16 (ASCO 2015 Conference slides) [Depo. Ex. 176].
44.	During her June 1, 2015 presentation, Dr. Arlene Chan presented a slide deck that identified that the rate of treatment discontinuation due to diarrhea for neratinib users was 16.8%.	Ex. 32 at 17 (ASCO 2015 Conference slides) [Depo. Ex. 176].
45.	Following a February 12, 2015 Leerink conference, Leerink Equity Research analyst Howard Liang did not issue any report discussing the diarrhea rate in the ExteNET trial or reporting that the diarrhea rate was expected to be in the 30%-40% range.	Ex. 85 (February 20, 2015 Leerink Equity Research analyst report). Ex. 86 (March 10, 2015 Leerink Equity Research analyst report). Ex. 87 (April 21, 2015

NO.	UNCONTROVERTED FACT	EVIDENCE
		Leerink Equity Research analyst report).
46.	On February 26, 2015, following a February 25, 2015 RBC conference, RBC Capital Markets analyst Simos Simeonidis issued a report that included "[n]eratinib is known to cause Grade 3 diarrhea in 30% of the breast cancer patients in its clinical trials."	Ex. 88 at PUMA00002436 (RBC Capital Markets analyst report: "Key Takeaways from Breast Cancer Panel at RBC Healthcare Conference").
47.	Alan Auerbach has admitted to his knowledge of the ExteNET trial efficacy and safety results as of July 22, 2014.	Ex. 89 at Nos. 5-6 [Defendants' Responses to Plaintiff's Second Set of Interrogatories to All Defendants, dated January 17, 2017]. Ex. 90 at Nos. 4-6, 11 [Alan H. Auerbach's Second Amended Responses to Plaintiff's First Set of Requests for Admission, dated February 21, 2017]. Ex. 91 at Nos. 23-25 [Alan Auerbach's Responses to

NO.	UNCONTROVERTED FACT	EVIDENCE
		Plaintiff's Second Set of Requests for Admission, dated September 18, 2017]. Ex. 3 at 135:9-21 [Auerbach Depo.].
48.	On July 29, 2018, at 11:14 AM Phill Gross of Adage Capital informed Alan Auerbach that Pfizer's earnings "[c]all just ended . . . Clearly PFE [Pfizer] feels like they did not see the [ExteNET] data they should have when they renegotiated the royalty rate." One minute later, Gross emailed Alan Auerbach to say, "[y]ou will have to prove to them that you had no idea what ExteNET looked like on Friday."	Ex. 92 at Adage 0091; Ex. 93 at Adage 0094.
49.	On July 30, 2014 at 5:43 PM, Alvin Wong's July 17, 2014 email with the subject line "Topline Efficacy Results" was sent from Alan Auerbach's Puma email address (ahauerbach@pumabiotechnology.com) to his personal email address (ahauerbach.cgrb@gmail.com).	Ex. 94 [Depo. Ex. 468 (with associated metadata)].
50.	Prior to Alvin Wong's July 17, 2014	Ex. 94 [Depo. Ex. 468 (with

NO.	UNCONTROVERTED FACT	EVIDENCE
	email with the subject line "Topline Efficacy Results" being sent from Alan Auerbach's Puma email address to his personal email address, the date on Wong's July 17, 2014 email was changed to July 18, 2014.	associated metadata)].
51.	Alvin Wong did not send Alan Auerbach an email on July 18, 2014 at 11:34 PM with the subject line "Topline Efficacy Results."	Ex. 96 at No. 49 [Alan Auerbach's Amended Responses to Plaintiff's Fourth Set of Requests for Admissions, dated December 20, 2017].
52.	The metadata associated with the July 30, 2014 email identifies that Alan Auerbach is the custodian, recipient, and sender of the email.	Ex. 94 [Depo. Ex. 468 (with associated metadata)].
53.	An email located in Alan Auerbach's "Deleted" email folder and dated August 12, 2014 at 12:32 AM includes the text and from, to, and cc lines of Alvin Wong's July 17, 2014 email with the subject line "Topline Efficacy Results."	Ex. 95 [Depo. Ex. 469 (with associated metadata)].
54.	Prior to Alvin Wong's July 17, 2014 email with the subject line "Topline Efficacy Results" being saved in Alan Auerbach's "Deleted" email folder on	Ex. 95 [Depo. Ex. 469 (with associated metadata)].

NO.	UNCONTROVERTED FACT	EVIDENCE
	August 12, 2014 at 12:32 AM, the date on Wong's July 17, 2014 email was changed to July 19, 2014.	
55.	Alvin Wong did not send Alan Auerbach an email on July 19, 2014 at 11:35 PM with the subject line "Topline Efficacy Results."	Ex. 96 at No. 53 [Alan Auerbach's Amended Responses to Plaintiff's Fourth Set of Requests for Admission, dated December 20, 2017].
56.	The metadata associated with the August 12, 2014 at 12:32 AM email saved in Alan Auerbach's "Deleted" email folder identifies that Auerbach is the custodian of the document.	Ex. 95 [Depo. Ex. 469 (with associated metadata)].
57.	An email located in Alan Auerbach's "Drafts" email folder and dated August 12, 2014 at 5:16 PM includes portions of the text and the from, to, and cc lines of Alvin Wong's July 17, 2014 email with the subject line "Topline Efficacy Results."	Ex. 97 [Depo. Ex. 470 (with associated metadata)].
58.	Prior to Alvin Wong's July 17, 2014 email with the subject line "Topline Efficacy Results" being saved in Alan Auerbach's "Drafts" email folder on August 12, 2014 at 5:16 PM, the date	Ex. 97 [Depo. Ex. 470 (with associated metadata)].

NO.	UNCONTROVERTED FACT	EVIDENCE
	and time on Wong's July 17, 2014 email was changed to July 20, 2014 at 1:35 PM.	
59.	Prior to Alvin Wong's July 17, 2014 email with the subject line "Topline Efficacy Results" being saved in Alan Auerbach's "Drafts" email folder on August 12, 2014 at 5:16 PM, the following text was added or deleted from Wong's original July 17, 2014 email: Deleted: "We have schedule a meeting to discuss the results and to answer any questions." Added: Can we schedule a meeting today to discuss the results and to answer any questions?" Deleted: "We'd like to discuss the communication plan and when we can forward the news to the rest of the company, study sites, Tom Fleming, and IDMC." Deleted: "We are excited about the	*Compare* Ex. 28 [Depo. Ex. 123], *with* Ex. 97 [Depo. Ex. 470 (with associated metadata)].

NO.	UNCONTROVERTED FACT	EVIDENCE
	results . . . .”	
60.	Alvin Wong did not send Alan Auerbach an email on July 20, 2014 at 1:35 PM with the subject line “Topline Efficacy Results.”	Ex. 96 at No. 61 [Alan Auerbach’s Amended Responses to Plaintiff’s Fourth Set of Requests for Admission, dated December 20, 2017].
61.	The metadata associated with the August 12, 2014 at 5:16 PM email saved in Alan Auerbach’s “Drafts” email folder identifies that Auerbach is the custodian of the document.	Ex. 97 [Depo. Ex. 470 (with associated metadata)].
62.	On July 28, 2014, Pfizer President Garry Nicholson sent a letter to Alan Auerbach asserting that Puma was obligated to disclose the ExteNET clinical trial data to Pfizer and requesting that Puma provide Pfizer with the ExteNET study data, including a topline report of the results referenced in Puma’s July 22, 2014 press release.	Ex. 98. Ex. 99, ¶9 [Declaration of Vatnak Vat-Ho on Behalf of Pfizer, Inc.].
63.	On August 1, 2014, Alan Auerbach responded to Garry Nicholson’s letter and stating that “Puma did not have any clinical data from the ExteNET trial while the term sheet [License	Ex. 100 at PUMA00242578 [Depo. Ex. 466].

NO.	UNCONTROVERTED FACT	EVIDENCE
	Agreement] was being negotiated."	
64.	On August 5, 2014 Garry Nicholson responded to Alan Auerbach's August 1, 2014 letter and stated that Pfizer believed that Puma had "breached the . . . Agreement" and "violated its duty of good faith and fair dealing" in failing to disclose the ExteNET trial data during the negotiation of the Amendment. Pfizer thereby triggered the dispute resolution process under §16.2 of the License Agreement, and maintained that it was entitled to receive the full results of the ExteNET trial immediately.	Ex. 101 at PUMA00239932-33. Ex. 99, ¶10 [Declaration of Vatnak Vat-Ho on Behalf of Pfizer, Inc.].
65.	Pfizer and Puma held an in-person meeting on August 18, 2014, and exchanged further correspondence on August 20, 2014, whereby both parties agreed to escalate the dispute resolution discussions to the "DR Executives," Alan Auerbach and Garry Nicholson, as provided in §16.2 of the License Agreement.	Ex. 99, ¶11 [Declaration of Vatnak Vat-Ho on Behalf of Pfizer, Inc.].
66.	On September 4, 2014, Pfizer Assistant General Counsel Katherine Yang sent a	Ex. 102 at PFI00047235-37.

NO.	UNCONTROVERTED FACT	EVIDENCE
	letter to Alan Auerbach stating that the parties were entering the final stage of the dispute resolution process and that, based on public records and discussions with Puma to date, Pfizer was "convinced that it was defrauded" by Puma's failure to share information regarding the ExteNET trial results with Pfizer prior to the date the parties formally executed the License Agreement Amendment. The letter also included that Pfizer could not reach a resolution and avoid legal action "without seeing the topline report for the ExteNET study as well as all available safety and other data for the study," so that Pfizer could "assess the impact of Puma's failure to provide the data before the execution date [of the License Agreement Amendment]."	Ex. 99, ¶13 [Declaration of Vatnak Vat-Ho on Behalf of Pfizer, Inc.].
67.	On September 9, 2014, Alan Auerbach and representatives from Latham & Watkins had a call with representatives of Pfizer regarding Pfizer's request for information about the ExteNET trial results as of July 18, 2014.	Ex. 103 [Depo. Ex. 480].

NO.	UNCONTROVERTED FACT	EVIDENCE
68.	On September 12, 2014, Pfizer representative Vatnak Vat-Ho sent an email to Alan Auerbach with "a list of the documents and data that we are requesting." Included in the list was: • "Any slides, tables, or other written documentation discussed at the meeting, referenced by Mr. Alan Auerbach, on the afternoon of July 18, 2014 on the ExteNET study." • "Any slides, tables, or other written documentation discussed at any other meetings regarding the ExteNET study, and any meeting minutes or other recording of such discussions." • "Any written documentation (including slides, tables and other written reports) provided to Puma or prepared by Puma regarding the ExteNET study results up to the present."	Ex. 103 at PUMA00241048-49 [Depo. Ex. 480].
69.	Vatnak Vat-Ho's September 12, 2014 email to Alan Auerbach also included a request for "efficacy and safety analyses" that included: "Primary Efficacy Analysis • Disease-free survival (DFS) as	Ex. 103 at PUMA00241049-50 [Depo. Ex. 480].

NO.	UNCONTROVERTED FACT	EVIDENCE
	defined in the SAP: median by arm, percentages at {1 year, 2 years, 3 years, and any other time points analyzed} by arm, HR and corresponding confidence interval, p-value, Kaplan-Meier plot. Please confirm that all DFS events meet the definition per the primary endpoint as defined in the SAP."	
70.	Vatnak Vat-Ho's September 12, 2014 email to Alan Auerbach requested: "Safety analyses, including p values, specifically: Withdrawals due to toxicity" and "Discontinuations, n (%), due to . . . Adverse Event."	Ex. 103 at PUMA00241051 [Depo. Ex. 480].
71.	On September 16, 2014, Alan Auerbach emailed representatives of Pfizer in response to Vatnak Vat-Ho's September 12, 2014 correspondence and attached what he described as "the written documentation from the meeting on July 18, 2014 to discuss the top line results of the ExteNET study."	Ex. 104 at PUMA00241178 [Depo. Ex. 481].
72.	The attachment to Alan Auerbach's September 16, 2014 email is not the written documentation from the meeting on July 18, 2014 to discuss the topline	*Compare* Ex. 104 at PUMA00241180-85 [Depo. Ex. 481], *with* Ex. 28 at PUMA00014627-56 [Depo.

NO.	UNCONTROVERTED FACT	EVIDENCE
	results of the ExteNET study	Ex. 123].
73.	The neratinib Top-line Efficacy Analyses document that Alan Auerbach received on July 17, 2014 for the July 18, 2014 meeting was a 30-page document. The version of the Top-line Efficacy Analyses that Alan Auerbach sent to Pfizer on September 16, 2014 was five pages.	*Compare* Ex. 104 at PUMA00241180-85 [Depo. Ex. 481], *with* Ex. 28 at PUMA00014627-56 [Depo. Ex. 123].
74.	"July 18, 2014" was added to the cover page of the version of the Top-line Efficacy Analyses that Alan Auerbach sent to Pfizer on September 16, 2014.	*Compare* Ex. 104 at PUMA00241180 [Depo. Ex. 481], *with* Ex. 28 at PUMA00014627 [Depo. Ex. 123].
75.	The table of contents for the Top-line Efficacy Analyses document that Alan Auerbach received on July 17, 2014 for the July 18, 2014 meeting was removed from the version of the Top-line Efficacy Analyses that Auerbach sent to Pfizer on September 16, 2014.	*Compare* Ex. 104 at PUMA00241181 [Depo. Ex. 481], *with* Ex. 28 at PUMA00014628-29 [Depo. Ex. 123].
76.	The 2 years + 28 days DFS rate columns for neratinib and placebo in Table 3.0-1, including the identification of the 93.9 DFS rate for neratinib and the 91.6 DFS	*Compare* Ex. 104 at PUMA00241183 [Depo. Ex. 481], *with* Ex. 28 at PUMA00014632 [Depo. Ex.

NO.	UNCONTROVERTED FACT	EVIDENCE
	rate for placebo, in the Top-line Efficacy Analyses document that Alan Auerbach received on July 17, 2014 for the July 18, 2014 meeting was removed from the version of the Top-line Efficacy Analyses that Auerbach sent to Pfizer on September 16, 2014.	123].
77.	The DFS and DFS-DCIS Rate Summary (Table 3.0-2), including the 2.3% absolute difference in DFS rates for the ITT population, in the Top-line Efficacy Analyses document that Alan Auerbach received on July 17, 2014 for the July 18, 2014 meeting was removed from the version of the Top-line Efficacy Analyses that Auerbach sent to Pfizer on September 16, 2014.	*Compare* Ex. 104 at PUMA00241183 [Depo. Ex. 481], *with* Ex. 28 at PUMA00014632 [Depo. Ex. 123].
78.	Section 4, titled "Intent-to-Treat Population (ITT)," including section 4.1 (titled "Disease-free Survival") and Figure 4.1-1 (the two year KM curves for the ITT population), in the Top-line Efficacy Analyses document that Alan Auerbach received on July 17, 2014 for the July 18, 2014 meeting was removed from the version of the Top-line Efficacy	*Compare* Ex. 104 at PUMA00241184 [Depo. Ex. 481] *with* Ex. 28 at PUMA00014634-44 [Depo. Ex. 123].

NO.	UNCONTROVERTED FACT	EVIDENCE
	Analyses that Auerbach sent to Pfizer on September 16, 2014.	
79.	Section 5, titled "Amended Intent-to-Treat Population (aITT)," including section 5.1 (titled "Disease-free Survival"), in the Top-line Efficacy Analyses document that Alan Auerbach received on July 17, 2014 for the July 18, 2014 meeting was removed from the version of the Top-line Efficacy Analyses that Auerbach sent to Pfizer on September 16, 2014.	*Compare* Ex. 104 at PUMA00241184 [Depo. Ex. 481], *with* Ex. 28 at PUMA00014645-56 [Depo. Ex. 123].
80.	The written documentation from Puma's July 18, 2014 meeting to discuss the topline safety results of the ExteNET trial, including the Study 3004: Summary of Safety slide deck and topline safety tables Alvin Wong sent to Alan Auerbach on July 18, 2014, were not sent to Pfizer.	Ex. 25 [Depo. Ex. 124].
81.	On September 19, 2014, Alan Auerbach emailed a letter to Pfizer's Katherine Yang, in which he claimed: "The preliminary results from the ExteNET trial are showing an absolute DFS difference of approximately three	Ex. 105 at PUMA00241290-91 [Depo. Ex. 482]. Ex. 99, ¶18 [Declaration of Vatnak Vat-Ho on behalf of Pfizer, Inc.].

NO.	UNCONTROVERTED FACT	EVIDENCE
	percent between treatment and control arms" and "[w]e are in the process of fully validating this data and sending it to you as part of the analyses that you requested and we mentioned would be available in 3-4 weeks."	
82.	In his September 19, 2014 letter to Pfizer, Alan Auerbach also wrote: "In your email, you also asked about the continued separation of the DFS curves. Again, we are still in the process of fully validating this data and ask Pfizer to recognize there are many different definitions of disease free survival and different patient populations. It appears, based on our preliminary analysis, that the absolute difference in the DFS curves is separating by approximately 0.5% per year. We are in the process of fully validating this data and sending it to you as part of the analyses that you requested and that we mentioned would be available in 3-4 weeks."	Ex. 105 at PUMA00241291 [Depo. Ex. 482].
83.	In his September 19, 2014 letter to Pfizer, Alan Auerbach also wrote: "Furthermore, we stated that we would	Ex. 105 at PUMA00241290 [Depo. Ex. 482].

NO.	UNCONTROVERTED FACT	EVIDENCE
	be providing Pfizer with this data on a rolling basis as it became available over this 3-4 week period to help facilitate Pfizer's review. Specifically, we said we would be able to send you the safety data as early next week and would likely be able to send you more detailed DFS data next week as well."	
84.	On September 24, 2014, Alan Auerbach emailed Pfizer's Katherine Yang and attached what he described as "the analysis of the adverse event information from the ExteNET trial."	Ex. 106 at PUMA00241433 [Depo. Ex. 483].
85.	The attachments to Alan Auerbach's September 24, 2014 email are five slides from the 12-slide deck titled "Study 3004: Summary of Safety" that Alvin Wong sent Auerbach on July 18, 2014.	*Compare* Ex. 25 at PUMA00014834.00001-.00012 [Depo. Ex. 124], *with* Ex. 106 at PUMA00241435-39 [Depo. Ex. 483].
86.	On September 28, 2014, Alan Auerbach emailed Pfizer's Katherine Yang and attached what he described as "the analysis of the Top Line Efficacy for the ExteNET trial. This analysis includes information on the DFS rates and hazard ratios for each of the primary and secondary endpoints of the trial."	Ex. 107 at PUMA00241518 [Depo. Ex. 484].

NO.	UNCONTROVERTED FACT	EVIDENCE
87.	The attachment to Alan Auerbach's September 28, 2014 email is a portion of a single page (page 6) of the Top-line Efficacy Analyses Alvin Wong sent Alan Auerbach on July 17, 2014, with the charts modified to remove the ITT population results (including the 93.9% DFS rate for the neratinib arm, the 91.6% DFS rate for the placebo arm, and the 2.3% absolute DFS difference).	*Compare* Ex. 28 at PUMA00014632 [Depo. Ex. 123], *with* Ex. 107 at PUMA00241520 [Depo. Ex. 484].
88.	On October 11, 2014, Alan Auerbach sent a letter to Pfizer's Katherine Yang in which he wrote "that the information Puma is currently providing to Pfizer post-dates the [July 18, 2014] execution of the Amendment to the License Agreement" and "Pfizer must also recognize that the vast majority of the information it has requested from Puma does not exist 'on the shelf,' but must be specially created in response to Pfizer's requests."	Ex. 108 at PUMA00241804 [Depo. Ex. 485].
89.	In his October 11, 2014 letter to Pfizer, Alan Auerbach also wrote: "However, because some patients in the ExteNET trial enrolled as early as 2009, there are	Ex. 108 at PUMA00241805 [Depo. Ex. 485].

NO.	UNCONTROVERTED FACT	EVIDENCE
	some patients that have been followed by DFS for longer than two years post-enrollment. We are in the process of gathering information related to those patients for Pfizer."	
90.	On October 27, 2014, Alan Auerbach sent an email to himself, with the subject line PFE, in which he wrote: "Puma has not shared any information with Pfizer regarding the disease free survival data from the ExteNET trial (the primary endpoint of the ExteNET trial was disease free survival). Pfizer has not seen the disease free survival data nor has Pfizer seen the Kaplan Meier curves for the ExteNET trial."	Ex. 109 [Depo. Ex. 486].
91.	On September 18, 2017, Alan Auerbach represented to plaintiff that the basis for his July 22, 2014 claim that "'it looks like the curves are continuing to separate'" beyond two years was based on the KM curves at PUMA00242055.	Ex. 82 at No. 13 [Defendants' Puma Biotechnology, Inc. and Alan Auerbach's Responses to Plaintiff's Fifth Set of Interrogatories to All Defendants, dated September 18, 2017].
92.	PUMA00242055 is a copy of one of the "optimistic scenario" simulated DFS and DFS-DCIS curves that were not	Ex. 79 (email from Alan Auerbach to Bin Yao re: DFS and DFS-DCIS simulation

NO.	UNCONTROVERTED FACT	EVIDENCE
	generated until October 30, 2014 and that Alan Auerbach sent to Pfizer on November 5, 2014.	results; simulation of DFS and DFS-DCIS Beyond two years) [Depo. Ex. 473]. Ex. 81 at PUMA00022378 [Depo. Ex. 474]. Ex. 39 [Depo. Ex. 475].
93.	On November 16, 2017, Alan Auerbach admitted that the KM curves at PUMA00242055 did not support any claim that "'it looks like the curves are continuing to separate'" beyond two years. He further stated he had been "informed of preliminary data" for DFS events beyond two years and "[b]ased on [this preliminary data] concluded that the Kaplan-Meier curves were, in fact, continuing to separate on a year-over-year basis after two years."	Ex. 146 at No. 13 [Defendants' Puma Biotechnology, Inc. and Alan Auerbach's Supplemental Responses to Plaintiff's Fifth Set of Interrogatories to All Defendants, dated November 16, 2017].
94.	On December 15, 2014, the FDA sent a letter to Puma, signed by Jeannette O'Donnell and Todd Palmby, enclosing a copy of the official meeting minutes from the FDA's November 25, 2014 Type C meeting with Puma regarding its	Ex. 110 [Depo. Ex. 489]. Ex. 111, ¶2 [Declaration of Jeannette Dinin].

NO.	UNCONTROVERTED FACT	EVIDENCE
	investigational new drug application for neratinib (IND 066783).	
95.	The FDA's December 15, 2014 letter initially listed the incorrect IND number, and FDA subsequently sent an updated version listing the correct IND number (IND 006783) on December 16, 2014.	Ex. 111, ¶2 [Declaration of Jeannette Dinin].
96.	On January 7, 2015, in response to a request from William Hicks, counsel for the underwriters of Puma's January 2015 stock offering, Alan Auerbach sent an email to Hicks stating "[p]lease find attached the minutes from our recent meeting with FDA for neratinib which is being provided to you for regulatory diligence in advance of our update call on Friday."	Ex. 112 at PUMA00273645 [Depo. Ex. 491].
97.	Attached to Alan Auerbach's January 7, 2015 email to William Hicks was a version of the official meeting minutes from the FDA's November 25, 2014 Type C meeting with Puma that had been altered to, among other deletions and changes, remove all references to the DFS results from the ExteNET trial, including a table titled "Primary and	*Compare* Ex. 110 [Depo. Ex. 489], *with* Ex. 112 [Depo. Ex. 491], *and* Ex. 113 [Depo. Ex. 493].

NO.	UNCONTROVERTED FACT	EVIDENCE
	Secondary Efficacy for Study 3004," and change certain of the FDA's responses to questions.	
98.	The metadata associated with the attachment to Alan Auerbach's January 7, 2015 email to William Hicks (the altered meeting minutes from the FDA's November 25, 2014 Type C meeting with Puma) identifies that Auerbach is the sole custodian and author of the altered document. The metadata also identifies that the document came from Auerbach's flash drive, and that the PDF of the document that was sent to Hicks was created on January 6, 2015 at 11:15 PM, from a Microsoft Word document entitled "2014-11-25_FDA_Type C Nonclin Meeting Minutes (ESPRIT)-draft 2.docx." Defendants have not produced that Microsoft Word document in this case.	Ex. 114 (with associated metadata). Ex. 115 at 2 (confirming that altered FDA record was located in one of Alan Auerbach's flash drives).
99.	It is contrary to the FDA's procedures to change the substance of meeting minutes after they are created.	Ex. 111, ¶6 [Declaration of Jeannette Dinin].
100.	No one at the FDA had discussions with Puma about making changes to the	Ex. 111, ¶6 [Declaration of Jeannette Dinin]

NO.	UNCONTROVERTED FACT	EVIDENCE
	official meeting minutes from the FDA's November 25, 2014 Type C meeting with Puma.	
101.	ASCO's 2015 Confidentiality Policy explicitly provides for a self-executing exception where a publicly traded company is "legally required to disclose certain data or other information" to comply with the federal securities laws.	Ex. 35 at HsuvPumaASCO_000004021-22 (ASCO Confidentiality Policy, SEC Exception) [Depo. Ex. 116].
102.	Neither Puma nor anyone else associated with the ExteNET abstract and presentation at the 2015 ASCO conference sought an SEC exception to the confidentiality policy.	Ex. 2 at 29:16-31:3 [ASCO 30(b)(6) Depo.].
103.	Defendants deny that Charles Eyler had access to the non-public results of the ExteNET trial prior to May 13, 2015.	Ex. 116 at No. 19 [Defendants' Responses to Plaintiff's Sixth Set of Interrogatories to All Defendants, dated November 29, 2017].
104.	On February 18, 2015, Puma employee Paul Kim sent Charles Eyler a "full list of individuals who may have had access to information related to 3004 [ExteNET] in the mid-2014 timeframe." Kim's list included Eyler.	Ex. 53 at PUMA00247506-07 [Depo. Ex. 458].

NO.	UNCONTROVERTED FACT	EVIDENCE
105.	Charles Eyler did not respond to Paul Kim's email identifying Eyler as an "individual[] who may have had access" to information about the ExteNET trial, and Eyler never informed Kim that his list was not accurate.	Ex. 6 at 206:15-207:23 [Eyler Depo.].
106.	Charles Eyler "help[ed] spearhead[]" Puma's response to an insider-trading investigation by FINRA, including gathering documents for Puma's counsel, Latham & Watkins.	Ex. 6 at 173:2-17, 174:23-175:3 [Eyler Depo.]. Ex. 3 at 514:8-13, 515:6-9 [Auerbach Depo.].
107.	On November 25, 2014, Puma's counsel sent FINRA a letter and Puma documents regarding the ExteNET trial results.	Ex. 57 at FINRA0003018, 25-39, 106-43 [Depo. Ex. 456].
108.	A copy of Puma's counsel's November 25, 2014 letter to FINRA was provided to Charles Eyler.	Ex. 6 at 178:12-180:19 [Eyler Depo.]. Ex. 3 at 519:6-16 [Auerbach Depo.].
109.	Charles Eyler was responsible for confirming that any employee who wished to sell their Puma securities was not in possession of material, non-public information.	Ex. 117 at PUMA00000882-83 [Depo. Ex. 108]. Ex. 54 at PUMA00240724-25 [Depo. Ex. 340].

NO.	UNCONTROVERTED FACT	EVIDENCE
		Ex. 6 at 98:23-101:6 (Eyler testifying that preclearance process remained the same before and after December 2014) [Eyler Depo.]. Ex. 3 at 119:25-120:5 (Alan Auerbach stating that "[i]n order to preclear a transaction, it had to be cleared by either me or Charles Eyler and there had to be a determination that you were not in receipt of any material nonpublic information") [Auerbach Depo.].
110.	On December 22, 2014, Puma's Associate Director of Medical Writing, Fuad Mehraban, emailed Charles Eyler and informed him "I don't think there will be any time in the near future that I don't see or have access to data that is not in the public domain, related to 3004 [ExteNET]."	Ex. 55 at PUMA00151633 [Depo. Ex. 461].
111.	Eleven minutes after receiving Fuad Mehraban's email, Charles Eyler pre-	Ex. 55 at PUMA00151633 [Depo. Ex. 461].

NO.	UNCONTROVERTED FACT	EVIDENCE
	cleared Mehraban's sale of Puma securities, stating "I think you are fine to exercise for the time being."	
112.	Following Charles Eyler's pre-clearance of Fuad Mehraban's sale of Puma securities, Mehraban sold 2,750 shares on December 23, 2014 and 11,000 shares on December 24, 2014, for total proceeds of approximately $2.6 million.	Ex. 118 at STX_000030-31 [Depo. Ex. 209].
113.	Between December 22, 2014 and May 4, 2015, Charles Eyler pre-cleared at least 116 sales of Puma stock by at least 75 Puma officers and employees.	Ex. 119 at No. 42 [Charles R. Eyler's Amended Responses to Plaintiff's Second Set of Requests for Admission, dated October 23, 2017].
114.	Between December 22, 2014 and May 4, 2015 Puma officers and employees whose stock sales had been pre-cleared by Charles Eyler sold at least 66,897 shares of Puma stock for proceeds of over $146.5 million.	Ex. 119 at No. 42 [Charles R. Eyler's Amended Responses to Plaintiff's Second Set of Requests for Admission, dated October 23, 2017]. Ex. 118 [Depo. Ex. 209].
115.	Each of the following Puma employees who was identified on the "list of individuals who may have had access to information related to 3004 [ExteNET] in the mid-2014 timeframe" was	Ex. 53 at PUMA00247506-07 [Depo. Ex. 458]. Ex. 118 at STX_000029-36 [Depo Ex. 209].

<table>
<tr><th>NO.</th><th>UNCONTROVERTED FACT</th><th>EVIDENCE</th></tr>
<tr><td></td><td>precleared to sell stock by Charles Eyler and sold Puma stock between December 22, 2014 and April 21, 2015 at prices ranging from $183.62 per share to $251.37 per share, as follows:
<table>
<tr><th>Name</th><th>Net Shares Sold</th><th>Proceeds</th></tr>
<tr><td>Alvin Wong</td><td>11,000</td><td>$2,189,721.60</td></tr>
<tr><td>Pamela Wilson</td><td>14,400</td><td>$3,033,022.93</td></tr>
<tr><td>Mei Ling Chang-Lok</td><td>17,499</td><td>$3,387,655.46</td></tr>
<tr><td>Preeti Chirmule</td><td>42,165</td><td>$9,177,846.30</td></tr>
<tr><td>Leanne McCulloch</td><td>9,000</td><td>$1,915,907.07</td></tr>
<tr><td>Rolando Ruiz</td><td>1,312</td><td>$262,354.84</td></tr>
<tr><td>George Nauyok</td><td>13,333</td><td>$2,764,468.46</td></tr>
<tr><td>Fuad Mehraban</td><td>13,750</td><td>$2,623,854.53</td></tr>
<tr><td>Franklin Sanchez</td><td>9,999</td><td>$1,924,293.39</td></tr>
<tr><td>Bin Yao</td><td>15,000</td><td>$3,221,210.31</td></tr>
<tr><td>Alshad Lalani</td><td>9,999</td><td>$2,269,584.23</td></tr>
<tr><td>Todd Stallings</td><td>23,000</td><td>$5,194,362.27</td></tr>
<tr><td>Yining Ye</td><td>5,000</td><td>$1,124,916.78</td></tr>
<tr><td>Richard Williams</td><td>27,332</td><td>$6,230,162.91</td></tr>
</table></td><td>Ex. 119 at No. 42 [Charles R. Eyler’s Amended Responses to Plaintiff’s Second Set of Requests for Admission, dated October 23, 2017].</td></tr>
<tr><td>116.</td><td>Claire Sherman, Puma’s Director of Biostatistics, who was also on the “list of</td><td>Ex. 118 at STX_000029 [Depo. Ex. 209].</td></tr>
</table>

NO.	UNCONTROVERTED FACT	EVIDENCE
	individuals who may have had access to information related to 3004 [ExteNET] in the mid-2014 timeframe," sold 18,333 shares of Puma stock on December 4, 2014, for proceeds of $4,007,371.	
117.	From November 4, 2014 to November 6, 2014, Richard B. Phillips, Puma's Senior Vice President, Regulatory Affairs, Quality Assurance and Pharmacovigilance, who was also on the "list of individuals who may have had access to information related to 3004 [ExteNET] in the mid-2014 timeframe," sold 109,249 shares of Puma stock for proceeds of over $26 million.	Ex. 118 at STX_000029 [Depo. Ex. 209].
118.	On March 2, 2015, Charles Eyler signed Puma's Form 10-K for the year ended December 31, 2014, "pursuant to the requirements of the Securities Exchange Act of 1934."	Ex. 120 at 52 (Puma's 2014 Form 10-K) [Depo. Ex. 104]. Ex. 6 at 93:16-18 [Eyler Depo.].
119.	By signing Puma's 2014 Form 10-K, Charles Eyler understood that he was attesting to the accuracy of the document.	Ex. 6 at 93:16-94:9 [Eyler Depo.].
120.	On January 20, 2015, Charles Eyler signed Puma's Form S-3ASR for Puma's	Ex. 121 at II-5 (Puma's Form S-3ASR for January 2015

NO.	UNCONTROVERTED FACT	EVIDENCE
	January 2015 stock offering, "[p]ursuant to the requirements of the Securities Act of 1933."	Offering) [Depo. Ex. 146].
121.	By signing Puma's Form S-3ASR, Charles Eyler understood that he was attesting to the accuracy of the document.	Ex. 6 at 269:9-270:6 [Eyler Depo.].
122.	On January 21, 2015, Puma sold 1.15 million shares of common stock at $190.00 per share, for total proceeds of $218.5 million and net proceeds of $205.1 million.	Ex. 122 at PUMA00245171 (Prospectus Supplement) [Depo. Ex. 105]. Ex. 123 at JPM000488 (January 27, 2015 Puma press release). Ex. 124 at PUMA00232800 (Puma's 2015 Form 10-K).
123.	As of mid-2014, absent the proceeds from the January 21, 2015 offering or another source of capital, Puma could not have expected to fund its operations beyond December 31, 2015.	Ex. 125, ¶¶16, 43 [Expert Report of Professor Brett Trueman, Ph.D.].
124.	If Puma had conducted a stock offering on July 21, 2014, prior to Defendants' false and misleading statements, Puma would have had to sell 2.55 million	Ex. 125, ¶52 [Expert Report of Professor Brett Trueman, Ph.D.].

NO.	UNCONTROVERTED FACT	EVIDENCE
	shares (222% more than it sold in January 2015) to raise the same amount of capital ($218.5 million).	
125.	If Puma had conducted a stock offering on July 21, 2015, after the disclosure of the ExteNET trial results at ASCO, Puma would have raised only $114.7 million (48% less than it raised in January 2015) if it sold the same amount of shares (1.15 million).	Ex. 125, ¶55 [Expert Report of Professor Brett Trueman, Ph.D.].
126.	If Puma had conducted a stock offering on July 21, 2015, after the disclosure of the ExteNET trial results at ASCO, Puma would have had to sell 2.19 million shares (91% more than it sold in January 2015) to raise the same amount of capital ($218.5 million).	Ex. 125, ¶55 [Expert Report of Professor Brett Trueman, Ph.D.].
127.	Alan Auerbach's total compensation for 2014 was $17,797,606.	Ex. 58 at 22 (Puma's 2014 DEF 14A).
128.	Alan Auerbach's compensation for 2014 was 230% higher than his reported compensation for 2013.	Ex. 58 at 22 (Puma's 2014 DEF 14A).
129.	Charles Eyler's total compensation for 2014 was $4,499,599.	Ex. 58 at 22 (Puma's 2014 DEF 14A).
130.	Charles Eyler's compensation for 2014 was 250% higher than his reported	Ex. 58 at 22 (Puma's 2014 DEF 14A).

NO.	UNCONTROVERTED FACT	EVIDENCE
	compensation for 2013.	
131.	According to Puma, a "significant portion" of its executives' 2014 compensation was "tied to performance."	Ex. 58 at 30 (Puma's 2014 DEF 14A).
132.	For 2014, one of the factors considered in determining executive compensation was that in "the 2014 fiscal year alone, the price of our common stock increased approximately 82.8%, closing at $189.27 on December 31, 2014, up from the closing price of $103.53 on December 31, 2013."	Ex. 58 at 30 (Puma's 2014 DEF 14A).
133.	For 2014, one of the factors considered in determining executive compensation was that Puma "announced positive top line results from the Phase III clinical trial of neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer," (*i.e.*, ExteNET) in July 2014.	Ex. 58 at 30 (Puma's 2014 DEF 14A).
134.	The residual return for Puma's stock price on May 14, 2015 was -21.73% which equates to a loss of $40.96 per share.	Ex. 126, ¶¶124-125 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA].

NO.	UNCONTROVERTED FACT	EVIDENCE
		Ex. 127, ¶¶62-63 & Exhibit-4 [Report on Loss Causation and Damages by Professor Steven P. Feinstein, Ph.D., CFA]. Ex. 9 at 46:22-25 (Defendants' loss causation and damages expert found no mistakes in Dr. Steven Feinstein's statistical analysis) [Gompers Depo.].
135.	The May 14, 2015 residual return is statistically significant at the 99.9% level, meaning that there is less than a 0.1% chance that the residual return was caused by something other than the disclosure of company-specific information.	Ex. 126, ¶124 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA]. Ex. 127, ¶¶59, 63 & Exhibit-4 [Report on Loss Causation and Damages by Professor Steven P. Feinstein, Ph.D., CFA].
136.	The -21.73% residual return for Puma's stock price on May 14, 2015 was substantially caused by the May 13, 2015 disclosure of the actual ExteNET trial DFS rates and Grade 3 and higher diarrhea rate.	Ex. 127, ¶¶7, 32-34, 64 [Report on Loss Causation and Damages by Professor Steven P. Feinstein, Ph.D., CFA]. Ex. 31 (May 13, 2015 ASCO

NO.	UNCONTROVERTED FACT	EVIDENCE
		Abstract #508) [Depo. Ex. 158].
137.	The residual return for Puma's stock price on June 1-2, 2015 was -28.73% which equates to a loss of $46.24 per share.	Ex. 126, ¶¶128-129 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA]. Ex. 127, ¶¶65-66 & Exhibit-4 [Report on Loss Causation and Damages by Professor Steven P. Feinstein, Ph.D., CFA]. Ex. 9 at 46:22-25 (Defendants' loss causation and damages expert found no mistakes in Dr. Steven Feinstein's statistical analysis) [Gompers Depo.].
138.	The June 1-2, 2015 residual return is statistically significant at the 99.9% level, meaning that there is less than a 0.1% chance that the residual return was caused by something other than the disclosure of company-specific information.	Ex. 126, ¶129 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA]. Ex. 127, ¶66 & Exhibit-4 [Report on Loss Causation and

NO.	UNCONTROVERTED FACT	EVIDENCE
		Damages by Professor Steven P. Feinstein, Ph.D., CFA]. Ex. 9 at 46:22-25 (Defendants' loss causation and damages expert found no mistakes in Dr. Steven Feinstein's statistical analysis) [Gompers Depo.].
139.	The residual return for Puma's stock price on June 1, 2015 was -13.07%.	Ex. 126, ¶129 n.70 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA].
140.	The June 1, 2015 residual return is statistically significant at the 99.9% level, meaning that there is less than a 0.1% chance that the residual return was caused by something other than the disclosure of company-specific information.	Ex. 126, ¶129 n.70 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA].
141.	The residual return for Puma's stock price on June 2, 2015 was -14.06%.	Ex. 126, ¶124 n.70 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA].

NO.	UNCONTROVERTED FACT	EVIDENCE
142.	The June 2, 2015 residual return is statistically significant at the 99.9% level, meaning that there is less than a 0.1% chance that the residual return was caused by something other than the disclosure of company-specific information.	Ex. 126, ¶124 & Exhibit-7 [Report on Market Efficiency by Professor Steven P. Feinstein, Ph.D., CFA].
143.	The KM curves for the ExteNET trial as of 2 years ± 28 days were publicly disclosed for the first time on June 1, 2015 in a presentation by Dr. Arlene Chan at ASCO.	Ex. 32 [Depo. Ex. 176]. Ex. 65, ¶71 (Defendants' Answer). Ex. 128 at No. 18 (Charles R. Eyler's Second Amended Responses to Plaintiff's Requests for Admission Nos. 15-18, dated March 15, 2017) [Depo. Ex. 463]. Ex. 129 at No. 10 (Alan H. Auerbach's Second Amended Responses to Plaintiff's Requests for Admission Nos. 7-10, dated March 15, 2017).
144.	The 16.8% discontinuation rate for ExteNET participants on neratinib due to	Ex. 32 [Depo. Ex. 176].

NO.	UNCONTROVERTED FACT	EVIDENCE
	diarrhea AEs was publicly disclosed for the first time on June 1, 2015 in a presentation by Dr. Arlene Chan at ASCO.	Ex. 65, ¶72 (Defendants' Answer). Ex. 129 at No. 10 (Alan H. Auerbach's Second Amended Responses to Plaintiff's Requests for Admission Nos. 7-10, dated March 15, 2017).
145.	The fact that only 61% of ExteNET participants on neratinib completed the full 12 months of treatment was publicly disclosed for the first time on June 1, 2015 in a presentation by Dr. Arlene Chan at ASCO.	ECF No. 376-3 at 29-30 (transcript of June 1, 2015 ASCO question-and-answer session attached as Ex. 42 to the Declaration of Kristin N. Murphy in Support of Defendants' Motion for Summary Judgment).
146.	On June 1-3, 2015, following the ASCO presentation, the following analyst firms issued reports regarding Puma: 1. Bank of America Merrill Lynch; 2. Cowen and Company; 3. Leerink Partners LLC; 4. RBC Capital Markets; 5. Stifel; and 6. UBS Securities LLC.	Ex. 131 (Bank of America Merrill Lynch analyst report: "ExteNET still supports FDA approval") [PUMA00218743-49]. Ex. 132 (Cowen and Company analyst report: "ExteNET As Advertised, But Questions Remain On FDA Strategy And

NO.	UNCONTROVERTED FACT	EVIDENCE
		Market Oppy") [Depo. Ex. 326]. Ex. 133 (Leerink analyst report: "No Surprises in ExteNET Presentation – 3-Year Follow-Up Likely Closely Watched") [PUMA000218826-32]. Ex. 134 (RBC Capital Markets analyst report: "ExteNET curves separate, subgroup data are robust; more tonight at the PBYI webcast") [PUMA00218661-66]. Ex. 135 (Stifel analyst report: "Puma Biotech – Still Crazy After all These Veers") [PUMA00041533-39]. Ex. 136 (UBS analyst report: "ExteNET Reaction Mixed, but 8.6%pt Delta is Nice") [PUMA00008909-14].

NO.	UNCONTROVERTED FACT	EVIDENCE
147.	Analyst reports issued by the following firms on June 1-3, 2015 specifically discussed the KM curves and/or the diarrhea AE discontinuation rate: 1. Cowen and Company; 2. Leerink Partners LLC; 3. RBC Capital Markets; and 4. UBS Securities LLC.	Ex. 132 (Cowen and Company analyst report: "ExteNET As Advertised, But Questions Remain On FDA Strategy And Market Oppy") [Depo. Ex. 326]. Ex. 133 (Leerink analyst report: "No Surprises in ExteNET Presentation – 3-Year Follow-Up Likely Closely Watched") [PUMA000218826-32]. Ex. 134 (RBC Capital Markets analyst report: "ExteNET curves separate, subgroup data are robust; more tonight at the PBYI webcast") [PUMA00218661-66]. Ex. 136 (UBS analyst report: "ExteNET Reaction Mixed, but 8.6%pt Delta is Nice") [PUMA00008909-14].
148.	Investment bank analysts are biased in	Ex. 7 at 114:19-117:14

NO.	UNCONTROVERTED FACT	EVIDENCE
	favor of potential and actual banking clients.	[Feinstein Depo.]. Exs. 59-64 (articles discussing analyst bias).
149.	Bank of America Merrill Lynch's June 2, 2015 analyst report regarding Puma identified that Puma "is or was, within the last 12 months, an investment banking client"; that the bank "has received compensation from [Puma] for non-investment banking services or products within the past 12 months"; and the bank "or an affiliate was a manager of a public offering of securities of [Puma] within the last 12 months."	Ex. 131 at PUMA00218747 (Bank of America Merrill Lynch analyst report: "ExteNET still supports FDA approval") [PUMA00218743-49].
150.	Cowen and Company's June 1, 2015 analyst report regarding Puma identified that Puma: "has been [a] client[] of Cowen and Company, LLC in the past 12 months"; that "during the past 12 months, Cowen and Company, LLC provided IB [investment banking] services" to Puma; and "Cowen and Company and/or its affiliates managed or co-managed a public offering of Puma Biotechnology within the past twelve	Ex. 132 at CW000039 (Cowen and Company analyst report: "ExteNET As Advertised, But Questions Remain On FDA Strategy And Market Oppy") [Depo. Ex. 326].

NO.	UNCONTROVERTED FACT	EVIDENCE
	months."	
151.	Leerink Partners LLC's June 2, 2015 analyst report regarding Puma identified that "[i]n the past 12 months, the Firm has received compensation for providing investment banking services to Puma"; and the bank "has acted as a co-manager for a public offering of Puma Biotechnology, Inc. in the past 12 months."	Ex. 133 at PUMA00218831 (Leerink analyst report: "No Surprises in ExteNET Presentation – 3-Year Follow-Up Likely Closely Watched") [PUMA00218826-32].
152.	Stifel was selected by Puma to co-manage the Company's first stock offering following June 1, 2015.	Ex. 137 at 1 (Puma Rule 424(b)(5) Prospectus Supplement, filed October 21, 2016).
153.	UBS Securities LLC's June 1, 2015 analyst report regarding Puma identified that "[w]ithin the past 12 months, UBS AG, its affiliates or subsidiaries has received compensation for investment banking services from [Puma]"; and Puma "is, or within the past 12 months has been, a client of UBS Securities LLC, and investment banking services are being, or have been, provided."	Ex. 136 at PUMA00008912, (UBS analyst report: "ExteNET Reaction Mixed, but 8.6% pt Delta is Nice") [PUMA00008909-14].
154.	Alan Auerbach had day-to-day oversight of Puma's operations during the Class	Ex. 14 at 25:13-34:23, 81:5-84:6 [Puma 30(b)(6) Depo.].

NO.	UNCONTROVERTED FACT	EVIDENCE
	Period and was directly or indirectly involved in Puma's public statements.	Ex. 138 at PUMA00000870-71, 77 [Depo. Ex. 110]. Ex. 120 at PUMA00197409, 11 [Depo. Ex. 104].
155.	Charles Eyler had day-to-day oversight of Puma's operations during the Class Period and was directly or indirectly involved in Puma's public statements.	Ex. 14 at 25:13-34:23, 81:5-84:6 [Puma 30(b)(6) Depo.]. Ex. 138 at PUMA00000870-71, 77 [Depo. Ex. 110]. Ex. 120 at PUMA00197410, 12 [Depo. Ex. 104].

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