



1 TAKEDA PHARMACEUTICAL CO., LTD., )  
2 et al., )  
3 Plaintiffs, )  
4 v. )  
5 TWI PHARMACEUTICALS, INC., )  
6 Defendant. )

7 Before the court is a motion from Defendants and Declaratory Judgment Plaintiffs Par  
8 Pharmaceutical, Inc. and Handa Pharmaceuticals LLC, and Defendants Impax Laboratories, Inc.  
9 and TWi Pharmaceuticals, Inc. (collectively, “Defendants”) to supplement their invalidity  
10 contentions across three cases to add five additional references and two additional enablement and  
11 written description arguments.<sup>1</sup> Plaintiffs and Declaratory Judgment Defendants Takeda  
12 Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc. and Takeda  
13 Pharmaceuticals America, Inc (collectively, “Takeda”) oppose. After considering the arguments,  
14 the court DENIES the motion.<sup>2</sup>

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16 **I. BACKGROUND**

17 A review of the parties’ patent local rule disclosures is necessary to evaluate the accused  
18 infringers’ diligence.

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- 20 • On November 4, 2013, Defendants served their invalidity contentions pursuant to  
Patent L.R. 3-3<sup>3</sup>
  - 21 • On December 9, 2013, Takeda included additional references, including the Bergstrand  
22 reference, within its preliminary claim constructions disclosure.<sup>4</sup>

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24 <sup>1</sup> See Docket No. 108. For clarity, the court only will refer to the ’1927 case except as otherwise  
25 indicated below. For the purposes of this order, the court will refer to Defendants’ arguments  
regarding enablement and written description generically as 112 arguments.

26 <sup>2</sup> Because the court has stayed the ’1927 case in light of the parties’ settlement, the court  
DENIES-AS-MOOT Defendants’ motion with respect to that case.

27 <sup>3</sup> See Docket No. 110 at ¶ 2.

28 <sup>4</sup> See *id.* at ¶ 3; see also Docket No. 110-2 at 10.

- 1 • On December 9,<sup>5</sup> 2013, Defendants submitted their initial proposed claim constructions of disputed terms.
- 2 • In January, after reviewing one of Takeda’s references – the Bergstrand reference, which
- 3 discusses and cites conflicting reports in the literature about the effect of food on the
- 4 administration of Proton Pump Inhibitors – Defendants determined the Andersson,
- 5 Brummer, Moules, Röhss and Thomson references were relevant to a possible “food effect”
- 6 on therapeutic efficacy.<sup>6</sup>
- 7 • On January 22, 2014, Defendants disclosed four of the references to Takeda.<sup>7</sup>
- 8 • On January 31, 2014, Defendants disclosed the fifth reference that had been inadvertently
- 9 omitted from its prior disclosure.<sup>8</sup>
- 10 • On February 6, 2014, Takeda and Defendants filed their joint claim construction and
- 11 prehearing statement on the docket.<sup>9</sup>
- 12 • On March 27, 2014, Takeda filed its opening claim construction brief.<sup>10</sup>
- 13 • On April 24, 2014, Defendants notified Takeda of their revised proposed constructions
- 14 through their claim construction brief.<sup>11</sup>
- 15 • On May, 6, 2014, Mylan served its invalidity contentions in the parallel *Takeda v. Mylan*
- 16 case, Case No. 14-cv-00314-LHK-PSG.<sup>12</sup>
- 17 • On May 12, 2014, Defendants sought Takeda’s stipulation to allow Defendants to amend
- 18 their contentions to conform to Mylan’s. The same day, Takeda rejected the offer.<sup>13</sup>
- 19 • On May 29, 2014, Defendants met and conferred with Takeda about their intention to seek
- 20 leave to amend their invalidity contentions. The same day, Takeda informed Defendants it
- 21 would oppose Defendants motion.<sup>14</sup>

19 <sup>5</sup> See Docket No. 110 at ¶ 6.

20 <sup>6</sup> See *id.* at ¶¶ 4-5.

21 <sup>7</sup> See *id.* at ¶ 6 (citing Docket No. 110-9, Ex. I).

22 <sup>8</sup> See *id.* at ¶ 6 (citing Docket No. 110-10, Ex. J).

23 <sup>9</sup> See Docket No. 77.

24 <sup>10</sup> See Docket No. 79.

25 <sup>11</sup> See Docket No. 110 at ¶¶ 7-8 (citing Docket No. 110-13, Ex. M).

26 <sup>12</sup> See *id.* at ¶ 11 (citing Docket No. 110-14, Ex. N).

27 <sup>13</sup> See *id.* at ¶¶ 13-14 (citing Docket No. 110-15, Ex. O and Docket No. 110-16, Ex. P).

28 <sup>14</sup> See *id.* at ¶¶ 15-16 (citing Docket No. 110-17, Ex. Q and Docket No. 110-18, Ex. R).

## II. LEGAL STANDARDS

1 Patent L.R. 3-6 permits amendment of invalidity contentions “only by order of the Court  
2 upon a timely showing of good cause.”<sup>15</sup> The text of the rule provides a non-exhaustive list of  
3 circumstances which, absent prejudice to the non-moving party, may support a finding of good  
4 cause:  
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6 (a) A claim construction by the Court different from that proposed by the party seeking  
7 amendment;

8 (b) Recent discovery of material, prior art despite earlier diligent search; and

9 (c) Recent discovery of nonpublic information about the Accused Instrumentality which  
10 was not discovered, despite diligent efforts, before the service of the Infringement  
Contentions.”<sup>16</sup>

11 The rules require parties to define their theories of infringement early on in the course of  
12 litigation.<sup>17</sup> By requiring the non-moving party to show good cause, Patent L.R. 3-6 balances the  
13 parties’ rights to develop new information in discovery along with the need for certainty in legal  
14 theories at the start of the case.<sup>18</sup> The good cause inquiry considers first whether “the party seeking  
15 leave to amend acted with diligence in promptly moving to amend when new evidence” was  
16 revealed.<sup>19</sup> In considering the party’s diligence, the critical question is whether the party “could  
17 have discovered” the new information “earlier had it acted with the requisite diligence.”<sup>20</sup> The  
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<sup>15</sup> Patent L.R. 3-6.

22 <sup>16</sup> *Id.*

23 <sup>17</sup> *See O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1359 (Fed. Cir. 2006)  
24 (“The Northern District of California has adopted local rules that require parties to state early in the  
litigation and with specificity their contentions with respect to infringement and invalidity.”).

25 <sup>18</sup> *See id.* at 1366 (“The rules thus seek to balance the right to develop new information in  
26 discovery with the need for certainty as to the legal theories.”).

27 <sup>19</sup> *Id.* at 1363.

28 <sup>20</sup> *Google Inc. v. Netlist, Inc.*, Case No. 4:08-cv-04144-SBA, 2010 WL 1838693, at \*2  
(N.D. Cal. May 5, 2010).

1 burden is on the moving party to show diligence.<sup>21</sup> The court then considers whether there would  
2 be undue prejudice to the non-moving party.<sup>22</sup> If the court finds that the moving party was not  
3 diligent in amending its infringement contentions, there is no need to consider the question of  
4 prejudice to the non-moving party, although a court in its discretion may elect to do so.<sup>23</sup>

### 5 III. DISCUSSION

#### 6 A. The Five Additional Prior Art References

7 Although Defendants became aware of the prior art references by January of 2014, they did  
8 not seek leave to amend their contentions until Mylan served its invalidity contentions in a parallel  
9 case. Defendants have not offered a compelling explanation for why service in the *Mylan* case is  
10 relevant to the court's assessment of Defendants' diligence in this case. Defendants' concern for  
11 the judicial workload of this court is well-taken,<sup>24</sup> but cannot play into the court's assessment of  
12 diligence.<sup>25</sup> The local rules require parties to diligently amend their infringement contentions.

13 Merely disclosing new references to the other side does not delineate why the new references are  
14 invalidating. By waiting four months to seek leave, Defendants were not diligent, even if they did  
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17 <sup>21</sup> See *O2 Micro*, 467 F.3d at 1355 (“The burden is on the movant to establish diligence rather than  
18 on the opposing party to establish a lack of diligence.”).

19 <sup>22</sup> See *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys.*,  
20 Case No. 3:05-cv-04158-MHP, 2008 WL 624771, at \*2 (N.D. Cal. Mar. 4, 2008) (“This inquiry  
21 first considers whether plaintiff was diligent in amending its contentions and then considers  
22 prejudice to the non-moving party.”).

23 <sup>23</sup> See *O2 Micro*, 467 F.3d at 1368 (affirming the district court's decision refusing leave to amend  
24 upon finding the moving party was not diligent, without considering the question of prejudice to  
25 the non-moving party); see also *Leland Stanford Junior Univ.*, 2008 WL 624771, at \*3.

26 <sup>24</sup> See Docket No. 114 at 5 (“It was reasonable for Defendants to file their motion to amend after  
27 Mylan submitted its invalidity contentions, as doing so avoided the need for filing serial motions to  
28 amend.”); *id.* at 9 (“Defendants filed their motion after the submission of Mylan's invalidity  
contentions in order to conserve judicial resources by reducing the need for filing serial motions to  
amend.”).

29 <sup>25</sup> See *Genentech, Inc. v. Trustees of Univ. of Pennsylvania*, Case No. 5:10-cv-2037-LHK-PSG,  
30 2011 WL 3204579, at \*1-2 (N.D. Cal. July 27, 2011) (rejecting Genentech's argument “that any  
delay in seeking leave to add these contentions is excusable in light of the likelihood that it would  
have to seek leave again after the issuance of the claim construction” order and explaining that no  
“exception is provided simply because a further amendment might be justified after a claim  
construction” is issued).

1 not intend to sandbag. Absent diligence, the court does not reach the issue of prejudice.<sup>26</sup> The  
2 additional references are out.

3 **B. The New Section 112 Arguments**

4 Defendants urge that they were diligent in seeking leave to introduce two additional  
5 Section 112 invalidity arguments. Here, too, they were not. Defendants represent that their  
6 arguments grew out of Takeda's claim construction positions that were revealed in Takeda's  
7 opening claim construction brief.<sup>27</sup> Takeda points out that Defendants were on notice of its  
8 positions far earlier: Takeda had served its initial infringement contentions,<sup>28</sup> initial claim  
9 constructions<sup>29</sup> and the joint claim construction and prehearing statement well in advance of this  
10 motion.<sup>30</sup> The only predicate decision underlying the introduction of these additional Section 112  
11 arguments was Defendants' election to adopt a portion of Takeda's constructions. Nothing was  
12 sprung on Defendants to excuse the period between Defendants' knowledge of Takeda's positions  
13 and their motion for leave.<sup>31</sup>

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17 <sup>26</sup> This case is distinguishable from *Apple v. Samsung* where the undersigned granted Apple leave  
18 to amend its infringement contentions despite Apple's failure to establish diligence. *See Apple Inc.*  
19 *v. Samsung Electronics Co., Ltd.*, Case No. 5:12-cv-00630-LHK, 2012 WL 5632618, at \*5  
20 (N.D. Cal. Nov. 15, 2012). First, Apple's original contentions were "listed in Apple's 'Claims  
21 Summary Chart,' or the table of contents for their June 15 contentions." *Id.* Second, "duplicates of  
22 other charts were served in place of the second set of omitted charts." *Id.* The court therefore  
23 concluded that precluding "Apple from bringing these claims because of an administrative mistake  
24 would be an unnecessarily harsh result." *Id.* In the current case, no honest error or administrative  
25 mistake was to blame. On the contrary, Defendants had the references in hand, but consciously  
26 waited to seek leave.

27 <sup>27</sup> *See* Docket No. 79.

28 <sup>28</sup> On September 20, 2013, Takeda served its initial infringement contentions.

<sup>29</sup> On December 9, 2013, Takeda served its initial claim constructions.

<sup>30</sup> On February 6, 2014, Takeda and Defendants filed their joint claim construction and prehearing  
statement on the docket. *See* Docket No. 77.

<sup>31</sup> Any notice Defendants provided to Takeda of the additional Section 112 arguments does not  
cure Defendants' deficient diligence. Early disclosure speaks more to prejudice than diligence. If  
anything that disclosure suggests that this motion could have brought much earlier. Nor does the  
issuance of Judge Koh's constructions cure the deficit. *See supra* note 25.

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By waiting until late May to seek leave to add additional Section 112 arguments,  
Defendants plainly have not been diligent. Absent diligence, leave is not warranted.

**IT IS SO ORDERED.**

Dated: July 23, 2014

  
PAUL S. GREWAL  
United States Magistrate Judge