

**IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE**

ABBVIE ENDOCRINE INC., )  
 )  
 Plaintiff, )  
 )  
 v. ) C.A. No. 2020-0953-SG  
 )  
 TAKEDA PHARMACEUTICAL )  
 COMPANY LIMITED, )  
 )  
 Defendant. )

**MEMORANDUM OPINION**

Date Submitted: August 3, 2021  
Date Decided: September 22, 2021

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**GLASSCOCK, Vice Chancellor**

Before me is a dispute between AbbVie Endocrine Inc. (“AbbVie” or the “Plaintiff”), a pharmaceutical distributor, and Takeda Pharmaceutical Company Limited (“Takeda” or the “Defendant”), a pharma manufacturing giant. The parties have a contractual relationship to purchase and sell a drug used principally to treat cancer. The Plaintiff initially sought specific performance of that supply contract (the “Supply Agreement”)—deliveries under which were interrupted following a problematic inspection and resulting enforcement proceedings by the U.S. Food and Drug Administration (the “FDA”)—as well as damages for breach of the contract.

This matter was tried in April and May 2021 on the Plaintiff’s request for injunctive relief. For the reasons explained therein, I denied that relief by a Memorandum Opinion dated September 7, 2021.<sup>1</sup> The other issue tried in April and May was the Plaintiff’s request for a declaratory judgment that the Defendant is liable to it for breaching the Supply Agreement; in other words, the trial in the matter was bifurcated, with the April and May phase addressing liability (as well as injunctive relief), leaving for the next phase of trial, if necessary, the quantum of damages.

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<sup>1</sup> *AbbVie Endocrine Inc. v. Takeda Pharmaceutical Co. Ltd.*, 2021 WL 4059793 (Del. Ch. Sept. 7, 2021) [hereinafter “*AbbVie I*”]. The matter was expedited with respect to the request for injunctive relief; accordingly, I issued a decision on the issue separately, reserving on liability, the issue addressed here.

For the reasons that follow, I find that the Defendant has breached various aspects of the Supply Agreement, and is liable in damages.

## I. ABBVIE I

This opinion concerns the performance of the Supply Agreement entered into between Takeda and the predecessor-in-interest to AbbVie. As set out in *AbbVie I*, the parties have a supplier-distributor relationship wherein Takeda manufactures leuprolide acetate-containing drug products and AbbVie distributes one such drug product by the brand name of Lupron Depot (“Lupron”). The Supply Agreement is a requirements contract which mandates that, among other things, Takeda fulfill the firm orders of AbbVie with respect to Lupron. In 2020 and 2021, certain compliance issues came to light at one of Takeda’s manufacturing facilities (the “Hikari Facility”), which ultimately caused a disruption in the Lupron supply chain. Takeda was unable to fulfill AbbVie’s firm orders beginning in 2020. This failure to fulfill firm orders constitutes, per the Plaintiff, a breach of the Supply Agreement. These disruptions continue to date.

In April and May of 2021 I held a three-day trial in this matter.<sup>2</sup> The parties submitted supplemental papers and records, and I heard post-trial oral argument on August 3.<sup>3</sup> I released *AbbVie I*, a post-trial memorandum opinion, on September 7,

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<sup>2</sup> See Trial Tr., Dkt. Nos. 165–168.

<sup>3</sup> See Tr. Of 8.3.21 Post-Trial Oral Arg., Dkt. No. 190 [hereinafter “Oral Arg. Tr.”]; Pl’s Post-Trial Br., Dkt. No. 172; Def.’s Opening Post Trial Br., Dkt. No. 171.

which addressed solely the Plaintiff's requested injunctive relief.<sup>4</sup> I did not assess the question of breach at that time.<sup>5</sup> This Memorandum Opinion considers the liability of the Defendant for breach of the Supply Agreement. This Section offers a summary of the facts necessary to the determination of liability.

### *A. Factual Background*

This Memorandum Opinion adopts the factual statement set forth in *AbbVie I*.<sup>6</sup> The further facts presented in this post-trial memorandum opinion are either stipulated to in the parties' pre-trial stipulation or were proven by a preponderance of evidence at trial.<sup>7</sup>

#### 1. The Supply Agreement

On or around April 30, 2008, Takeda and the predecessor entity to AbbVie entered into the Supply Agreement, which identifies the Plaintiff's and the Defendant's rights and obligations regarding the manufacture, supply, and sale of Lupron.<sup>8</sup> The Supply Agreement was amended on September 4, 2009 and July 17, 2019<sup>9</sup> and the parties agree that it is a valid and enforceable contract.<sup>10</sup>

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<sup>4</sup> See generally *AbbVie I*, 2021 WL 4059793.

<sup>5</sup> See generally *id.*

<sup>6</sup> *AbbVie I*, 2021 WL 4059793 at \*2–\*5.

<sup>7</sup> Where the facts are drawn from exhibits jointly submitted at trial, they are referred to according to the numbers provided on the parties' joint exhibit list and with page numbers derived from the stamp on each JX page ("JX \_\_, at \_\_").

<sup>8</sup> Joint Pre-Trial Stipulation ¶¶ 8–9, Dkt. No. 156 [hereinafter "Stip."].

<sup>9</sup> Stip. ¶ 8.

<sup>10</sup> Stip. ¶ 10.

In its post-trial argument, the Plaintiff argued that the Defendant had breached the Supply Agreement in four ways, implicating five provisions.<sup>11</sup> The relevant provisions are as follows.

Section 9.2(a) provides that: “[AbbVie] shall . . . provide Takeda . . . with (i) a firm order for the quantities of Product that [AbbVie] will require . . ., [and] (ii) a good faith estimate of the quantities of Product that [AbbVie] will require” in specified future periods.<sup>12</sup> It then provides that “Takeda shall fulfill all such firm orders (subject to the allocation procedure described in Section 9.4).”<sup>13</sup>

Section 9.4 provides Takeda with the right to allocate Lupron “[i]f Takeda is unable, for any reason beyond its reasonable control . . . to supply sufficient quantities of Product to meet Takeda’s needs, [AbbVie’s] requirements, and third party orders that Takeda is contractually obligated to fill.”<sup>14</sup>

Section 9.6(a) provides that “Takeda . . . shall . . . maintain in its inventory a safety stock . . . solely dedicated to and for use by [AbbVie] in sufficient quantities to meet [AbbVie’s] anticipated demand for Product, as reflected in the then applicable forecast by [AbbVie], for the following twelve (12) month period, as

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<sup>11</sup> Oral Arg. Tr. 12:21–24, 13:1–17.

<sup>12</sup> Stip. ¶ 18.

<sup>13</sup> Stip. ¶ 18.

<sup>14</sup> Stip. ¶ 20.

follows: (i) . . . a supply of Product in sufficient quantities to meet [AbbVie]’s and its Affiliates’ anticipated demand for at least the first three (3) months.”<sup>15</sup>

Section 16.1(a) provides that “Takeda shall be exclusively responsible for . . . compliance of its . . . manufacturing facilities and processes utilized for purposes of manufacture, packaging, storing prior to delivery, and delivery of Product with all Applicable Laws . . . including Good Manufacturing Practices and all other Applicable Laws.”<sup>16</sup>

Finally, Section 21.3 provides that “[e]ach of the Parties shall be excused from the performance of its obligations hereunder in the event such performance is prevented by a cause beyond the reasonable control of such Party, including acts of God . . . .”<sup>17</sup>

Takeda, for its part, points to Section 8.1(a), which addresses best efforts as follows: “Subject to the provisions of this Agreement, [AbbVie] shall purchase . . . and Takeda or its Affiliates shall sell and deliver to [AbbVie] . . . [AbbVie]’s and its Affiliates’ requirements for the Territory of Product . . . . Takeda shall, and shall cause its Affiliates to, use best efforts to supply [AbbVie]’s and its Affiliates’ requirements of Product for the Territory.”<sup>18</sup>

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<sup>15</sup> Stip. ¶ 21.

<sup>16</sup> Stip. ¶ 22.

<sup>17</sup> Stip. ¶ 24.

<sup>18</sup> Stip. ¶ 17.

The Supply Agreement must be construed under Illinois law.<sup>19</sup>

## 2. FDA Inspection and Results<sup>20</sup>

In late 2019, Takeda began realizing certain manufacturing difficulties associated with leuprorelin products' production. First, on or around October 28, 2019, an autoclave at the Hikari Facility, used for sterilization purposes critical to the production of leuprorelin products including Lupron, failed its annual requalification test.<sup>21</sup> The FDA conducted a planned inspection (the "Inspection") of the Hikari Facility in November, which ultimately led to the issuance of a "Form 483" identifying observations made by the FDA agent that might constitute violations of the Food Drug and Cosmetic Act or related Acts.<sup>22</sup> Following Takeda's responses to the Form 483, in March 2020, the FDA issued an Official Action Indicated Letter (the "OAI Letter") that stated that the FDA had observed an "unacceptable state of compliance" with current good manufacturing practice ("cGMP") during the Inspection.<sup>23</sup> In June 2020, the FDA issued a warning letter (the "June Warning Letter") relating to the Inspection which "summarize[d] significant violations" of cGMP.<sup>24</sup> Further, in February 2021, the FDA issued an

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<sup>19</sup> Stip. ¶ 26.

<sup>20</sup> The remedial efforts undertaken by Takeda in connection with the FDA inspection in November 2019 are described in detail in *AbbVie I*.

<sup>21</sup> Stip. ¶ 38.

<sup>22</sup> Stip. ¶¶ 39, 40; *see also AbbVie I*, 2021 WL 4059793 at \*3.

<sup>23</sup> JX 1992, at 3.

<sup>24</sup> Stip. ¶ 43.

Establishment Inspection Report (the “EIR”) which more comprehensively addressed the violations observed as part of the Inspection.<sup>25</sup> That report specifically stated that the FDA was “concerned with the number of [c]GMP deficiencies” identified at the Hikari Facility in November 2019.<sup>26</sup>

The FDA inspected the Hikari Facility again in July 2021 (the “Follow-Up Inspection”).<sup>27</sup> Following that investigation, the Hikari Facility remains under “Official Action Indicated” status.<sup>28</sup>

### 3. Impact on AbbVie and Takeda

The manufacturing difficulties and associated delays Takeda has experienced as a result of the FDA inspection and its own investigations have caused a disruption to the supply line of leuprorelin products, including Lupron. This disruption has in turn had myriad effects on AbbVie and Takeda, certain of which are discussed in more detail below.

#### *a. The Allocation Schedule*

The shortage of leuprorelin products impacted AbbVie’s ability to distribute Lupron to the market, but also impacted Takeda’s ability to market similar products in Asia. To combat the shortage, Takeda produced an allocation schedule in June

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<sup>25</sup> JX 2527, at 22.

<sup>26</sup> *Id.*

<sup>27</sup> Oral Arg. Tr. 16:6–9.

<sup>28</sup> Oral Arg. Tr. 16:13–15.

2020, which indicated where the leuprorelin products able to be produced would be diverted.<sup>29</sup>

AbbVie has continued to submit firm orders to Takeda despite the allocation schedule.<sup>30</sup> The allocation schedule produced in June 2020 and the various later iterations have allowed for AbbVie to receive *some* lots of Lupron, but not in sufficient numbers to satisfy AbbVie’s firm orders.<sup>31</sup>

*b. Safety Stock Inventory*

Takeda and AbbVie both generally maintain a “safety stock” of leuprorelin and Lupron.<sup>32</sup> Safety stock is inventory, separate from firm orders placed, that generally acts as a backup in the event of a supply chain disruption or a failure to order the sufficient amount of product.<sup>33</sup> It essentially acts as a “working inventory” to ensure that product is always available should a patient or doctor require it.<sup>34</sup>

One indirect result of Takeda’s supply chain disruption led to AbbVie working through all of *its* safety stock in order to satisfy patient need.<sup>35</sup> When supply

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<sup>29</sup> Stip. ¶ 44.

<sup>30</sup> See, e.g., Exs. A–G to Pl.’s Mot. to Suppl. R., Dkt. No. 178.

<sup>31</sup> See, e.g., Trial Tr. 20:3–7, Dkt. No. 165; Def.’s Answer and Defenses to Pl.’s Verified Compl. ¶ 51, Dkt. No. 38.

<sup>32</sup> Trial Tr. 49:11–13, Dkt. No. 165 (discussing AbbVie’s safety stock); Stip. ¶ 21 (discussing Takeda’s safety stock).

<sup>33</sup> Trial Tr. 82:11–12, 83:2–6, Dkt. No. 165.

<sup>34</sup> *Id.*

<sup>35</sup> Trial Tr. 83:7–17, Dkt. No. 165.

chain disruptions were first experienced in April 2020, AbbVie used its safety stock on hand to supply patients until August 2020.<sup>36</sup>

Takeda, too, depleted its safety stock as a result of the supply chain disruption. Evidence at trial showed that the available product fell below target as of April 2020 and was projected to remain below target through March 2021.<sup>37</sup> Takeda's post-trial opening brief indicated that the safety stock inventory remained insufficient as of June 2021.<sup>38</sup>

*c. The Resulting Damages*

As was described briefly in *AbbVie I*, AbbVie alleges many losses stemming from Takeda's failure to produce sufficient lots of Lupron. These include loss of customers, loss of reputation, loss of doctors, loss of market share and loss of overall sales.<sup>39</sup> I find that AbbVie has experienced injury sufficient to sustain a finding of liability under applicable law;<sup>40</sup> the quantum of cognizable damages—if any—remains AbbVie's burden for the upcoming damages portion of the trial.

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<sup>36</sup> *Id.*

<sup>37</sup> JX 1761, at 28.

<sup>38</sup> *See* Def.'s Post Trial Opening Br., Dkt. No. 171. "Historically, if a Lupron lot were delayed by Takeda's quality processes, AbbVie would not necessarily be aware of or impacted by the delay because Takeda had the ability to ship product from its existing safety stock inventory . . . . [T]hat inventory has been depleted." *Id.* at 51.

<sup>39</sup> *AbbVie I*, 2021 WL 4059793 at \*5.

<sup>40</sup> The Supply Agreement is subject to the law of Illinois.

## II. ANALYSIS

As explained above, AbbVie contends that Takeda has breached the Supply Agreement in four ways: failure to comply with good manufacturing practices; failure to fulfill firm orders; failure to maintain safety stock; and allocation of leuprorelin products per an allocation schedule. I find three of these four arguments convincing and discuss each in turn.

### *A. Takeda has breached the Supply Agreement.*

To prove a breach of contract claim in Illinois, the applicable forum for interpreting the Supply Agreement, the following four elements must be satisfied: (1) the existence of a valid and enforceable contract; (2) performance by the Plaintiff; (3) breach by the Defendant; and (4) resultant injury to the Plaintiff.<sup>41</sup> Elements (1) and (2) are not disputed.<sup>42</sup> Elements (3) and (4) will be considered in further detail with respect to each theory of breach below.

#### 1. Failure to Operate the Hikari Plant in Compliance with Good Manufacturing Practices

Under Section 16.1(a) of the Supply Agreement, Takeda “shall be exclusively responsible for” ensuring compliance of its manufacturing facilities and processes associated with manufacturing, packaging, storage and delivery of Lupron with

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<sup>41</sup> See *Pepper Constr. Co. v. Palmolive Tower Condos.*, 59 N.E.3d 41, 66 (Ill. App. Ct. 2016) (citing *Coghlan v. Beck*, 984 N.E.2d 132 (Ill. App. Ct. 2013)).

<sup>42</sup> Stip. ¶ 10; Pl.’s Post-Trial Br. 32, Dkt. No. 172.

applicable laws, “including those . . . of the FDA . . . , including Good Manufacturing Practices . . . .”<sup>43</sup>

Takeda argues that the best efforts clause in Section 8.1(a) of the Supply Agreement mitigates its obligation to remain in compliance with cGMP. It would have me read the Supply Agreement to require solely that Takeda undertake its “best efforts” to satisfy the cGMP obligation. The canons of contract construction do not allow this result, as, under Illinois law, specific provisions must prevail over more general provisions.<sup>44</sup> Section 16.1(a) does not require best efforts as written;<sup>45</sup> to impose this lower standard, one would have to find that Section 8.1(a) should be grafted onto Section 16.1(a). But Section 8.1(a), by its own terms, refutes this conclusion, as it begins, “Subject to the provisions of this Agreement . . . .”<sup>46</sup> Subjecting Section 8.1(a), regarding best efforts, to Section 16.1(a), requires imposition of a higher standard—that of strict compliance rather than best efforts.<sup>47</sup>

The Inspection demonstrated that, as of November 2019, Takeda’s operations at the Hikari Facility were not in compliance with cGMP. As such, Takeda breached

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<sup>43</sup> Stip. ¶ 23.

<sup>44</sup> See *Am. Fed’n of State, Cty. & Mun. Emps. v. State Labor Relations Bd.*, 653 N.E.2d 1357, 1364 (Ill. App. Ct. 1995) (holding that courts must give effect to specific clauses over general clauses as a matter of contract construction).

<sup>45</sup> See Stip. ¶ 23.

<sup>46</sup> Stip. ¶ 17.

<sup>47</sup> I note that nothing in the record indicates that Takeda, which was in sole control of its manufacturing facilities, used best efforts to comply with cGMP in the time leading up to the 2019 FDA inspection; and that the resulting breaches of contract would thus not be saved by a “best efforts” standard in any event.

its obligation under the Supply Agreement to comply with Good Manufacturing Practices, and element (3) is satisfied.<sup>48</sup>

Was there a resultant injury to AbbVie? I find that there was. Takeda's attempts to remedy the results of the Inspection led to delays—to be sure, delays that were occasioned in a sincere attempt to bring the Hikari Facility back into compliance with cGMP and to satisfy regulators—but these delays led to an unavailability of product that has affected AbbVie's ability to timely provide Lupron to patients. This lack of inventory has harmed AbbVie through loss of customers and doctors as well as loss of market share. As such, the breach of Takeda's obligation to maintain the Hikari Facility under cGMP caused injury to AbbVie.

## 2. Failure to Fulfill Firm Orders

Section 9.2 of the Supply Agreement requires AbbVie to provide Takeda with firm orders for the first quarter in any eight-calendar-quarter period, and indicates that Takeda “shall fulfill all such firm orders (subject to the allocation procedure described in Section 9.4).”<sup>49</sup> AbbVie is also responsible for providing Takeda with

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<sup>48</sup> The Follow-Up Inspection conducted in July 2021 did not clear Takeda of its Official Action Indicated status. Takeda's counsel posited in post-trial oral argument that Takeda may actually now be in compliance with cGMP, as the FDA does not update a company's status until a letter is sent 90 days after inspection. Oral Arg. Tr. 114:23–34, 115:1–11. I need not reach the question of whether Takeda remains in breach at this time.

<sup>49</sup> Stip. ¶ 18.

a “good faith estimate” for the second and third quarters of that same eight-calendar-quarter period.<sup>50</sup>

Reference is made in Section 9.2 to an “allocation procedure” contained within the Supply Agreement.<sup>51</sup> Section 9.4 of the Supply Agreement lays out an allocation schedule that must be followed in the event that Takeda is unable, “for any reason beyond its reasonable control,” to produce enough leuprorelin products to satisfy its own needs, AbbVie’s needs, and the needs of any other third parties with whom Takeda has contracted.<sup>52</sup> Here, Takeda is unable to produce enough leuprorelin products, but the reason for this shortage is manifestly within its reasonable control.<sup>53</sup> Takeda’s failure to ameliorate the manufacturing issues thus does not activate the allocation schedule outlined in Section 9.4, and this language does not alter the analysis of Section 9.2.

The evidence shown at trial indicates that Takeda did not supply AbbVie with enough inventory to fulfill AbbVie’s firm orders from the months of April 2020 until at least March 2021.<sup>54</sup> Over that time period, 106 lots of Lupron had been ordered, with only 41 delivered.<sup>55</sup>

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<sup>50</sup> *Id.*

<sup>51</sup> Stip. ¶ 18.

<sup>52</sup> Stip. ¶ 20.

<sup>53</sup> Causes beyond the reasonable control of a party are delineated in Section 21.3 of the Supply Agreement. *See* Stip. ¶ 24.

<sup>54</sup> Trial Tr. 19:19–24, 20:3–7, Dkt. No. 165.

<sup>55</sup> Trial Tr. 20:3–7, Dkt. No. 165.

Takeda argues, nonetheless, that it has complied with the Supply Agreement. It argues that there is no “timeliness” requirement in the contract, and that, accordingly, there exists no requirement that firm orders be delivered to Abbvie by “dates certain.” Further, Takeda argues that it is only required to use best efforts to supply firm orders, in any event, under the Supply Agreement.<sup>56</sup> Therefore, per Takeda, so long as Takeda uses its best efforts to make the required deliveries at some point in time, Takeda has fulfilled its obligations under the Supply Agreement. This theory cannot prevail, for it would lead to absurdity in result.<sup>57</sup> The very nature of the firm order obligations in the Supply Agreement is time-based—the orders must be placed with respect to calendar quarters.<sup>58</sup> AbbVie did not contract for medical products that would be delivered at any time convenient to Takeda; the contract requires AbbVie to submit both its firm orders and attendant estimates, based on projected need in a given quarter.<sup>59</sup> Further, for the reasons set out above with respect to the cGMP obligation, the specific mandatory requirement to supply firm orders trumps the general “best efforts” language of Section 8.1(a). To the

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<sup>56</sup> Def.’s Answering Post-Trial Br. 5, Dkt. No. 176.

<sup>57</sup> See *Suburban Auto Rebuilders, Inc. v. Associated Tile Dealers Warehouse, Inc.*, 902 N.E.2d 1178, 1190 (Ill. App. 2009) (citing *Health Prof’ls, Ltd. v. Johnson*, 791 N.E.2d 1179 (Ill. App. 2003)) (“Courts will construe a contract reasonably to avoid absurd results”).

<sup>58</sup> See Stip. ¶ 18 (“[Abbvie shall provide Takeda] with (i) a firm order for the quantities of Product that [Abbvie] will require *during the first quarter* of such eight (8) quarter period, (ii) a good faith estimate of the quantities of Product that [Abbvie] will require *during the second and third quarters* of such eight (8) quarter period . . .”) (emphasis added).

<sup>59</sup> *Id.*

extent there is ambiguity in this regard, Takeda's own witness stated in his deposition that the firm orders were "binding."<sup>60</sup> Thus, I find that breach has occurred under Section 9.2 of the Supply Agreement.

It is clear here as well that AbbVie has experienced injury as a result of the breach of Section 9.2. The lack of inventory prevented AbbVie from distributing the Lupron and directly impacted AbbVie's sales. As a result, I find that elements (3) and (4) are satisfied, and that Takeda breached the Supply Agreement by failing to fulfill AbbVie's firm orders.

### 3. Failure to Maintain a Safety Stock of Leuprorelin<sup>61</sup>

The Supply Agreement also contains a requirement that Takeda keep a "safety stock" of three months' worth of Lupron, to be maintained "at all times" and "solely dedicated to and for use by [AbbVie]."<sup>62</sup> At trial, the evidence demonstrated that Takeda did not have adequate reserves of safety stock to satisfy its contractual obligations.<sup>63</sup> In particular, the "Apr 2020 update" to the "AbbVie US Finished

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<sup>60</sup> Oral Arg. Tr. 24:8–24.

<sup>61</sup> Takeda argues that, because this claim was not alleged in AbbVie's complaint, any breach under Supply Agreement Section 9.6(a) could not suffice as a basis for recovery. *See* Def.'s Answering Post-Trial Br. 5, Dkt. No. 176. However, Court of Chancery Rule 15(b) allows issues not raised by the pleadings to be tried by the express or implied consent of the parties, and to thus be treated "in all respects as if they had been raised in the pleadings." Ct. Ch. R. 15(b). AbbVie included in the Pre-Trial Order, stipulated to by Takeda, AbbVie's intent to demonstrate Takeda's breach of Section 9.6(a) of the Supply Agreement. *See* Stip. ¶ 53. Evidence with respect to the same was presented at trial. As such, AbbVie may seek relief on the safety stock theory, despite its lack of inclusion in the complaint.

<sup>62</sup> Stip. ¶ 20.

<sup>63</sup> JX 1761, at 28.

Goods Safety Stock Plan” produced by Takeda showed a deficiency in the amount of safety stock available beginning in April 2020 and projected to continue through March 2021.<sup>64</sup> Because the amount of safety stock Takeda reserved for AbbVie fell below required parameters, I conclude that there was a breach.

The resultant injury here is part and parcel of the same injury caused by the failure to fulfill firm orders. If Takeda had safety stock on hand, it could provide product to AbbVie and mitigate some of the delays associated with firm orders. Because no safety stock is available, delays in production result in an immediate shortage of Lupron available to AbbVie, which again has caused loss of sales, customers, doctors and market share. Thus, a resultant injury does exist, which occurred when the safety stock was required to satisfy AbbVie’s firm orders. Element (4) is thus satisfied, and Takeda is liable for breach of contract.

#### 4. Use of an Allocation Schedule

AbbVie’s final contention is that Takeda’s allocation schedule also constitutes a breach of the Supply Agreement under Sections 9.4 (as above) and 21.3 (a force majeure clause). On this front I am unable to agree.

The Supply Agreement does not, by its terms, prohibit the creation and use of an allocation schedule.<sup>65</sup> In fact, the Supply Agreement expressly contemplates the

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<sup>64</sup> *Id.*

<sup>65</sup> *See generally* JX 1849.

possibility of allocation of leuprorelin products in Section 9.4.<sup>66</sup> Takeda would be required to implement an allocation schedule under Section 9.4 if it was unable, due to any reason beyond its reasonable control (generally itemized in Section 21.3), to supply sufficient quantities of leuprorelin products to each of AbbVie and its affiliates, third party orders, and Takeda itself.<sup>67</sup> As AbbVie's counsel argues, this section is inapplicable, because the reasons for insufficient production *are* within Takeda's control.<sup>68</sup> That is, Takeda controls its production facilities, and it is its own failure to comply with cGMP at that facility, together with its attempts to remediate the failure and satisfy the regulators, that have caused a shortage of product. Thus, while Section 9.4 is not triggered, its existence is instructive.

In other words, nothing in the contract prohibits an allocation schedule, *per se*. However, imposition of an allocation schedule may cause breach of a duty under the Supply Agreement, leaving Takeda liable for breach of that provision. Here, Takeda is allocating production because it is unable, due to reasons under its reasonable control, to supply enough leuprorelin products. The current allocation schedule merely aggravates the existing breaches in the failures to fulfill firm orders and to maintain enough safety stock; it is not itself a breach. Thus, element (3)

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<sup>66</sup> Stip. ¶ 20.

<sup>67</sup> *Id.*

<sup>68</sup> Oral Arg. Tr. 28:3–20.

cannot be satisfied, and I decline to find that Takeda breached the Supply Agreement by use of an allocation schedule.

### **III. CONCLUSION**

Takeda has breached the Supply Agreement and is liable for breach of contract. The parties should confer and inform me as to a schedule for the remaining matters for trial, and whether a form of order at this stage is desirable.