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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

DENIS MULLIGAN, individually and on  
behalf of all others similarly situated,

Plaintiff,

v.

IMPAX LABORATORIES, INC., *et al.*,

Defendants.

No. C-13-1037 EMC

No. C-13-1566 EMC

**CONSOLIDATED CASES**

**ORDER DENYING DEFENDANTS'  
MOTION TO DISMISS CLASS  
COMPLAINT**

**(Docket No. 66)**

HAVERHILL RETIREMENT SYSTEM,  
individually and on behalf of all others  
similarly situated

Plaintiff,

v.

IMPAX LABORATORIES, INC., *et al.*,

Defendants.

**I. INTRODUCTION**

Plaintiffs Boilermaker-Blacksmith National Pension Trust and Haverhill Retirement System (“Plaintiffs”) have filed the instant securities class action alleging that Defendant Impax Laboratories (“Impax”) and its CEO (Larry Hsu) and CFO (Arthur Koch) made false and misleading material statements. These statements pertained to Impax’s response to various FDA notices and warnings regarding problems in the manufacturing and quality control processes at Impax’s manufacturing facility. Specifically, Plaintiffs allege that Defendants failed to disclose the true

1 nature of the problems present in the facility and misrepresented the scope, nature, and efficacy of  
2 the remediation efforts made in response to the FDA warnings. Defendants have moved to dismiss  
3 on a number of grounds, including: (1) that the alleged misstatements are protected under the Private  
4 Securities Litigation Reform Act's ("PSLRA") safe harbor provision for forward looking statements,  
5 (2) that they constitute "mere puffery," and (3) that there are insufficient allegations suggesting that  
6 the statements were false when made. Finally, Defendants argue that the Plaintiffs' allegations fail  
7 to give rise to a "strong inference" of scienter as required. The Court **DENIES** Defendants' motion  
8 to dismiss.

## 9 **II. FACTUAL & PROCEDURAL BACKGROUND**

10 Defendant Impax Laboratories is a pharmaceutical company that "engages in the  
11 development, manufacture, and marketing of bio-equivalent pharmaceutical products referred to as  
12 generics as well as branded products." First Amended Complaint ("FAC") ¶ 2. Impax maintains a  
13 manufacturing facility in Hayward, California. *Id.*

### 14 A. FDA Inspection and Noncompliance Procedures

15 The Food and Drug Administration ("FDA") is statutorily required to inspect all  
16 manufacturing facilities such as Impax's Hayward facility every two years, but given a lack of  
17 resources, the FDA has prioritized certain facilities over others. *Id.* ¶ 37. The purpose of these  
18 inspections is to ensure that the facility is in compliance with applicable laws and to "ensure[] the  
19 quality of drug products by carefully monitoring drug manufacturers' compliance with the FDA's  
20 Current Good Manufacturing Practice ('cGMP') regulations." *Id.* ¶ 35, 36. cGMP regulations  
21 constitute "*minimum requirements* for the methods, facilities, and controls used in manufacturing,  
22 processing, and packaging of a drug product." *Id.* ¶ 36 (citation omitted).

23 Plaintiff's First Amended Complaint contains a voluminous description of the inspection  
24 process and procedures the FDA employs where a manufacturing facility is found to not be in non-  
25 compliance with cGMP. The Court need not recount the entire discussion on this point. Relevant  
26 for purposes of the instant motion, Plaintiff alleges that trained FDA "investigators tour facilities,  
27 accompanied at all times by the inspected company's staff, and cite factual observations of  
28 significant deviations from the" statutes the FDA enforces. *Id.* ¶ 42. These deviations are recorded

1 in a “Form 483” which is presented and explained to the company’s management. *Id.* A Form 483  
 2 is intended for use in “notifying the inspected establishment’s top management in writing of  
 3 **significant objectionable conditions**, relating to products and/or processes” observed during the  
 4 inspection. *Id.* ¶ 44 (citation omitted). While the investigators may note whether an observation is  
 5 recurring/not-corrected, it need not do so. *Id.* Investigators then draft an Establishment Inspection  
 6 Report (“EIR”) which contains more detail than a Form 483 and may contain additional  
 7 objectionable conditions in the manufacturing facility than those listed in the Form 483. *Id.* ¶ 43.  
 8 Management of a company that receives a Form 483 has an opportunity to provide written responses  
 9 to the FDA. *Id.* ¶ 46. If the FDA finds a company’s responses to a Form 483 to be inadequate, it  
 10 may issue a Warning Letter. *Id.*

11 Plaintiffs provide the following definition of a “Warning Letter” (emphases in original):

12 A Warning Letter is a correspondence that notifies regulated industry  
 13 about violations that FDA has documented during its inspections or  
 14 investigations. Typically, a Warning Letter notifies a responsible  
 15 individual or firm that the Agency considers one or more products,  
 16 practices, processes, or other activities to be in violation of the Federal  
 17 Food, Drug, and Cosmetic Act (the Act), its implementing regulations  
 18 and other federal statutes. ***Warning Letters should only be issued for  
 violations of regulatory significance, i.e., those that may actually  
 lead to an enforcement action if the documented violations are not  
 promptly and adequately corrected.*** A Warning Letter is one of the  
 Agency’s principal means of achieving prompt voluntary compliance  
 with the Act.

19 *Id.* ¶ 47 (quoting FDA, *Regulatory Procedures Manual* 4.1 (2012)). Prior to issuing a Warning  
 20 Letter, the FDA considers: (1) The company’s compliance history; (2) the nature of the violation at  
 21 issue; and (3) the overall adequacy of the firm’s corrective action. *Id.* The FDA’s policy states that  
 22 a Warning Letter “should not be issued if the agency concludes that a firm’s corrective actions are  
 23 adequate and that the violations that would have supported the letter have been corrected.” *Id.*  
 24 (citation omitted).

25 B. FDA Inspections, Form 483s, and Warning Letter Regarding Impax’s Hayward Facility

26 1. 2009, 2010, and 2011 FDA Inspections and Form 483s

27 In 2009, two FDA inspectors inspected Impax’s Hayward facility between July 27 and  
 28 August 7, 2009. *Id.* ¶ 55. They presented Impax’s VP of Regulatory Affairs & Compliance (Mr.

1 Mark Shaw) a Form 483 which enumerated four categories of deficiencies, supported by  
2 observations of nine specific events. *Id.* These four categories of deficiencies were:

- 3 (1) the “quality system, for failure to investigate root causes of out of specification  
4 (‘OOS’) events;
- 5 (2) facilities and equipment, for failure to validate (*e.g.*, investigate and justify) standards  
6 Impax set for cleaning;
- 7 (3) laboratory systems, for failure to update weight calibration and for three instances of  
8 failure to note in data notebooks that certain retesting samples emanated from a  
9 particular sample that failed; and
- 10 (4) production systems, for failure to stop operations and investigate when product  
11 powder ‘was flowing in a steady stream’ outside of the plastic enclosure on a piece of  
12 equipment.”

13 *Id.* The FAC alleges two specific occasions where product was erroneously packaged and Impax  
14 failed to document the root cause of these deviations were contained in the 2009 Form 493 – “failure  
15 to document the probable root cause for product erroneously packaged without desiccant on two  
16 occasions or to document the probable root cause related to that deviation’s impact on product  
17 quality.” *Id.* ¶ 52(a) (emphasis omitted)

18 Between April 7, 2010 and April 22, 2010, three different FDA inspectors toured Impax’s  
19 Hayward facility. *Id.* ¶ 57. These inspectors again provided Mr. Shaw a Form 483 for “[s]ignificant  
20 cGMP deficiencies.” *Id.* This Form 483 “contained *seven* Observations covering nine events  
21 related to manufacturing standards and review of manufacturing.” *Id.* The deficiencies were  
22 generally grouped into three categories:

- 23 (1) Standard operating procedures for “scientifically unsupported cleaning procedures  
24 and deficiencies in completeness;
- 25 (2) test methods, for failure to establish the sensitivity and accuracy of QC testing  
26 methods; and
- 27 (3) lack of review of deviations with regard to metal contamination in product.”

28

1 *Id.* The FAC specifically alleges the Form 483 called out Impax’s “failure to thoroughly review  
2 any unexplained discrepancy whether or not the batch has already been distributed’ and a failure to  
3 address the root cause in the investigation of metal contamination.” *Id.* ¶ 52(b); 58.

4 Six months after receiving the April 2010 Form 483, Arthur Koch – Impax’s Chief Financial  
5 Officer at the time – participated in a Goldman Sachs Healthcare Conference. When asked about the  
6 Form 483s Impax had received from the FDA, Mr. Koch replied that Impax had “gotten a small  
7 number of minor 483s that [Impax] addressed promptly.” *Id.* ¶ 59. He also noted that they had  
8 perceived an increased level of scrutiny by the FDA, and that there was a clear focus on quality by  
9 the FDA. *Id.* ¶ 60. He told the participants that Impax had been able to “enjoy a very good FDA  
10 inspection record,” notwithstanding the Form 483s. *Id.*

11 On January 21, 2011, Impax received a third Form 483 following a two month inspection.  
12 *Id.* ¶ 61. The 2011 Form 483 identified five observations relating to deficiencies in the  
13 manufacturing process or the auditing of the manufacturing process. *Id.* ¶ 62. These were:

- 14 (1) the failure to review “any unexplained discrepancy” – which was marked as a  
15 “repeat” observation by the FDA;
- 16 (2) the lack of control procedures to “validate the performance of manufacturing  
17 processes” thus “potentially causing variability of in-process material”;
- 18 (3) the failure to maintain the equipment “in a manner that would prevent malfunctions  
19 and contamination”;
- 20 (4) the “failure to follow and concurrently document process control procedures”; and  
21 (5) the “failure to establish written procedures.”

22 *Id.* In addition, during the 2011 inspection, an FDA investigator gave Impax’s management a  
23 “verbal warning” for misleading the inspection team. *Id.* ¶ 85. Plaintiff alleges that Impax’s  
24 Director of Technical Services misled an investigator by “referring several times to the metal  
25 contamination in Oxymorphone HCL extended-release as ‘grey particulates’ and continued to do so  
26 until shown documentation showing the “particulates” were, in fact, metal. *Id.*

27 In explaining the “Repeat Observation” – that Impax had failed to thoroughly review any  
28 unexplained discrepancy – the Form 483 pointed to a number of issues. First, it noted that there was

1 continued metal contamination in the product – an issue that had been highlighted for Impax in the  
2 2010 Form 483. *Id.* ¶ 66. In fact, Impax had initiated and closed four “Corrective And Preventative  
3 Actions” (“CAPAs”) to correct this issue, apparently without success. Second, the Form 483 faulted  
4 Impax for failing to properly investigate low-weight capsules in two batches of Impax’s Fenofibrate  
5 products. *Id.* ¶ 67. Additional failures to investigate discrepancies included the failure to identify  
6 the cause of a pungent vinegar-like odor in one of Impax’s products, the presence of black specs in  
7 another (and the failure of Impax to replace equipment causing the specks), and the use of powder  
8 ingredient instead of granular ingredient as required by one product’s specifications. *Id.* ¶ 65. Both  
9 the Form 483 and subsequent EIR noted that these deficiencies were a violation of 21 C.F.R. §  
10 211.192 which requires unexplained discrepancies to be thoroughly investigated. *Id.*

11 The remaining observations generally faulted Impax’s quality control. For instance, the EIR  
12 explained that Impax employees were using pre-filled “batch records” instead of contemporaneously  
13 filling in batch records during the manufacturing process. *Id.* ¶ 69. The FDA inspectors expressed a  
14 belief that technicians were doing this to “save time” and thus were not providing a real-time record  
15 that could then be used in the investigation and resolving of any deviations in finished product that  
16 might result. *Id.* ¶¶ 69, 70. Further, the Form 483 and EIR noted inadequate and perfunctory  
17 investigations into potential discrepancies. *Id.* ¶¶ 73-74. Similarly, the FDA inspectors identified  
18 aging machines which were warped, had chipping paint (which created the risk of paint getting in  
19 pills), and frequent lubrication leaks. *Id.* ¶¶ 75-82. Plaintiff alleges that a number of Impax  
20 technicians – now serving as confidential witnesses for Plaintiff – attempted to tell Impax officials  
21 about the need for new equipment, but were ignored. *See id.* ¶ 75-84.

## 22 2. FDA Issues a Warning Letter to Impax and Impax’s Public Response

23 Impax subsequently received a Warning Letter from the FDA. The Warning Letter stated  
24 that the FDA had reviewed Impax’s response to the 2011 Form 483 and found that it “lacks  
25 sufficient corrective actions.” *Id.* The Warning Letter specifically called out Impax’s lack of  
26 written procedures to “monitor and validate” the manufacturing processes that could have been  
27 responsible for variations in finished products. It further noted the “Repeat Observation” from the  
28

1 2010 and 2011 Form 483s regarding the failure to thoroughly investigate batches not meeting  
2 specifications (for example, through metal contamination). *Id.* ¶ 87.

3 On June 6, 2011, Impax released a press release announcing receipt of the Warning Letter.  
4 *Id.* ¶ 86. This press release included a quote from Larry Hsu – CEO of Impax – which stated:

5 “Impax remains committed to providing the highest quality products  
6 to our customers and working with the FDA to diligently resolve any  
7 issues. . . . We intend to promptly respond to the FDA’s letter, and  
8 have already begun to implement changes and establish procedures  
9 that address the observations cited during hte inspection. We will  
10 work diligently to remedy and outstanding issues in a timely  
11 manner. . . . We don’t anticipate that this manufacturing setback will  
12 delay our ongoing research and development activities. We expect to  
13 continue to develop our generic pipeline of 82 products and two brand  
14 products.”

11 *Id.* ¶ 154 (emphases omitted). Plaintiff alleges that during this time, analysts “responded cautiously  
12 but optimistically” to the press release, with one analyst report stating that the Warning Letter would  
13 likely cause a “temporary halt to approval of pending ANDA [Abbreviated New Drug Application]  
14 applications from the Hayward facility” and that the issues in the Warning Letter “appear fixable,  
15 and should have no long term negative impact” on Impax. *Id.* ¶ 88 (emphases omitted).

16 In an earnings call on August 2, 2011, Mr. Hsu allegedly informed investors that remedial  
17 measures implemented in response to the Warning Letter were nearing completion. *Id.* ¶ 156. He  
18 stated: “Many commitments in our responses are nearing completion as a result of our work since  
19 we received the Form 4[8]3. . . . We hope to be able to close out the warning letter in the next six to  
20 eight months.” *Id.* (emphases omitted). On the same day, Impax released a press release regarding  
21 its Q2 2011 financial results. This press release stated, in part:

22 In late June 2011, we submitted our warning letter response and will  
23 continue to cooperate with the FDA to resolve the observations. We  
24 have already made significant manufacturing and quality control  
25 systems improvements and believe we have addressed a number of the  
26 FDA’s observations.

25 *Id.* ¶ 158 (emphases omitted). Two days later, Mr. Hsu and Mr. Koch signed Impax’s SEC Form  
26 10-Q for Q2 2011. Like the prior press release, this quarterly report stated, in part:

27 We have taken a number of steps to thoroughly review our quality  
28 control and manufacturing systems and standards and are working  
with several third-party experts to assist us with our review. . . . [W]e

1           have made significant quality improvements and are working to  
2           complete the material elements of our internal work as quickly as  
3           possible.

3 *Id.* ¶ 160 (emphases omitted).

4           Three months later in November 2011, Impax officials continued to make similar statements.  
5 In a November 1, 2011 earnings call, Mr. Koch, referring to the clearing of the Warning Letter,  
6 stated “where we are now is on track, and, therefore, I think investors can be comfortable that we’re  
7 where we need to be” and then stated that they expected to hit a deadline of February 2012 for  
8 clearing the warning letter. *Id.* ¶ 162. Two days later, the Form 10-Q for Q3 2011 was released and  
9 stated, in part:

10           We have made significant quality improvements and are working to  
11           complete the material elements of our efforts as quickly as possible  
12           with the goal of being able to close out the warning letter by the end of  
13           February 2012. . . . [W]e cannot assure the FDA will be satisfied with  
14           our responses and corrective actions and/or will not identify additional  
15           observations upon their re-inspection. Unless and until our corrective  
16           action is completed to the FDA’s satisfaction, it is possible we may be  
17           subject to additional regulatory action by the FDA as a result of the  
18           current or future FDA observations . . . .

15 *Id.* ¶ 164 (emphases omitted). Similarly, at a Health Care Conference on November 11, 2011, Mr.  
16 Koch stated a belief that the warning letter would be closed out “before March 1, 2012, in time to  
17 preserve our first-to-file exclusivity on Trilipix, our next pipeline product.” *Id.* ¶ 166.

18           As a result of these assurances from Impax officials, analysts issued reports which stated that  
19 management was “optimistic about [the] potential resolution” of the FDA Warning Letter and that  
20 analysts were “encouraged by m[anagement]’s focus in resolving the FDA Warning Letter.” *Id.* ¶  
21 89. Finally, during an earnings call on February 28, 2012, Mr. Hsu stated “we have done everything  
22 we can including the mock inspections and everything. So we’re pretty confident at this point we  
23 will be able to handle this FDA inspection smoothly.” *Id.* ¶ 168 (emphases omitted).

24           During these months following the issuance of the Warning Letter, Impax officials and the  
25 FDA were in frequent contact. Plaintiff alleges that on June 27, 2011, August 5, 2011, and  
26 September 9, 2011, Impax officials wrote letters to the FDA providing “lengthy detail of the  
27 remedial measures that Impax intended to implement” as well as proposing updated standard  
28 operating procedures for metal detection. *Id.* ¶ 90. Notwithstanding these letters, the FDA sent



1 Impax a letter on October 4, 2011 requesting “additional details” and “clarification.” *Id.* ¶ 91. The  
2 FDA’s letter stated that it “remain[ed] concern[ed] with the corrective and preventative actions to  
3 the metal contamination in [Impax’s] drug products” as Impax was apparently “continu[ing] to rely  
4 on surface inspection” in the new standard operating procedures. *Id.* Accordingly, the FDA  
5 reminded Impax that “surface inspection by itself is not a satisfactory method to confirm or dismiss  
6 metal contamination.” *Id.* Finally, it noted that Impax had still failed to identify the root cause or  
7 causes of the underlying metal contamination. *Id.*

8 Impax responded with a number of letters detailing additional Corrective And Preventative  
9 Actions taken and ultimately, on January 18, 2012, informed the FDA that it had completed its  
10 response to the May 2011 Warning Letter. *Id.* ¶ 92.

11 3. 2012 FDA Inspection and Form 483

12 In early 2012, Impax brought in a third-party consulting firm – TEVA – to audit its Hayward  
13 manufacturing facility. *Id.* ¶ 94. Notwithstanding this fact, Impax received its fourth Form 483 on  
14 March 28, 2012. *Id.* ¶ 93. This Form 483 identified five general observations, supported by three  
15 separate examples. *Id.* Three of the observations related to the QC Laboratory: (1) drug products  
16 not being rejected when they failed to meet established standards; (2) investigations into the failure  
17 of a particular batch of product did not extend into other batches of the same products; and (3)  
18 standard operating procedures for testing and sampling were not followed. *Id.*

19 Observations 4 and 5 related directly to manufacturing processes. Observation 4 noted that  
20 Impax had failed to follow written production and process control procedures. *Id.* ¶ 94. For  
21 example, investigators noted that equipment which had been improperly stored in a manufacturing  
22 room was then used in production and sometimes contained an unidentified residue. *Id.* Further,  
23 they noted that equipment failures requiring non-routine maintenance were not consistently  
24 investigated. *Id.* Observation 5 involved a “failure to document and investigate discrepancies that  
25 arise during the course of manufacturing and QC analytical testing.” *Id.* ¶ 95. Examples included  
26 “unexpected manufacturing discrepancies, including but not limited to critical equipment failures.”  
27 *Id.*

28

1 Impax responded to the 2012 Form 483 in public by stressing that the issues involved were  
2 independent from those which had led to the Warning Letter. *Id.* ¶ 97. For example, during a May  
3 1, 2012 earnings call, Mr. Hsu called the 2012 Form 483 a “temporary roadblock” and stated that the  
4 FDA’s reinspection relating to the May 2011 warning letter had been conducted and they were “not  
5 aware of any outstanding issue left on that.” *Id.* ¶ 170. Similarly, at a healthcare conference in June  
6 2012, Mr. Koch stated: “It’s important to understand, there were no repeat observations, so that’s a  
7 way to be satisfied that the items included under the original warning letter are resolved to the  
8 satisfaction of the agency.” *Id.* ¶ 174. He further noted that the issues in the 2012 Form 483 were  
9 only in the QC Lab and that the FDA “only get to that spot if they’re satisfied with what’s going on  
10 in manufacturing.” *Id.* Finally, in September 2012, Mr. Hsu stated: “When the inspection – the re-  
11 inspection occurred in February and March, the inspector looked at the manufacturing areas, and  
12 there was no question no outstanding issue at all. They were pretty happy with what they have  
13 seen.” *Id.* ¶ 176 (emphases omitted).

14 4. 2013 FDA Inspection and Form 483

15 On March 4, 2013, Impax announced that the FDA had conducted a re-inspection based on  
16 the 2011 Warning Letter as well as a general GMP inspection and had received a fifth Form 483. *Id.*  
17 ¶ 180. This most recent 2013 Form 483 included twelve observations – three of which were labeled  
18 as “repeat observations” from the 2011 Form 483 (i.e., observations of issues that existed before the  
19 Warning Letter). *Id.* That day, during a conference call with investors, Mr. Hsu stated that the  
20 “FDA standard is . . . much higher today versus a few years ago” and that “everyone knows to fix  
21 the quality it takes time.” *Id.* ¶ 182. He also stated:

22 “So I think from that point of view, we now learned the lesson that this  
23 is no longer [sic] internal program. We’re going to have to really  
24 work with the FDA, keep them posted on the progress and we’re going  
25 to have to get there [sic] as many consultants as we can to help on this  
whole thing which we are doing now, okay? And so, my thinking is  
that it does have the increased urgency significantly on this internal  
program.”

26 *Id.* Analysts reacted negatively to the 2013 Form 483, asserting during the conference call that it  
27 “almost seems like [Impax] keep[s] studying for the wrong exam” and that the new Form 483 was  
28 “obviously very indicative of some systematic issue.” *Id.* ¶ 183. Another analyst noted:

1 “I think there is a disconnect between what you all are doing and what  
2 our expectations are. We would’ve expected you were putting  
3 maximal effort that, the program was going as fast as possible, that  
4 you would have hired as many consultants as you possibly would have  
needed. So it seems from an outsider these things don’t make a ton of  
sense why you keep on getting a lot of questions around it.”

5 *Id.* The market also responded drastically, with Impax common stock going from \$20 per share to  
6 \$14.80 per share – causing Impax to lose 26% of its market capitalization. *Id.* ¶ 184.

7 Plaintiff alleges that Impax officials issued statements in 2013 that were wholly inconsistent  
8 with their prior statements from 2011 that the Warning Letter would only take twelve to eighteen  
9 months to clear. For example, during a March 6, 2013 presentation, Mr. Hsu stated that “one of the  
10 important thing[s] we learned in the last two years is quality improvement is a continuing process.  
11 It’s not something you can put a lot of money and resources and get it done in one year, and then say  
12 we’re done with the business.” *Id.* ¶ 185 (emphasis added). Similarly, during a May 2013  
13 conference call, he stated that “it takes time, the [quality improvement program] can take two, three  
14 years to get implement[ed] on those [changes], okay.” *Id.* ¶ 186.

15 C. Impax’s Alleged Awareness of Pervasive Manufacturing and QC Deficiencies

16 Plaintiffs allege that Impax knew that the Hayward facility had pervasive manufacturing and  
17 QC deficiencies, such that it had no reasonable basis to assure investors that it could clear the FDA  
18 Warning Letter in a timely manner. The basis of these allegations depend primarily on confidential  
19 witnesses who were allegedly employed by Impax during the relevant period.

20 According to Confidential Witness 1 – a Manufacturing Technician II with Impax from 2006  
21 through 2013 – Impax would frequently make temporary, “band aid” changes to their processes but  
22 quickly revert to their original practice once the FDA inspection ended. For example, this CW  
23 recalled that sometime after the 2011 Warning Letter, the FDA instructed Impax to place various  
24 ingredients involved in separate phases of production in separate rooms to avoid cross  
25 contamination. *Id.* ¶ 102. Impax did this, but one week after the FDA investigators left, all the  
26 ingredients were returned to their original location in the warehouse, re-exposing them to potential  
27 cross-contamination. *Id.* Similarly, Confidential Witness 5 – a Senior Manufacturing Supervisor  
28 from 2002 through 2012 – noted that when Impax knew the FDA was inspecting the facility, they

1 would stop production of certain products to minimize the production of dust and hide from the FDA  
2 that they had inadequate dust collection procedures. *Id.* ¶ 103. Similarly, Confidential Witness 11 –  
3 a Warehouse Supervisor from 2009 through 2013 – states that in the weeks prior to the 2012 and  
4 2013 FDA inspections, he was ordered to move equipment and supplies from the manufacturing  
5 facility and “hide” them in a dirty, not-secure warehouse that the FDA did not know about. *Id.* ¶  
6 105-06. After the FDA inspection was finished, he would be ordered to return the equipment from  
7 the warehouse to the manufacturing facility. *Id.* ¶ 107.

8 Plaintiffs further allege that other confidential witnesses have attested to the fact that  
9 sanitation and cleanliness were frequently a problem at the Hayward manufacturing facility. For  
10 example, Confidential Witness 12 – a Manufacturing Technician and Tooling Specialist from 2006  
11 through 2012 – states that on a number of occasions when a panel came off a machine – exposing  
12 the machine and product to contamination – he was ordered to keep the machine running instead of  
13 shutting it down for sterilization as required. *Id.* ¶ 110. Confidential Witness 5 states that during  
14 town hall meetings with executive members, manufacturing technicians complained about the lack  
15 of appropriate cleaning equipment and insufficient cleaning areas. *Id.* ¶ 113. Other employees  
16 found insects in the main manufacturing facility. The company’s procedures require production to  
17 stop processing batches if insects were found, but shift managers would instruct the technicians to  
18 just ‘keep going.’ *Id.* ¶ 114.

19 Plaintiffs and their confidential witnesses also assert that Impax officials were primarily  
20 concerned with wrapping up paperwork and closing investigations, rather than actually fixing  
21 problems. *Id.* ¶ 116. For example, Confidential Witness 2 – a Supervisor at the Hayward  
22 manufacturing facility from 2002 through April 2011 – reported that a Manufacturing Compliance  
23 Manager was “more concerned about the timeline” of paperwork completion than “determining the  
24 true cause of a problem.” *Id.* ¶ 116. Further, other confidential witnesses reported haphazard or  
25 incomplete record keeping. Confidential Witness 4 – a manufacturing technician from February  
26 2011 through January 2012 – noted that when there was an error on product batch records, the  
27 manufacturing technicians would simply write “entry error” on any batch record amended rather  
28 than determining what actually caused the error. *Id.* ¶ 118. Similarly, Confidential Witness 7 – a

1 Quality Assurance Investigation Consultant employed by the Validant consulting firm – reports that  
2 Impax recorded data in a convoluted way, preventing him from resolving a number of investigations  
3 due to gaps in data. *Id.* ¶ 123. He was further discouraged from initiating Corrective and  
4 Preventative Actions (“CAPAs”) to establish new training and practices in this area. *Id.*

5 The FAC alleges that technicians routinely violated standard operating procedures.  
6 Confidential Witness 4 asserts that on a number of occasions, the technicians left machines  
7 unsupervised during production. *Id.* ¶ 129. Further, this witness alleges that more senior  
8 technicians would disregard standard operating procedures – and order more junior technicians to do  
9 the same – in favor of their own personal habits or procedures they felt were superior. *Id.* ¶ 130. By  
10 way of example, Confidential Witness 4 reported that technicians would clean a machine by simply  
11 rinsing it with plain water despite the fact that operating procedures required it to be rinsed with  
12 distilled water, soap scrubbed, and then rinsed a second time. *Id.* In addition, Confidential Witness  
13 10 – a former Associate Director of HR – had to take disciplinary action against manufacturing  
14 technicians who used barrels of obsolete materials in the production process. *Id.* ¶ 132. To  
15 demonstrate that there was an awareness and tacit tolerance of standard operating procedures being  
16 violated, Plaintiffs allege that at a meeting following issuance of the Warning Letter, various  
17 technicians complaint about how the standard operating procedures slowed production. *Id.* ¶ 135. A  
18 supervisor responded by saying “That is the way you’re supposed to do it. If you think you can do it  
19 better, then so be it” before adding that “if you get caught doing it the wrong way, you’ll get in  
20 trouble.” *Id.*

21 Plaintiffs also allege that Impax’s facilities were simply unequipped to handle GMP  
22 regulations and could not adopt wholesale QC improvements given the limitations in the facilities,  
23 equipment, space, and technology. During a town hall meeting shortly after the 2011 Warning  
24 Letter, Mr. Hsu purportedly stated that “the way [Impax] [was] doing business was fine back in the  
25 day, but the FDA became more sophisticated” and acknowledged that Impax needed to change. *Id.*  
26 ¶ 145. According to Plaintiffs’ Confidential Witnesses, however, the publicly announced goal of  
27 clearing the Warning Letter by February 2012 was “not realistic” and that it was unlikely that Impax  
28 would pass an FDA inspection given the scope of the problems at the manufacturing facility and the

1 nature of the equipment. *Id.* ¶ 146. The facilities and equipment at Impax’s Hayward facility are  
2 alleged to have been significantly out-dated with little to no automation. *Id.* ¶ 147. Similarly, none  
3 of its lab data or notebooks were kept digitally. *Id.* ¶ 148.

4 Plaintiffs ultimately allege that senior management either had knowledge, or recklessly  
5 disregarded evidence of, the above issues. They support this allegation by reference to the multiple  
6 levels of review of manufacturing batch records. For instance, Confidential Witness 6 notes that  
7 when a batch was under investigation, the entire batch was held for 20-25 days during which the  
8 product did not leave the plant. *Id.* ¶ 151. This would, allegedly, cause the supply staff to become  
9 “stressed.” *Id.* As a result, Plaintiffs allege that “even if executives attempted to ignore QC gaps,  
10 they nonetheless would inevitably become aware of the pervasive QC shortfalls by virtue of their  
11 investment in releasing product for distribution to meet sales goals.” *Id.* Confidential Witness 6  
12 specifically alleges that “I know for a fact that if we happened to get a deviation with a product, Jeff  
13 [Blumenfeld– Senior Director of Manufacturing–] would be called over to the building where  
14 exec[utive]s are and have a meeting. There were instances where Jeff was called over to Larry  
15 [Hsu] to discuss what was going on with this or that product.” *Id.* This witness further alleges that  
16 Mr. Blumenfeld “regularly met in person on a weekly basis with Defendant Hsu, while Blumenfeld  
17 and Hildenbrand (VP of Operations) met even more frequently.” *Id.* ¶ 151.

18 In summary, Plaintiffs allege that over the span of three years, from 2009 through 2012, the  
19 FDA repeatedly warned Defendants of their deficient manufacturing conditions, failure to properly  
20 document and investigate discrepancies, and failure to properly conduct quality control procedures.  
21 Despite these warnings, Plaintiffs allege – through a number of confidential witnesses – that  
22 Defendants either failed to undertake any action to address these concerns or applied temporary  
23 fixes or otherwise sought to hide issues from the FDA (for example, by hiding material, machinery,  
24 and the like). At the same time, however, Defendants are alleged to have made repeated statements  
25 trumpeting the remediation efforts they had employed to address the FDA’s concerns.

### 26 **III. DISCUSSION**

27 Under Federal Rule of Civil Procedure 12(b)(6), a party may move to dismiss based on the  
28 failure to state a claim upon which relief may be granted. *See* Fed. R. Civ. P. 12(b)(6). While “a

1 complaint need not contain detailed factual allegations . . . it must plead ‘enough facts to state a  
2 claim to relief that is plausible on its face.’” *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th  
3 Cir.2009). “A claim has facial plausibility when the plaintiff pleads factual content that allows the  
4 court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”  
5 *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009); *see also Bell Atl.*  
6 *Corp. v. Twombly*, 550 U.S. 544, 556, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). “The plausibility  
7 standard is not akin to a ‘probability requirement,’ but it asks for more than sheer possibility that a  
8 defendant acted unlawfully.” *Iqbal*, 129 S.Ct. at 1949.

9 Plaintiffs allege two causes of action. First, they argue that Defendants violated Section  
10 10(b) of the Securities Exchange Act by disseminating false statements regarding Impax’s ability to  
11 respond to the FDA Warning Letter. *See* 15 U.S.C. § 78j(b) (prohibiting “manipulative or  
12 deceptive” devices or contrivances in connection with the purchase or sale of securities). Second,  
13 they assert a cause of action alleging a violation of Section 20(a) of the Securities Exchange Act.  
14 *See id.* § 78t(a) (imposing joint and several liability on any individual who “directly or indirectly”  
15 controls any person liable for a violation of the Exchange Act).

16 Where, as here, the plaintiffs assert a claim for securities fraud pursuant to § 10(b) and Rule  
17 10b–5, the plaintiffs must allege: “(1) a material misrepresentation or omission of fact, (2) scienter,  
18 (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5)  
19 economic loss.” *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1014 (9th Cir.2005) (citing *Dura*  
20 *Pharm., Inc. v. Broudo*, 544 U.S. 336, 341–42, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005)). To allege  
21 a claim pursuant to § 20(a), the plaintiffs must allege: “(1) a primary violation of federal securities  
22 law, and (2) that the defendant exercised actual power or control over the primary violator.”  
23 *Howard v. Everex Sys.*, 228 F.3d 1057, 1065 (9th Cir.2000). Here, the primary violation claimed is a  
24 violation of § 10(b) and Rule 10b–5. If Plaintiffs fail to plead a claim for securities fraud under  
25 § 10(b) and Rule 10b–5, the § 20(a) claim fails as well.

26 To assert a § 10(b) and Rule 10b–5 claim, the plaintiffs must meet the particularity  
27 requirements of Federal Rule of Civil Procedure 9(b). *In re Daou Sys.*, 411 F.3d at 1014. Rule 9(b)  
28 states that “in all averments of fraud or mistake, the circumstances constituting fraud or mistake

1 shall be stated with particularity.” The pleading requirement is further heightened by the Private  
 2 Securities Litigation Reform Act (“PSLRA”), which requires that a plaintiff “plead with particularity  
 3 both falsity and scienter.” *Id.* To properly plead falsity, a securities fraud complaint must “specify  
 4 each statement alleged to have been misleading, the reason or reasons why the statement is  
 5 misleading, and if an allegation regarding the statement or omission is made on information and  
 6 belief, state with particularity all facts on which that belief is formed.” *Zucco Partners, LLC v.*  
 7 *Digimarc Corp.*, 552 F.3d 981, 990–91 (9th Cir.2009) (citation omitted). Likewise, to properly  
 8 plead scienter, the complaint must “state with particularity facts giving rise to a strong inference that  
 9 the defendant acted with the required state of mind.” *Id.* at 991 (quoting 15 U.S.C. § 78u–4(b)(2)  
 10 (2006)). In determining whether there is a “strong inference,” the court must find sufficient  
 11 allegations of scienter such that “a reasonable person would deem the inference of scienter cogent  
 12 and at least as compelling as any opposing inference one could draw from the facts alleged.” *Id.*  
 13 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324, 127 S.Ct. 2499, 168  
 14 L.Ed.2d 179 (2007)). Thus, the court must consider the complaint in its entirety and “compare the  
 15 malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow  
 16 the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as  
 17 any opposing innocent inference.” *Id.*

18 A. Plaintiffs Have Adequately Alleged a False Statement of Material Fact

19 The FAC alleges that the following statements made by Defendants are false or misleading  
 20 statements of material fact:

- 21 • **June 6, 2011 Press Release:** “Impax remains committed to providing the highest quality  
 22 products to our customers and working with the FDA to diligently resolve any issues. . . . We  
 23 intend to promptly respond to the FDA’s letter, and have already begun to implement  
 24 changes and establish procedures that address the observations cited during the inspection.  
 25 We will work diligently to remedy any outstanding issues in a timely manner . . . . We don’t  
 26 anticipate that this manufacturing setback will delay our ongoing research and development  
 27 activities. We expect to continue to develop our generic pipeline of 82 products and two  
 28 brand products.” FAC ¶ 154.
- **August 2, 2011 Earnings Call, Mr. Hsu Statement:** “Many commitments in our responses  
 are nearing completion as a result of our work since we received the Form 4[8]3.... We hope  
 to be able to close out the warning letter in the next six to eight months.” FAC ¶ 156.



- 1 • **August 2, 2011 Press Release:** “We have already made significant manufacturing and  
 2 quality control systems improvements and believe we have addressed a number of the FDA’s  
 observations.” FAC ¶ 158.
- 3 • **2011 Q2 10-Q Report:** “We have taken a number of steps to thoroughly review our quality  
 4 control and manufacturing systems and standards and are working with several third-party  
 5 experts to assist us with our review . . . . [W]e have made significant quality improvements  
 and are working to complete the material elements of our internal work as quickly as  
 possible.” FAC ¶ 160.
- 6 • **November 1, 2011 Earnings Call, Mr. Koch Statement:** “[W]here we are now is on track,  
 7 and, therefore, I think investors can be comfortable that we’re where we need to be and we  
 expect to hit that target [of the February 2012 deadline].” FAC ¶ 162.
- 8 • **2011 Q3 10-Q Report:** “We have made significant quality improvements and are working  
 9 to complete the material elements of our efforts as quickly as possible with the goal of being  
 able to close out the warning letter by the end of February 2012. However, FDA  
 10 re-inspection is required to close out the warning letter, the timing of the re-inspection is  
 wholly dependent upon FDA’s availability, and we cannot assure the FDA will be satisfied  
 11 with our responses and corrective actions and/or will not identify additional observations  
 upon their re-inspection. Unless and until our corrective action is completed to the FDA’s  
 12 satisfaction, it is possible we may be subject to additional regulatory action by the FDA as a  
 result of the current or future FDA observations . . . .” FAC ¶ 164.
- 13 • **November 11, 2011, Mr. Hsu Statement:** “With so much of our future and our value in our  
 14 pipelines, we cannot tolerate meaningful deviations from cGMP such as those outlined in the  
 letter. We have made a commitment to quality that is evidenced in many ways beyond our  
 15 response to the FDA’s letter, including we have begun to upgrade our management and our  
 systems so that future inspections as well as the necessary re-inspection go well. The agency  
 16 frequently cites that a firm’s quality standards emanate from the top and we have developed  
 a very simple clear message. We will comply, we will stay abreast of developments in our  
 17 industry and we will remain compliant as we build our business. The tasks necessary to  
 address the three issues raised in the letter are well underway and an even greater effort to  
 18 upgrade our global quality system was initiated at the direction of our new leadership in both  
 quality and manufacturing . . . . [w]e believe we can close out the warning letter before  
 19 March 1, 2012, in time to preserve our first-to-file exclusivity on Trilipix, our next pipeline  
 product. Of course this estimate depends heavily on the timing of the FDA’s review. . . .”  
 20 FAC ¶ 166.
- 21 • **February 28, 2012 Earnings Call, Mr. Hsu Statement:** “As we pointed out in the past that  
 22 we cannot adjust on the timing [on a reinspection from the FDA], but from our end we have  
 done everything we can including the mock inspections and everything. So we’re pretty  
 confident at this point we will be able to handle this FDA inspection smoothly.” FAC ¶ 168.
- 23 • **May 1, 2012 Earnings Call, Mr. Hsu Statement:** “Even though the recent FDA inspection  
 24 had no repeat deficiencies or observations from those cited in the 2011 warning letter, we are  
 disappointed to have a new [F]orm 483 related to our quality control laboratory. We have  
 25 responded to the FDA on the items mentioned in this 483 and will continue to work as  
 quickly as possible to resolve these items. . . . It remains the top priority throughout the  
 26 company . . . . [W]e will continue to devote every available resource in order to achieve and  
 maintain FDA compliance. This temporary roadblock has not prevented us from continuing  
 27 to manufacture . . . . [A]t this point, [the] FDA has conducted the reinspection in connection  
 to the [May 2011] warning letter and as of today we’re not aware of any outstanding issues  
 28 left on that.” FAC ¶ 170.

- 1 • **May 16, 2012 Statements by Mr. Koch and Mr. Hsu:** “[W]e’re very confident that we’ll  
2 be able to deal with all of the issues we face and resolve this current report as quickly as  
3 possible” and “While we don’t know the exact the timing on that, but [sic] we have a real  
4 confidence that we will get the issue resolved.” FAC ¶ 172.
- 5 • **June 7, 2012 Statement by Mr. Koch:** “The[] [FDA] went on to do a full cGMP  
6 inspection. They went into the QC lab, that’s the last stop before the product is distributed,  
7 and observed these additional items. It’s important to understand, there were no repeat  
8 observations, so that’s a way to be satisfied that the items included under the original  
9 warning letter are resolved to the satisfaction of the agency . . . . [The new cited violations  
10 are] in the QC lab and that is – that only – they only get to that spot if they’re satisfied with  
11 what’s going on in manufacturing. It’s only a policy and procedures kind of comment and  
12 issue. We were able to revise the policies and procedures before the inspectors left the  
13 office. So it’s a very easy thing to address. Now we [are] working with them on their  
14 remaining questions as to our current product.” FAC ¶ 174.
- 15 • **September 20, 2012 Statement by Mr. Hsu:** “When the inspection – re-inspection  
16 occurred in February and March, the inspector looked at the manufacturing areas, and there  
17 was no question no outstanding issue at all. They were pretty happy with what they have  
18 seen. However, they did look at the QC lab, when the[y] look[ed] at it they found some  
19 problem[s], procedure problem[s].” FAC ¶ 176.
- 20 • **October 30, 2012 Earnings Call, Mr. Hsu Statement:** “But at this point, as I pointed out  
21 earlier, we’re confident we’ll get out of here, although timing, unfortunately, is not in our  
22 control, as we’re waiting for [the] FDA to take the action on that. But I think we feel well  
23 prepared for this.” FAC ¶ 178.

24 Defendants argue that the above statements are not actionable because: (1) Plaintiffs have failed to  
25 allege facts suggesting that the statements were false when made; (2) that the PSLRA’s “safe  
26 harbor” provision applies, and (3) the statements are non-actionable “puffing” or statements of  
27 opinion. The Court addresses each argument in turn.

28 1. Plaintiffs Have Adequately Alleged that the Statements Were False When Made

Defendants argue that Plaintiffs have failed to allege that the statements contained in the  
FAC were actually false when they were made. Under §78u-4(b)(1), plaintiffs must “specify each  
statement alleged to have been misleading, the reason or reasons why the statement is misleading,  
and, if an allegation regarding the statement or omission is made on information and belief . . . the  
complaint shall state with particularity all facts on which that belief is formed.” 15 U.S.C.  
§ 78u(b)(1). Thus, in order to be actionable the statement in question must have been false when  
made. *See Feyko v. Yuhe Intern., Inc.*, No. CV 11-05511 DDP (PJWX), 2013 WL 816409, at \*4  
(C.D. Cal. Mar. 5, 2013). Further, “[t]o be actionable under the securities laws, an omission must be  
misleading; in other words it must affirmatively create an impression of a state of affairs that differs

1 in a material way from the one that actually exists.” *Brody v. Transitional Hospitals Corp.*, 280  
 2 F.3d 997, 1006 (9th Cir. 2002).

3 a. For Purposes of the Motion to Dismiss, Plaintiffs Have Adequately Alleged  
 4 Defendants’ Statements Were False When Made

5 As to each challenged statement, Plaintiffs allege that the statement was “materially false and  
 6 misleading when made because they failed to disclose the following adverse material facts, which  
 7 were known to Defendants or recklessly disregarded by them and which, if disclosed, would have  
 8 rendered Defendants’ statements not misleading: that Impax was not equipped to address and  
 9 remedy the observations of GMP deficiencies as cited in the Warning Letter.” FAC ¶ 155, 157, 159,  
 10 161, 163, 165, 167, 169, 171, 173, 175, 177, 179. Plaintiffs state that Defendants were “not  
 11 equipped to address and remedy” the observations because:

- 12 • “(a) Impax had a practice and culture of implementing and reversing  
 13 corrective measures as a temporary solution to pass FDA onsite inspections.”  
*Id.* ¶ 155.
- 14 • “(b) Impax had a demonstrated history of problems with cleanliness and  
 15 sanitation exacerbated by its lack of space for its operations, the failure to stop  
 16 production when insects were found or as required when certain machinery  
 malfunctioned, and technicians chronically disregarded SOPs pertinent to  
 cleaning.” *Id.*
- 17 • “(c) Impax employees did not observe proper cGMP practices regarding  
 18 documentation and maintenance of adequate batch records because  
 19 technicians pre-filled or wholesale completed batch records rather than doing  
 20 so step-by-step, employees in the laboratory maintained a convoluted and  
 21 confusion system to record raw data, and technicians or audit teams failed to  
 22 fully investigate . . . deviations in production.” *Id.*
- 23 • (d) Impax had antiquated machinery that was in chronic disrepair . . .” *Id.*
- 24 • (e) “Impax had continually failed to locate all root causes of metal  
 25 contamination and the ‘black specks’ contamination in other tablets.” *Id.*
- 26 • “(f) Impax employees rampantly disregarded SOPs and trained new staff to  
 27 disregard SOPs . . .” *Id.*
- 28 • “(g) both before and after the Class Period . . . Impax repeatedly appointed or  
 failed to remove employees who were or became unqualified or untrained for  
 their positions.” *Id.*
- “(h) both before and after the Class Period, Impax facilities were generally  
 inadequate because they lacked sufficient space to avoid storing products  
 incorrectly in the hallways or non-conforming warehouses, equipment was  
 lacking or technologically insufficient to support proper cGMP practices.” *Id.*

- 1
- 2 • “(I) both before and after the Class Period . . . Impax failed to fully investigate and document deviations in manufacturing.” *Id.*

3  
4 In light of the extensive confidential witness allegations (discussed *infra*), and taking all  
5 inferences in the light most favorable to Plaintiffs, the Court concludes that Plaintiffs have  
6 adequately alleged that the statements contained in the FAC were false or misleading when made.  
7 The FAC alleges recurring and pervasive problems with the manufacturing and quality control  
8 processes at Impax’s Hayward facility – many of which were identified by the FDA on more than  
9 one occasion. Other allegations describe actions which call into question whether there was ever a  
10 true commitment to remedy the manufacturing and quality control problems. For example, Plaintiffs  
11 allege – through three separate confidential witnesses – that it was routine procedure for Defendants  
12 to implement “temporary” changes/improvements to pass an FDA inspection only to undo the  
13 change shortly after the inspection concluded. Some of these incidents are alleged to have occurred  
14 after the 2011 Warning Letter and Defendants’ statements about remediation efforts being  
15 employed. *Id.* ¶¶ 102-109.

16 Further, the 2011 Warning Letter highlighted two issues – (1) lack of written procedures to  
17 monitor and validate manufacturing processes that could have caused product variability and (2)  
18 failure to investigate deviations in the manufacturing process. *Id.* ¶ 87. However, notwithstanding  
19 the statements in 2011 that changes and procedures had been implemented to address the  
20 observations (and, in fact, that these changes were “nearing completion”), similar observations were  
21 raised by the FDA in the 2013 Form 483. Specifically, it is alleged that the 2013 Form 483 cited  
22 Impax’s “failure to thoroughly review an unexplained discrepancy and the failure of the batch or any  
23 of its components to meet . . . specifications.” *Id.* ¶ 99. Thus, similar issues were subsequently  
24 found 18 months after Defendants stated that they had implemented changes to address the FDA  
25 concerns.<sup>1</sup>

26

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27 <sup>1</sup> Both in their papers and at the hearing, the parties debated the significance of the FDA  
28 flagging, or not flagging, certain observations as “Repeat Observations.” The FAC has alleged that  
FDA inspectors may, but are not required to, mark a recurring or not corrected observation as  
a “Repeat Observation.” The Court need not resolve the significance of some observations being  
labeled as a “Repeat Observation” while others were not. Rather, the Court finds it sufficient for its

1 Of course, the fact that Defendants’ remediation efforts may have ultimately been  
2 unsuccessful or insufficient does not, on its own, establish the falsity of Defendants’ statement at the  
3 time they were made. *See N.Y. State Teachers’ Ret. Sys. v. Fremont Gen. Corp.*, No. 2:07-cv-5756-  
4 FMC-FFMx, 2009 WL 3112574, at \*10 (C.D. Cal. Sept. 25, 2009) (“[T]he fact that subsequent  
5 disclosures revealed that the remedial measures were not sufficient does not render false the  
6 individual Defendants’ contemporaneous statements about those measures.”). However, given the  
7 pervasive, recurring, and long-standing nature of the alleged problems identified in the FAC, the  
8 Court cannot conclude (at this stage) that Defendants’ statements regarding the remediation efforts  
9 being implemented were not false or misleading when made.

10 Similarly, the Court finds that Plaintiffs have adequately alleged that Defendants’  
11 representations regarding the nature of the 2012 Form 483 were false or misleading. Plaintiffs  
12 generally allege that Defendants misrepresented that the FDA’s concerns in the Form 483 only  
13 addressed the QC lab, and there were no issues with manufacturing. Plaintiffs have alleged that the  
14 2012 Form 483 did, in fact, refer to manufacturing issues. Specifically, the Form 483 targeted: (1)  
15 Defendants’ failure to follow “written production and process control procedures” with examples  
16 being Defendants’ storing equipment in the manufacturing room and being coated in unidentified  
17 product residue and equipment failures that were not consistently investigated; and (2) “failure to  
18 document and investigate discrepancies that arise during the course of manufacturing and QC  
19 analytical testing.” FAC ¶ 94-95.

20 The Court must view allegedly false statements “in full and in context at the time it was  
21 made.” *In re Syntex Corp. Securities Litig.*, 95 F.3d 922, 929 (9th Cir. 1996). Defendants attempt to  
22 argue that in context, the Defendants were simply asserting that there were no “Repeat  
23 Observations” regarding manufacturing in the 2012 Form 483. The Court disagrees. The FAC  
24 alleges Defendants made broad statements regarding the FDA’s purported approval of Impax’s  
25 manufacturing processes. For example: “When the inspection – re-inspection occurred in February  
26

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27 purposes of the Rule 12(b)(6) motion to note that the description of the observations from one year  
28 to another gives rise to a reasonable inference that problems were not adequately addressed or  
remediated.

1 and March, the inspector looked at the manufacturing areas, and there was no question no  
2 outstanding issue at all. They were pretty happy with what they have seen.” FAC ¶ 176. This is  
3 simply not true according to the FAC – the 2012 Form 483 highlighted issues with the  
4 manufacturing process. Further, even if the statement was meant to imply there were no *recurring*  
5 manufacturing issues identified, this, too, appears inaccurate. Specifically, the 2012 Form 483  
6 included as one of its observations the “failure to document and investigate discrepancies that arise  
7 during the course of manufacturing and QC analytical testing.” *Id.* ¶ 95. As discussed above, the  
8 FDA had previously highlighted (in 2009, 2010, and 2011) Impax’s failure to investigate deviations  
9 during the manufacturing process. *See id.* ¶ 87.

10 Accordingly, the Court concludes, for purposes of the motion to dismiss only, that Plaintiffs  
11 have alleged with sufficient particularity under the PSLRA and the plausibility standard of *Iqbal* and  
12 *Twombly* that the statements identified in the FAC were false or misleading when made.

13 b. The FAC Properly Alleges and Relies Upon Confidential Witnesses

14 In describing why Defendants’ representations were false when made, Plaintiffs rely  
15 extensively on factual allegations obtained from confidential witnesses. Defendants argue that the  
16 confidential witness allegations should be disregarded as unreliable. Under Ninth Circuit law, a  
17 “confidential witness must be ‘described with sufficient particularity to establish [his or her]  
18 reliability and personal knowledge’” – that is, “‘with sufficient particularity to support the  
19 probability that a person in the position occupied by the source would possess the information  
20 alleged.’” *Oclaro*, 2013 WL 2384244, at \*9 (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552  
21 F.3d 981, 995 (9th Cir. 2009)). In determining the reliability of confidential witnesses, the court  
22 must look at the “level of detail provided by the confidential sources, the corroborative nature of the  
23 other facts alleged (including from other sources), the coherence and plausibility of the allegations,  
24 the number of sources, the reliability of the sources, and similar indicia.” *Zucco Partners*, 552 F.3d  
25 at 995. The Ninth Circuit has held that numbering the confidential witnesses and describing the  
26 witnesses’ job description and responsibilities constitutes a “large degree of specificity,” especially  
27 where the witnesses’ exact title is used. *In re Daou Sys., Inc.*, 411 F.3d 1006, 1016 (9th Cir. 2005).

28

1 The Court finds that the FAC has provided sufficient, particularized allegations regarding the  
2 reliability and personal knowledge of the confidential witnesses. The FAC has identified thirteen  
3 confidential witnesses who have provided consistent accounts of the conditions, practices, and  
4 procedures of Impax within their respective spheres. While the Defendants assert that Plaintiffs  
5 have only utilized “vague job titles,” Plaintiffs assert they have used the actual titles used by Impax.  
6 A review of the complaint supports Plaintiffs’ assertion. *See, e.g.*, FAC ¶ 22 (CW 1 described as a  
7 “Manufacturing Technician II”); *id.* ¶ 24 (listing that CW 3 occupied the positions of  
8 “Manufacturing Technician I,” then served as “Production Engineering Associate,” and then as  
9 “Manufacturing Engineer”); *id.* ¶ 27 (listing CW 6 as “Associate Director of Manufacturing” and  
10 “Associate Plant Manager”). In addition, the FAC states to whom each confidential witness  
11 reported. The Court finds that the description of job titles and job responsibilities have been stated  
12 with sufficient particularity. *See In re Daou*, 411 F.3d at 1016 (“Plaintiffs here describe the  
13 confidential witnesses with a large degree of specificity. Plaintiffs number each witness and  
14 describe his or her job description and responsibilities. In some instances, plaintiffs provide the  
15 witnesses’ exact title and to which Daou executive the witness reported.”).

16 Defendants also argue that 9 of the confidential witnesses – CWs 1-4, 6, 10-13 – are not  
17 alleged to have any connection to Impax’s remediation efforts and therefore had “no personal  
18 knowledge as to whether or not Impax had the ability to resolve the warning letter.” Mot. to  
19 Dismiss at 17-18. Defendants view the inquiry too narrowly. Plaintiffs use the confidential  
20 witnesses in an attempt to demonstrate the pervasive and systemic nature of Impax’s problems and  
21 the purposefulness in failing to address and remedy these problems, from which the falsity of  
22 Defendants’ statements about Impax’s remedial efforts may be inferred. The question, therefore, is  
23 whether Plaintiffs have properly alleged facts suggesting that the confidential witnesses have  
24 personal knowledge about the incidents they address. The Court finds that they have. Defendants  
25 provide two examples – CW 5 and CW 8 – for which they argue Plaintiffs have provided only  
26 “vague allegations” of personal knowledge. Motion to Dismiss at 18. CW 5 is alleged to have been  
27 a “Senior Manufacturing Supervisor” who observed manufacturing technicians and “oversaw all  
28 aspects of manufacturing operations to facilitate compounding tableting, encapsulation, and

1 coating.” FAC ¶ 26. Plaintiffs further allege that CW5 “drafted work schedules and reviewed batch  
2 records, and was charged with maintaining compliance with FDA regulations.” *Id.* The FAC  
3 contains a number of specific incidents and issues that CW 5 allegedly witnessed first hand – from  
4 inadequate space, to inadequate cleaning facilities creating the risk of cross-contamination,  
5 inadequate and antiquated machinery, and the like. *Id.* ¶¶ 103, 113, 147. Similarly, CW 8 is  
6 alleged to have been a “Director of Global Training” who worked in quality assurance and “worked  
7 with contracts that Impax brought in to assist the Company with its quality improvements in  
8 response to FDA inspections.” *Id.* ¶ 29. Specifically, CW 8 “was responsible for the development  
9 and management of technical and regulatory training, and integrated quality compliance systems for  
10 Impax.” *Id.* The FAC alleges that CW 8 felt that there was insufficient quality assurance in the  
11 research and development department, was present in meetings with the FDA when the inspections  
12 occurred, that the problems highlighted by the FDA were “rather old” in that they had been going on  
13 for a long time, and that he felt the asserted remediation time frames were unrealistic. *Id.* ¶¶ 150,  
14 153.

15 The FAC contains sufficient allegations to establish the reliability of the confidential  
16 witnesses. Accordingly, the Court properly may consider the CWs and their allegations in  
17 determining whether Plaintiffs have properly alleged the statements were false when made.

18 2. The PSLRA Safe Harbor Does Not Apply

19 Under the PSLRA, a person may not be held liable for making an untrue statement of  
20 material fact if the statement is (1) a statement that is, and is identified as, a “forward-looking  
21 statement” and (2) is accompanied by “meaningful cautionary statements identifying important  
22 factors that could cause actual results to differ materially from those in the forward-looking  
23 statement.” 15 U.S.C. § 78u-5(c)(1)(A); *see also In re Cutera Securities Litig.*, 610 F.3d 1103, 1111  
24 (9th Cir. 2010). Under this “safe harbor” provision, a “forward-looking statement” is defined as  
25 “any statement regarding (1) financial projection, (2) plans and objectives of management for future  
26 operations, (3) future economic performance, or (4) the assumptions ‘underlying or related to’ any  
27 of these issues.” *Bartlet v. Affymax, Inc.*, 13-CV-01025-WHO, 2014 WL 231551, at \*13 (N.D. Cal.  
28



1 Jan. 21, 2014) (quoting *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W.*  
2 *Holding Corp.*, 320 F.3d 920, 936 (9th Cir. 2003)).

3 Plaintiff argues that the above identified statements do not constitute “forward-looking  
4 statements” because they are misrepresentations regarding the “historical and present” facts  
5 regarding Impax’s alleged manufacturing and quality control improvements. By contrast, in their  
6 motion to dismiss, Defendants point to other parts of the same comments as examples of “forward-  
7 looking” statements. *See, e.g., id.* ¶ 154 (“we intend to promptly respond the FDA’s letter . . . .”);  
8 *id.* ¶ 166 (“We will comply, we will stay abreast of developments in our industry.”). Defendants  
9 argue that these statements are forward-looking because they represent the likelihood and timing of  
10 a future event, specifically the remediation of the issues raised in the FDA Warning Letter.

11 In support of their argument, Defendants cite to a number of cases where statements  
12 regarding future FDA actions were found to be forward-looking for purposes of the safe harbor. For  
13 example, in *Kovtun v. Vivus, Inc.*, No. C 10-4957 PJH, 2012 WL 4477647 (N.D. Cal. Sept. 27,  
14 2012), plaintiffs alleged that defendant’s statements regarding the prospects of a new drug were false  
15 and misleading. The court found the safe harbor applicable, stating that “[p]rojections about the  
16 likelihood of FDA approval are forward-looking statements. They are assumptions related to the  
17 company’s plan for its product, and as such fall under the PSLRA’s safe harbor rule.” *Id.* at \*12; *see*  
18 *also In re Nuvelo, Inc. Securities Litig.*, No. C 07-4056 VRW (N.D. Cal. Dec. 4, 2008) (finding that  
19 “alleged misstatements about the likelihood of future success at phase 3 trials, regulatory approval,  
20 or commercialization of [the drug] alfimeprase all fit the definition of forward-looking statements  
21 under the PSLRA”).

22 The Court finds that the statements enumerated above do not fit within the PSLRA’s  
23 definition of a “forward-looking” statement. These statements all contain representations of present  
24 or historical fact – for example, the assertion that Impax had “begun” to institute changes to address  
25 the issues highlighted by the FDA, or that tasks to address these issues were “well under way.” The  
26 identified statement which comes the closest to fitting the definition of “forward-looking” is the  
27 November 1, 2011 statement by Mr. Koch asserting that Impax was “on track” and that investors  
28 could feel comfortable with where the company was. FAC ¶ 162. Even this statement, however, is

1 fundamentally a representation of present fact regarding the status of Impax’s response to the FDA  
2 Warning Letter. Further, as Plaintiffs have pointed out, at least one court has found similar “on  
3 track” language to be not forward-looking. *See In re MGM Mirage Sec. Litig.*, No. 2:09-cv-01558-  
4 GMN-VCF, 2013 WL 5435832, at \*7 (D. Nev. Sept. 26, 2013) (“However, statements that a project  
5 is “on-track,” “on-budget,” or “on-schedule,” are not forward-looking but statements relating to  
6 *current* conditions.”).

7 Defendant argues that notwithstanding the present-focus of these statements, they can  
8 constitute forward-looking statements because “[h]istorical statements can also be forward-looking  
9 if they are presented as factors underlying a projection or economic forecast.” *In re LeapFrog*  
10 *Enters., Inc. Securities Litig.*, 527 F. Supp. 2d 1033, 1046 (N.D. Cal. 2007). The Court disagrees.  
11 In *Westley v. Oclaro, Inc.*, 897 F. Supp. 2d 902 (N.D. Cal. 2012), plaintiffs argued that defendants’  
12 statements that they were “currently seeing a return of customer demand” and that “customer  
13 demand has recently increased” were false and misleading. *Id.* at 909. Despite the focus of these  
14 statements on *current* consumer demand, defendants argued that the statements were, in fact,  
15 forward-looking because the present-fact was “being used to make predictions about the future” and  
16 thus represented a “statement or assumption” underlying a forward-looking statement. *Id.* at 918;  
17 *see also* 15 U.S.C. § 78u-5(i)(1)(D). This Court rejected defendants’ argument, holding that  
18 notwithstanding the forward-looking context in which the statement was made, “[t]he fact remains  
19 that a statement about a past or current fact can demonstrably be proven false. That is what  
20 distinguished such facts from forward-looking predictions.” *Oclaro*, 897 F. Supp. 2d at 918.  
21 Accordingly, the Court found the safe harbor provision inapplicable.

22 This Court’s decision in *Oclaro* is supported by numerous cases from around the country  
23 which have held that statements of past or present *facts* are not covered by the safe harbor provision  
24 – even when they are inextricably tied with forward-looking statements. For example, in *Makor*  
25 *Issues & Rights, Ltd. v. Tellabs, Inc.*, 513 F.3d 702 (7th Cir. 2008), the Seventh Circuit stated that  
26 when a company:

27 told the world that sales of its 5500 system were ‘still going strong,’ it  
28 was saying both that current sales were strong and that they would  
continue to be so, at least for a time, since the statement would be

1 misleading if Tellabs knew that its sales were about to collapse. The  
2 element of prediction in saying that sales are ‘still going strong’ does  
3 not entitle Tellabs to a safe harbor with regard to the statement’s  
representation concerning current sales.

4 *Id.* at 705. Further, the Third Circuit has recognized that “[a] mixed present/future statement is not  
5 entitled to the safe harbor with respect to the part of the statement that refers to the present.”

6 *Institutional Investors Group v. Avaya, Inc.*, 564 F. 3d 242, 255 (3d Cir. 2009) (quoting *Makor*, 513  
7 F.3d at 705)); *see also EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865 (3d Cir. 2000)

8 (recognizing that a statement that “lengthy negotiations” had already taken place and that contracts  
9 were “imminent” could reasonably be construed as a “representation about the current state of

10 negotiations”). Similarly, the Southern District of New York has recognized that “[s]tatements that  
11 might arguably have some forward-looking aspect are unprotected by the PSLRA safe harbor

12 provision to the extent that they are premised on representations of present fact.” *In re Regeneron*

13 *Pharm. Inc. Sec. Litig.*, No. 03 Civ. 3111 RWS, 2005 WL 225288, at \*13 (S.D.N.Y. Feb. 1, 2005);

14 *see also Sgalambo v. McKenzie*, 739 F. Supp. 2d 453, 478 (S.D.N.Y. 2010) (finding statements that  
15 “incorporate forward-looking aspects into statements of present fact” are not covered by the PSLRA

16 safe harbor provision).

17 Because the Court concludes that the statements identified in the FAC on what Plaintiffs rely  
18 to state their claim are, at least in part, statements of present or historical fact and not forward-

19 looking, the Court concludes that the PSLRA safe harbor does not apply and need not address

20 whether Defendants’ cautionary language was “meaningful.” *See, e.g., City of Hialeah Employees’*

21 *Retirement Sys. & Laborers Pension Trust Funds v. Toll Brothers, Inc.*, No. 07-1513, 2008 WL

22 4058690, at \*2 (E.D. Pa. Aug. 29, 2008) (“[B]ecause these statements were not forward-looking . . .

23 the safe harbor provision of the PSLRA [is] inapplicable.”).

24 3. The Statements Do Not Constitute Unactionable “Puffing” or Opinions

25 Defendants further contend that the statements in the FAC cannot constitute material  
26 falsehoods, because they constitute general statements of corporate optimism – “mere puffery.”

27 “Vague statements of opinion are not actionable under the federal securities laws because they are

28 considered immaterial and discounted by the market as mere puffing.” *In re OmniVision Techs.*,

1 *Inc. Sec. Litig.*, 937 F. Supp. 2d 1090, 1102 (N.D. Cal. 2013) (quoting *Wenger v. Lumisys, Inc.*, 2 F.  
2 Supp. 2d 1231, 1245 (N.D. Cal. 1998)). As the Ninth Circuit has noted, “[w]hen valuing  
3 corporations, . . . investors do not rely on vague statements of optimism like ‘good,’ ‘well-regarded,’  
4 or other feel good monikers.” *In re Cutera*, 610 F.3d at 1111. Thus, courts have noted that  
5 “puffing” statements are generally “‘not capable of objective verification,’ and ‘lack[] a standard  
6 against which a reasonable investor could expect them to be pegged.’” *In re Cornerstone Propane  
7 Partners, L.P.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005) (quoting *Grossman v. Novell, Inc.*, 120  
8 F.3d 1112, 1119 (10th Cir. 1997)). For example, courts have found unactionable statements  
9 asserting “[w]e are very pleased with the learning from our pilot launch” and “so far we’re getting  
10 really great feedback.” *City of Royal Oak Retirement Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d  
11 1045, 1063 (N.D. Cal. 2012) (citing *Wozniak v. Align Tech., Inc.*, 850 F. Supp.2d 1029, 1036 (N.D.  
12 Cal. 2012)).

13 “When determining whether statements amounted only to puffery, the court must analyze the  
14 context in which the statements were made.” *In re Bridgepoint Educ., Inc. Sec. Litig.*, No. 3:12-CV-  
15 1737 JM (WMC), 2013 WL 5206216, at \*17 (S.D. Cal. Sept. 13, 2013). Even a statement of  
16 opinion or an expression of corporate optimism may be deemed actionable in certain circumstances  
17 because “there is a difference between enthusiastic statements amounting to general puffery and  
18 opinion-based statements that are anchored in ‘misrepresentations of existing facts.’” *In re Bank of  
19 Am. Corp. Sec., Derivative, & ERISA Litig.*, 757 F. Supp. 2d 260, 310 (S.D.N.Y. 2010) (quoting  
20 *Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir. 2000)). As the Ninth Circuit stated in *Casella v. Webb*,  
21 883 F.2d 805, 808 (9th Cir. 1989), “What might be innocuous ‘puffery’ or mere statement of opinion  
22 standing alone may be actionable as an integral part of a representation of material fact when used to  
23 emphasize and induce reliance upon such a representation.” Accordingly, the Court may not assess  
24 the statements listed in the FAC in a vacuum, “plucking the statements out of their context to  
25 determine whether the words, taken *per se*, are sufficiently ‘vague’ so as to constitute puffery,” but  
26 rather will examine the entire statement and its circumstances to determine if it is actionable.  
27 *Scratchfield v. Paolo*, 272 F. Supp. 2d 163, 176 (D.R.I. 2003).

28

1 As an initial matter, the Court notes that “puffery” is not-actionable under the PSLRA  
 2 because the law deems such statements so amorphous as to be immaterial. *See In re Omnivision*,  
 3 937 F. Supp. 2d at 1102. However, determining whether a given statement is material “entail[s]  
 4 fact-intensive assessments that are more properly left to the jury.” *Bricklayers & Masons Local*  
 5 *Union No. 5 Ohio Pension Fund v. Transocean Ltd.*, 866 F. Supp. 2d 223, 244 (S.D.N.Y. 2012).  
 6 Thus, “[i]n deeming a statement puffery at the motion to dismiss stage, courts must exercise great  
 7 caution.” *Id.*; *see also In re Spiegel, Inc. Sec. Litig.*, 382 F. Supp. 2d 989, 1028 (N.D. Ill. 2004)  
 8 (declining to hold that statements were puffery at the motion to dismiss stage because materiality  
 9 involves “delicate assessments of the inferences a reasonable shareholder would draw”).  
 10 Accordingly, this Court will only grant Defendants’ motion to dismiss on the ground that the  
 11 statements are “puffery” only if it concludes that the statement is “so obviously unimportant to a  
 12 reasonable investor that reasonable minds could not differ on the question of their unimportance.”  
 13 *In re Ford Motor Co. Sec. Litig.*, 381 F.3d 563, 570 (6th Cir. 2004) (citation omitted); *see also In re*  
 14 *Scientific-Atlanta, Inc. Sec. Litig.*, 239 F. Supp. 2d 1351, 1360 (N.D. Ga. 2002) (“A statement can be  
 15 dismissed as puffery as a matter of law only if it is immaterial because it is so exaggerated or so  
 16 vague that a reasonable investor would not rely on it in considering the ‘total mix’ of facts  
 17 available.”).

18 The Court finds that it cannot so conclude. To be sure, the statements include superlatives  
 19 which are indicative of the speaker’s opinion and are often seen in “puffing” statements – for  
 20 example, references to “significant” manufacturing and quality control improvements. *See* FAC ¶¶  
 21 158, 160. However, as the Court found above in its discussion over whether these statements are  
 22 “forward-looking,” the vast majority<sup>2</sup> of the statements identified in the FAC contain factual

23 \_\_\_\_\_  
 24 <sup>2</sup> The Court finds that the following statements represent either a non-actionable opinion or  
 mere puffery:

- 25 • **May 16, 2012 Statements by Mr. Koch and Mr. Hsu:** “[W]e’re very  
 26 confident that we’ll be able to deal with all of the issues we face and resolve  
 27 this current report as quickly as possible” and “While we don’t know the  
 exact the timing on that, but [sic] we have a real confidence that we will get  
 the issue resolved.” FAC ¶ 172.
- 28 • **October 30, 2012 Earnings Call, Mr. Hsu Statement:** “But at this point, as

1 representations at their core – that Defendants had responded to the FDA Warning Letter by  
 2 instituting various changes to the manufacturing and/or quality control procedures or processes.  
 3 *See, e.g.*, FAC ¶ 154 (“We . . . *have already begun to implement changes and establish procedures*  
 4 *that address the observations cited during the inspection.*”); *id.* ¶ 156 (“Many commitments in our  
 5 responses are nearing completion as a result of our work since we received the Form 4[8]3 . . .”).  
 6 Similarly, that certain statements are predicated with indications that the speaker “thought” or  
 7 “believed” a given statement does not change this result. *See In re Oxford Health Plans, Inc.*, 187  
 8 F.R.D. 133, 141 (S.D.N.Y. 1999) (“It is disingenuous to suggest that factual assertions are puffery  
 9 and opinion that no reasonable investor could reasonably rely on for their truth simply because  
 10 Oxford claims only to have stated that it believes in their truth.”).

11 With the two exceptions noted above in Footnote 1, the representations identified in the FAC  
 12 are distinguishable from those cases that Defendants have cited in support of their puffery argument.  
 13 For example, in *City of Royal Oak Retirement System v. Juniper Networks, Inc.*, the court found that  
 14 statements which simply “express[ed] confidence in Juniper’s business and outlook” were vague  
 15 assertions of corporate optimism. *Id.* at 1064. Among such statements were representations that  
 16 “[b]oth Verizon and AT&T are strong partners,” that it had “strong demand metrics and good  
 17 momentum,” and that “growth drivers give us . . . confidence.” *Id.* Similarly, in *Wozniak v. Align*  
 18 *Tech., Inc.*, the court found that statements that “[w]e are very pleased with the learning from our  
 19 pilot launch,” “we’re getting really great feedback,” “we are very pleased with our progress to date  
 20 on key strategic initiatives,” were mere puffery. *Wozniak*, 850 F. Supp. 2d at 1036.

21 Rather, the Court finds that this case is similar to *Bricklayers and Masons Local Union No. 5*  
 22 *Ohio Pension Fund v. Transocean Ltd.*, 866 F. Supp. 2d 223 (S.D.N.Y. 2012). There, Transocean –  
 23 a deepwater drilling company – represented in a merger agreement, proxy statement, and SEC Form  
 24 10-K that it had conducted “extensive” training and safety programs. *Id.* at 230. Approximately  
 25 three years later, the *Deepwater Horizon* disaster occurred, raising serious questions about

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27 I pointed out earlier, we’re confident we’ll get out of here, although timing,  
 28 unfortunately, is not in our control, as we’re waiting for [the] FDA to take the  
 action on that. But I think we feel well prepared for this.” FAC ¶ 178.

1 Transocean’s management, personnel, and equipment failures. *Id.* at 228. In a subsequent securities  
2 lawsuit, plaintiffs asserted that the representation regarding Transocean engaging in “extensive”  
3 training and safety was false and misleading. The district court rejected defendant’s argument that  
4 this statement constituted mere puffery: “In an industry as dangerous as deepwater drilling, it is to be  
5 expected that investors will be greatly concerned about an operator’s safety and training efforts. The  
6 Court cannot say, as a matter of law, that Transocean’s representation that such efforts were  
7 extensive was ‘obviously unimportant’” to shareholders. *Id.* at 244; *see also In re Spiegel*, 382 F.  
8 Supp. 2d at 1028 (finding statements that preferred credit card programs realized “significant”  
9 earnings and “solid” sales and earnings were not puffery at the motion to dismiss stage).

10 Here, the challenged statements were allegedly made by Defendants at a time when one of  
11 their two manufacturing facilities had received significant warnings from the FDA. It is reasonable  
12 to believe that investors in the pharmaceutical industry – an industry where regulatory compliance,  
13 not to mention consistency and sanitation in production, is essential – would find such an event  
14 disconcerting. This is especially the case when the very core of Impax’s business – its  
15 manufacturing facilities – was in potential jeopardy. Indeed, it is highly plausible that the investors  
16 would find statements by the company’s head officers that appropriate responses were “well  
17 underway” or nearly completed to be material. This is precisely the picture painted by the  
18 statements enumerated in the FAC. Defendants are alleged to have specifically represented to  
19 investors that they had undertaken significant manufacturing and quality control changes in their  
20 operations to rectify the issues highlighted by the FDA’s Form 483s and Warning Letter in a  
21 relatively short period of time. In other statements, Defendants assured investors that subsequent  
22 FDA warnings were unrelated to the prior incidents. At the same time, it is alleged that, in fact,  
23 Defendants did little in response and that similar issues continued to pervade Impax’s Hayward  
24 facility. Given this context, the Court cannot find at this stage that the alleged statements are simple  
25 statements of corporate optimism or mere puffery. They were not so “obviously unimportant” to  
26 shareholders as to warrant dismissal.

1 B. Plaintiffs Have Sufficiently Alleged Scienter Under the Core Operations Theory

2 Under the PSLRA, plaintiffs must plead “with particularity facts giving rise to a *strong*  
3 *inference*” that the Defendants acted with scienter when making the alleged false statements. 15  
4 U.S.C. § 78u-4(b)(2)(A) (emphasis added). In determining whether the facts give rise to a “strong”  
5 inference of scienter, “the court must take into account plausible opposing inferences.” *Tellabs, Inc.*  
6 *v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). “A strong inference of scienter must be  
7 more than merely plausible or reasonable – it must be cogent and at least as compelling as any  
8 opposing inference of nonfraudulent intent.” *Reese v. Malone*, — F.3d —, 2014 WL 555911, at \*6  
9 (9th Cir. Feb. 13, 2014). The inference must be that the “‘defendant[] made false or misleading  
10 statements either *intentionally* or with *deliberate recklessness*.’” *Id.* (quoting *Zucco*, 552 F.3d at 991  
11 (emphasis in original)).

12 Plaintiffs do not specifically allege direct evidence showing the key officers making the  
13 statements at issue – the CEO Mr. Hsu and the CFO Mr. Koch – had knowledge of the falsity of the  
14 statements. Rather, they rely on the “core operations” theory to show such knowledge.

15 Under that theory, scienter may be imputed “based on the inference that key officers have  
16 knowledge of the ‘core operations’ of the company.” *Id.* at \*13. Specifically, in “rare  
17 circumstances” allegations regarding management’s role “may be sufficient, without accompanying  
18 particularized allegations, where the nature of the relevant fact is of such prominence that it would  
19 be ‘absurd’ to suggest that management was without knowledge of the matter.” *Id.*; *see also Zucco*,  
20 552 F.3d at 1000 (“Nevertheless, reporting false information will only be indicative of scienter  
21 where the falsity is patently obvious – where the ‘facts [are] prominent enough that it would be  
22 ‘absurd to suggest’ that top management was unaware of them.” (quoting *Berson v. Applied Signal*  
23 *Tech., Inc.*, 527 F.3d 982, 989 (9th Cir. 2008)).

24 By way of example, in *No. 84 Employer-Teamster Joint Council Pension Trust Fund v.*  
25 *America West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003), plaintiffs alleged that defendants –  
26 including outside directors and shareholders of America West – made knowingly false statements  
27 regarding the company’s financial outlook and response to various operational problems.  
28 Specifically, plaintiffs alleged that aircraft maintenance had “deteriorated dramatically” as a result of



1 outsourcing of maintenance, leading to repeated FAA investigations and warnings. *Id.* at 926.  
2 Regardless, the defendants made extremely positive statements about the company’s financial  
3 outlook and asserted that maintenance and operational problems were behind the company. *Id.* at  
4 927. The Court found that plaintiff had adequately alleged that the shareholder and director  
5 defendants were aware of the misstatements made by America West’s officers and therefore had  
6 adequately alleged scienter. The Court stated, in part:

7 TPG argues that the issues regarding maintenance, safety, and the  
8 FAA investigation and settlement were “purely[] management issue[s]  
9 that never rose to the level of Board discussions or communications  
10 with any shareholders.” This argument is patently incredible. It is  
11 absurd to suggest that the Board of Directors would not discuss . . . the  
12 FAA investigations or negotiations, especially considering the fact that  
13 the FAA had indicated that it was considering penalties of up to \$11  
14 million.

12 *Id.* at 943 n.21.

13 Similarly, in *Berson v. Applied Signal Technology, Inc.*, 527 F.3d 982 (9th Cir. 2008), the  
14 plaintiffs alleged that defendants – Applied Signal’s CEO and CFO – made materially false  
15 statements regarding Applied Signal’s revenue by including in the company’s “backlog” report  
16 various contracts for which the government had issued “stop-work orders.” *Id.* at 985. This was  
17 significant because contracts for which the government had issued a “stop-work order” are often  
18 cancelled altogether, thus creating a great degree of risk that the company would never receive  
19 money for those contracts. *Id.* Thus, plaintiffs alleged that the “company’s backlog reports misled  
20 them into believing that Applied Signal was likely to perform work that, in reality, had been halted  
21 and was likely to be lost forever.” *Id.* The Ninth Circuit found that plaintiffs had adequately alleged  
22 scienter. The court acknowledged that “plaintiffs allege no particular facts indicating that  
23 [defendants] actually knew about the stop-work orders.” *Id.* at 987. Still the court found accepted  
24 the inference that the “high-level managers must have known about the orders because of their  
25 devastating effect on the corporation’s revenue.” *Id.* The Court noted that the inference was even  
26 stronger than in *America West* because “[d]efendants in *America West* were outside directors who  
27 did no more for the company than attend board meetings and serve on a board committee. Here, by  
28 contrast, [defendants] were directly responsible for Applied Signal’s day-to-day operations.” *Id.*

1 This case is similar to *America West* and *Applied Signal*. As in those cases, it is “absurd” to  
2 think that the CEO and CFO of a pharmaceutical company would be unaware of the alleged  
3 substandard, non-compliant conditions pervading their company’s manufacturing and quality control  
4 divisions – the heart of a company whose main business is manufacturing pharmaceuticals for public  
5 consumption. The idea that the defendants here would be unaware of these manufacturing and  
6 quality control problems is even more unlikely given the repeated Form 483s and the Warning Letter  
7 from the FDA. Form 483s are intended according to Plaintiffs, to inform “top management” of  
8 “significant objectionable conditions” according to Plaintiffs. FAC ¶ 44. Just as FAA warnings and  
9 failed inspections were considered so critical to the airline in *America West* such that outside  
10 directors were presumed to be aware, so to are FDA warnings and failed inspections crucial to a  
11 pharmaceutical company. An inference of scienter is strengthened by the allegation of pervasive  
12 and long standing problems which allegedly were covered up as a matter of policy at Impax.


13 Therefore, given the importance of manufacturing and quality control to the success of  
14 Impax and the fact that both areas of operation had been flagged by the FDA, it is a logical, and  
15 strong, inference that the defendants were aware of the alleged severe and pervasive problems in  
16 Impax’s Hayward facility.

17 Accordingly, the Court concludes for purposes of the motion to dismiss Plaintiffs have  
18 sufficiently alleged a strong inference of scienter.

19 This order disposes of Docket No. 66.

20  
21 IT IS SO ORDERED.

22  
23 Dated: April 18, 2014

24  
25   
26 EDWARD M. CHEN  
27 United States District Judge  
28