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 7, 2021

A. Thompson Bayliss and Joseph A. Sparco, of ABRAMS & BAYLISS LLP, Wilmington, Delaware; OF COUNSEL: Paul J. Loh, Jason H. Wilson, Peter Shimamoto, Ashley L. Kirk, Lika C. Miyake, Amelia L.B. Sargent, and Kenneth M. Trujillo-Jamison, of WILLENKEN LLP, Los Angeles, California, *Attorneys for Plaintiff AbbVie Endocrine Inc.*

Kevin R. Shannon, Christopher N. Kelly, and Daniel M. Rusk, IV, of POTTER ANDERSON & CORROON LLP, Wilmington, Delaware; OF COUNSEL: Fred A. Kelly, Jr., Joshua S. Barlow, and Tiffany Jang, of HAUG PARTNERS LLP, Boston, Massachusetts; David A. Zwally and Mark Basanta, of HAUG PARTNERS LLP, New York, New York; and Christopher Gosselin, of HAUG PARTNERS LLP, Washington, DC, *Attorneys for Defendant Takeda Pharmaceutical Company Limited.*

GLASSCOCK, Vice Chancellor

This brief Memorandum Opinion addresses the Plaintiff's request for expedited injunctive relief. The Plaintiff is a Delaware corporation, AbbVie Endocrine Inc. ("AbbVie"), a drug distributor. It receives its supply of a particular drug, Lupron, a leuprorelin product, used to treat, among other things, pain associated with cancer, from the Defendant, Takeda Pharmaceutical Co. Ltd. ("Takeda"), a large drug manufacturer located in Japan. Specifically, Takeda is the only source for Lupron in the world; AbbVie is accordingly entirely dependent on Takeda for its supply. AbbVie purchases its supply of Lupron through a requirements contract with Takeda and distributes it in Canada and the United States. Takeda, meanwhile, also markets similar leuprorelin products outside the U.S., notably in Japan and Asia.

Takeda manufactures the product to the specifications required by the U.S. Food and Drug Administration (the "FDA") in its plant in Hikari, Japan. Starting in 2019, both Takeda and the FDA inspector at the Hikari plant found protocol violations relating to the production of Lupron. Ultimately, this caused Takeda, with the consent of AbbVie, to agree to third-party quality control oversight. That, in turn—along with remediation efforts aimed at resolving the identified protocol violations, including a "hold" that disrupted manufacturing for multiple weeks—caused delays in manufacturing and distribution, resulting in a world-wide shortage of leuprorelin products, including Lupron, that continues today. Takeda was thus

unable to satisfy demand and was unable to fill AbbVie's firm orders as required by contract.

AbbVie brought this action, seeking, in addition to a declaratory judgment and damages, positive injunctive relief. The matter was expedited due to the Plaintiff's allegations of irreparable harm to its business reputation and goodwill, although the pace of the litigation has not always seemed to reflect expedition. In April and May, a four-day trial was held on the request for injunctive relief.

The relief sought by AbbVie has changed over the course of the litigation. It originally sought specific performance in addition to an order that all Lupron production be diverted to satisfy its contractual requirements. Currently, it seeks an order holding Takeda to supply AbbVie with one of three modification options to Takeda's projected leuprorelin production schedule as of April 2021. Because the evidence at trial convinces me that such an injunction would be unworkable, would lead to the necessity for the oversight of Takeda's operations by the Court, and would inevitably lead to contempt hearings at which Takeda's ability to comply with the injunction would be at issue, I conclude I cannot in equity grant the proposed injunctive relief. In other words, even if I find that Takeda has breached its contract with AbbVie, and that as a result AbbVie faces irreparable harm, the injunctive relief sought is unavailable. Accordingly, in light of the expedited nature of the requested injunctive relief, I issue this Memorandum Opinion denying the relief requested.

The remainder of the relief sought at this stage in the proceeding, a declaratory judgment that Takeda is in breach, requires no expedition in light of the fact that relief here will be limited to damages. Accordingly, I will issue a post-trial decision on breach in due course. An additional phase of trial on damages will follow, if required. The balance of this Memorandum Opinion explains my decision to deny injunctive relief.

I. BACKGROUND

The facts 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.[1]

A. The Parties and their Relationships

Plaintiff AbbVie is a Delaware corporation that distributes a drug under the brand name Lupron Depot ("Lupron"). Lupron is a leuprolide acetate product "approved by the FDA for the palliative treatment of advanced prostatic cancer, the management of endometriosis, to improve anemia due to vaginal bleeding from uterine fibroids, and the treatment of children with central precocious puberty."[2]

[1] 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 ___").
[2] Joint Pre-Trial Stipulation ¶¶ 1, 3, Dkt. No. 156 [hereinafter "Stip"].

Defendant Takeda is a Japanese corporation headquartered in Tokyo, Japan that manufactures drug products containing leuprolide acetate, including Lupron.[3]

The parties have a supplier-distributor relationship. The Defendant produces Lupron, supplies Lupron to the Plaintiff, and the Plaintiff finishes and packages Lupron for sale in Canada and the United States.[4] Takeda manufactures Lupron at two facilities, one in Hikari, Japan (the "Hikari Facility") and one in Osaka, Japan (the "Osaka Facility").[5]

On or around April 30, 2008, Takeda and the predecessor entity to AbbVie entered into a supply agreement regarding the Plaintiff's and the Defendant's rights and obligations regarding the manufacture, supply, and sale of Lupron (the "Supply Agreement").[6] The Supply Agreement was amended on September 4, 2009 and July 17, 2019[7] and the parties agree that it is a valid and enforceable contract.[8]

B. Factual Background

As the reader may have, by this point, surmised, the central dispute here arises from a disruption to Takeda's supply line that sharply decreased the amount of Lupron that Takeda is able to supply to AbbVie. The disruption constitutes, per the Plaintiff, a breach of the Supply Agreement. The Plaintiff seeks injunctive relief

[3] *Id.* ¶¶ 2, 6.
[4] *Id.* ¶ 6.
[5] *Id.* ¶ 7.
[6] *Id.* ¶¶ 8–9.
[7] *Id.* ¶ 8.
[8] *Id.* ¶ 10.

crafted to mitigate the irreparable harm allegedly caused by the breach. Crafting such relief is difficult, however, even if the balance of the equities weighed in favor of an injunction. To illustrate the difficulty, a recitation of the factual background of the alleged breach and the factors related to the equities is helpful.

1. The Hikari Plant Failure

Lupron is distributed in syringes;[9] accordingly, it cannot be sterilized once it is assembled.[10] Instead, its many components must be individually sterilized and assembled in a sterile environment in order to avoid introducing bacteria, mold, or viruses into the drug.[11] That sterilization—of both Lupron's components and equipment that is used in the assembly rooms, such as gowns and utensils—is done in a piece of equipment called an autoclave.[12]

On October 28, 2019, an autoclave at Takeda's Hikari Facility—one of two facilities at which Takeda produces Lupron—failed its annual requalification test.[13] Takeda informed AbbVie of the issue by November 6, 2019[14] and kept AbbVie updated as to its investigation.[15] From November 18, 2019 through November 26, 2019, the FDA conducted its planned inspection of the Hikari Facility.[16] During the

[9] Trial Tr. 10:15–17, Dkt. No. 165.
[10] *Id.* at 210:21–211:4.
[11] *Id.* at 211:1–4.
[12] *Id.* at 211:5–11.
[13] Stip. ¶ 38; JX 390.
[14] JX 396.
[15] *Id.*
[16] Stip. ¶ 39; JX 434.

inspection, the FDA inspector flagged the autoclave issue.[17] By November 21, 2019, Takeda had issued a hold for several Lupron batches produced in the Hikari Facility.[18] On November 22, 2019, the FDA inspector requested that Takeda put all lots of Lupron on hold, which communication Takeda promptly forwarded to AbbVie.[19]

On November 26, 2019, the FDA inspector issued a "Form 483."[20] Per the FDA website, "[a]n FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."[21] The Form 483 describes itself as listing "observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance."[22] Takeda's Form 483, issued November 26, 2019, included seven observations.[23] One of these observations was that "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile did

[17] JX 434.
[18] JX 407.
[19] JX 412.
[20] Stip. ¶ 40; JX 434.
[21] FDA Form 483 Frequently Asked Questions, U.S. Food & Drug Administration (Jan. 9, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions.
[22] JX 434.
[23] *Id.*

not include adequate validation of the aseptic and sterilization process."[24] In other words, the autoclave failure that Takeda had identified not a month earlier had also caught the eye of the FDA, and all Lupron batches at the Hikari facility were placed on an indefinite hold.[25] That hold lasted three weeks, ending in the third week of December 2019.[26]

The parties, however, did not thereafter receive much reprieve. On March 11, 2020, the FDA issued an Official Action Indicated letter ("OAI Letter"), indicating that the Hikari Facility was "considered to be in an unacceptable state of compliance with regards to current good manufacturing practice (CGMP)."[27] On or about May 8, 2020, Takeda discovered that an autoclave at the Hikari Facility, which was used in the production of leuprolide products, was operated in a way that deviated from standard operating procedures.[28] That deviation, according to Takeda employees, had existed for approximately five years.[29] And on June 9, 2020, the FDA issued a warning letter to Takeda regarding the November 2019 inspection of the Hikari Facility as well as Takeda's responses to the Form 483.[30]

[24] *Id.* at 2.
[25] Trial Tr. 100:18–22, Dkt. No. 165.
[26] *Id.* at 100:23–101:3.
[27] JX 623.
[28] Stip. ¶ 41.
[29] *Id.* ¶ 42.
[30] *Id.* ¶ 43.

In response to and concurrently with these discoveries, Takeda took remedial steps, including shutting down the Hikari Facility for periods of time in spring of 2020.[31] Takeda also, in June of 2020, approved a plan to allocate its remaining production capacity of leuprorelin products at the Hikari Facility between production for AbbVie and production for itself.[32] That allocation went into effect once the Hikari Facility came back online in July 2020.[33] Takeda's June 2020 allocation schedule includes allocations for itself so that leuprorelin products can be marketed in Japan and elsewhere in Asia.[34] Notably, the dosages produced for leuprorelin product sales in Japan differ from the Lupron dosages produced for use in the United States, such that the end result is a different product.[35] In other words, the leuprorelin product sold by Takeda in Asia is not wholly interchangeable with the Lupron provided to AbbVie by Takeda.

Takeda is the world's only supplier of Lupron;[36] accordingly, due in part to the allocation, AbbVie experienced shortages of Lupron and, by the end of August, AbbVie had run out of its stock of certain dosages of Lupron.[37] That shortage was exacerbated by further remedial steps necessitated by the Hikari Facility's

[31] JX 1020; Trial Tr. 103:5–8, Dkt. No. 165; Stip. ¶ 45.
[32] Stip. ¶ 44.
[33] *Id.* ¶ 45.
[34] *Id.* ¶ 44.
[35] Trial Tr. 628:19–21, Dkt. No. 167.
[36] Trial Tr. 12:22–23, Dkt. No. 165.
[37] *Id.* at 102:22–103:19.

deficiencies. In September 2020, the FDA mandated—and the parties agreed—that Takeda would engage third-party consultants Quantic and Gintegra, with the latter to perform batch certification until the next FDA inspection.[38] That quality control process is still in place and AbbVie continues to see shortages in Lupron supply to this day.[39]

2. Lupron Production Today

The production of Lupron requires a number of technical and precise steps. Lupron is assembled in "clean rooms" by personnel who must pass equipment and product through autoclaves for sterilization purposes.[40] In order to bring its manufacturing processes into compliance with FDA and internal standards, Takeda has increased the number of data entries and procedures attending this process, necessitating 25 to 30% more time to complete.[41] In addition, the manufacturing arena undergoes a complete disassembly, sterilization and in-depth cleaning and re-assembly one out of every six days.[42] Again, in order to improve its procedures, Takeda's performance of this process has increased in length; while Takeda previously was able to produce half of a batch of Lupron on these disassembly days, they are now unable to manufacture any product at all.[43]

[38] JX 1536.
[39] Tr. Of 8.3.21 Post-Trial Oral Arg., at 9:12–17, Dkt. No. 190 [hereinafter "Posttrial Tr."].
[40] Trial Tr. 613–614, Dkt. No. 167.
[41] *Id.* at 615:19–23.
[42] *Id.*
[43] *Id.* at 616:1–8.

The active ingredient is prepared first, which takes nine days per lot.[44] Upon production, the active ingredient goes through about 36 days of quality tests and approval, at which time it is approved to be dispensed.[45]

Lupron then undergoes lyophilization, which is, at a high level, a freeze-drying process.[46] While some lyophilization only requires six steps to complete, Lupron production requires about 25 steps,[47] including, among other things, dissolution, filtration, sterilization, and filling.[48] Lyophilization is a four-day process. At this point, microspheres have been produced.[49]

Following the microsphere production are 45 days' worth of quality testing comprised of six major tests.[50] If the microspheres pass the applicable tests, they are then dispensed into the final fill process, which occurs over two days.[51] Once filled, the syringes go through another inspection and certain safety devices are assembled.[52]

At this time, Takeda's quality assurance department begins to undertake its 33 quality control tests, which take place over about four weeks.[53] In parallel, Takeda

[44] *Id.* at 620:5–7.
[45] *Id.* at 620: 7–10.
[46] *Id.* at 617:5–7.
[47] *Id.* at 617:5–9.
[48] *Id.* at 617–618.
[49] *Id.* at 617:20–21.
[50] *Id.* at 622:5–7.
[51] *Id.* at 622 8–11.
[52] *Id.* at 624:20–22.
[53] *Id.* at 629:21–24, 631:19–22.

reviews the batch record associated with the manufacturing process to date, decides whether to move forward with the batch, and, if so, sends it to inspection.[54] The batch record is finalized, with any deviations, investigations or other matters of concern being reviewed.[55]

It is at this juncture that Quantic, a third-party consultant, participates. Quantic shadows and consults with the Takeda employees completing the batch record review and undertakes its own final review.[56] If the batch is acceptable, Quantic then provides its final sign-off along with a letter of approval.[57] Gintegra, a second third-party consultant, undertakes a similarly in-depth review following the Quantic review.[58] Gintegra may, and according to Takeda, often does, review the full camera footage of the manufacturing process to ensure best practices are followed.[59]

Assuming the batch passes muster, Lupron then undergoes a packaging phase and associated quality control particular to the packaging.[60] All told, the manufacturing process, including the additional rounds of review and record production devised to respond to the various recent issues, now takes anywhere from

[54] *Id.* at 630:19–20.
[55] *Id.* at 632:19–24.
[56] *Id.* at 634:4–9.
[57] *Id.*
[58] *Id.* at 634:11–12.
[59] *Id.* at 634:13–22.
[60] *Id.* at 632:7–18.

over 100 to over 120 days.[61] And any inspection failure may result in a batch being withheld from timely release to AbbVie.

At trial, Takeda provided extensive evidence of its attempts to comply with good manufacturing practices and FDA requirements at the Hikari facility. In addition to the hiring of the two quality control firms discussed above, Takeda made its own efforts at remediation. Examples include the hiring of additional personnel and consultants,[62] training of employees,[63] monthly communication with the FDA,[64] fixes and repairs including replacement of equipment,[65] facility calibration[66] and simplifying and translating the standard operating procedures at the Hikari facility.[67] Takeda estimates that it invested roughly $30 million into the remediation program last year.[68] Still, production of Lupron lags.

3. Impact on AbbVie

The shortage of Lupron has impacted AbbVie in a myriad of ways, including loss of customers,[69] loss of reputation,[70] loss of doctors,[71] loss of market share[72] and

[61] *Id.* at 637:4–6.
[62] *Id.* at 561:22–24.
[63] *Id.* at 562:12–17.
[64] *Id.* at 562:17–19.
[65] *Id.* at 563:5–17.
[66] *Id.*
[67] *Id.* at 611:6–11.
[68] *Id.* at 562:2–4.
[69] Trial Tr. 123:11–18, Dkt. No. 165.
[70] JX 2522, at 20–21.
[71] Trial Tr. 134:2–14, Dkt. No. 165.
[72] JX 2349, at Fig. 13.

ultimately overall sales.[73] For the purposes of this Memorandum Opinion, I will assume that the loss of customers, including doctors, loss of reputation and loss of market share experienced by AbbVie led to an injury not wholly repairable by damages.

C. Procedural History

The Plaintiff filed a Verified Complaint, a Motion for Preliminary Injunction and a Motion to Expedite on November 6, 2020.[74] The Verified Complaint includes two counts: (I) Breach of Contract for failure to fulfill firm orders placed under the Supply Agreement and (II) Breach of Contract for allocating manufacturing capacity for Lupron to Takeda and/or its affiliates.[75]

On November 16, 2020, the Defendant opposed both the Motion for Preliminary Injunction and the Motion to Expedite.[76] On November 20, 2020, I granted the Plaintiff's Motion to Expedite and denied the Plaintiff's Motion for Preliminary Injunction.[77] Discovery followed. A four-day trial took place April 27 through April 29 and May 3, 2021.[78] I heard post-trial argument on August 3, 2021, and I considered the matter fully submitted at that time.[79]

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[73] *Id.*, at Fig. 12.
[74] Verified Compl., Dkt. No. 1 [hereinafter "Compl."].
[75] *See id.* ¶¶ 113–114, 126.
[76] Def.'s Opp'n to Pl.'s Mot. to Expedite, Dkt. No. 9.
[77] Telephonic Hr'g re: Pl.'s Mot. to Expedite and the Ct.'s Ruling, Dkt. No. 34.
[78] *See* Trial Tr., Dkt. Nos. 165–168.
[79] *See* Posttrial Tr.

II. ANALYSIS

In order to justify consideration by this Court of the extraordinary remedy of final injunctive relief, a plaintiff must demonstrate a violation of a legal right, resulting irreparable harm and that the balance of the equities invokes equitable relief.[80] For purposes of this Memorandum Opinion, I assume without holding that Takeda has breached the Supply Agreement, that AbbVie has suffered irreparable harm, and that the balance of the equities favors AbbVie. Even assuming those three elements have been satisfied, however, this Court cannot provide the injunction AbbVie seeks, because equity will not permit imposition of an order with which a litigant cannot comply, or one that will require unworkable court involvement to ensure compliance. The evidence at trial, recounted above, indicates that production of Lupron is a complex operation currently subject to delay. The delay is due to detailed oversight required by problems at the manufacturing facility, and Takeda's attempts to remedy those problems. Takeda is not presently able to produce the requested Lupron on a timely basis, and any affirmative injunction requiring it to do so would necessarily require extensive judicial supervision and enforcement beyond the purview of the court system. Such judicial intervention, I note, would likely be

[80] *Vento v. Curry*, 2017 WL 1076725, at *2 (Del. Ch. Mar. 22, 2017) (quoting *Arnold v. Soc'y for Sav. Bancorp, Inc.*, 1993 WL 183698, at *4 (Del. Ch. May 29, 1993)).

inadequate in any event. Therefore, the requested injunctive relief is not available in equity.

A. Any potential injunctive relief could not practicably be enforced.

The injunctive relief AbbVie has sought throughout this case has undergone many evolutions. Originally, AbbVie sought both specific performance of the Supply Agreement, which would have required Takeda to perform its obligations under the Supply Agreement in full, and an injunction enjoining the Defendant from allocating either the supply or production capacity for Lupron to itself or to others.[81] AbbVie then retreated from both prongs of this original request; their Corrected Trial Brief called for solely specific performance.[82] At trial, the Plaintiff indicated that what they intended to seek was an order requiring that "Takeda meet their own plan," referring to an April 2021 update to the original June 2020 allocation schedule designed by Takeda (the "April 2021 Schedule").[83] This plainly differs from specific performance; adherence to the April 2021 Schedule would not require strict compliance from Takeda under the terms of the Supply Agreement.[84] Later in the course of the trial, AbbVie proposed three different modification options to the April 2021 Schedule (collectively, the "AbbVie Post-Trial Proposal").[85] They renewed

[81] Compl. ¶¶ 117, 128.
[82] Pl.'s Corrected Tr. Br. 71.
[83] Trial Tr. 33:3–11, Dkt. No. 165; *see also* JX 2981.
[84] *See* JX2981; *see also* JX 96.
[85] Trial Tr. 1110–15, Dkt. No. 168; *see also* Decl. of Stephen Laegeler under 10 *Del. C.* § 3927 [hereinafter "Laegeler Decl."].

this request in their Post-Trial Brief, although they still call the request one for specific performance, and characterize the AbbVie Post-Trial Proposal as seeking "reliable, sufficient, and timely supply" of Lupron.[86]

This request is no longer one for specific performance. AbbVie alleges at least three ongoing breaches of the Supply Agreement: that Takeda is failing to fill contractual "firm orders"; that Takeda has failed to maintain a "safety reserve" of product sufficient to prevent any supply disruptions; and that Takeda's failure to operate the Hikari plant in compliance with good manufacturing practices violates the agreement. The order the Plaintiff seeks—to compel Takeda to provide it with a reliable, sufficient, and timely supply of Lupron—would not cure the first breach and would not address the second and third. But it is quite apparent on the record created at trial that it is the second and third deficiencies that have led to the disrupted supply of Lupron. The problems at the Hikari plant will not allow Takeda to create a contractually compliant safety reserve of Lupron, or fill the firm orders, because the remediation at the facility and the employment of the outside consultants has led to a bottleneck in production that Takeda has thus far been unable to overcome. The various and changing iterations of the relief AbbVie has requested in this litigation indicate an inability even on the Plaintiff's part to determine exactly what type of injunctive relief might be an effective remedy. By no longer seeking strict

[86] Pl.'s Post-Trial Br. 41, 46.

performance of the Supply Agreement, AbbVie tacitly admits that Takeda cannot comply with its contractual performance to fulfill all of its firm orders for Lupron. Instead, they now seek a more limited form of relief, though they note that the AbbVie Post-Trial Proposal remains subject to revision or modification.[87]

Takeda maintains that it would be willing to fulfill all contractual requirements if it could;[88] it has demonstrated at trial that it cannot comply at this time, given the recent manufacturing setbacks it has experienced and the attendant delays imposed as it implements a more rigorous quality assurance and quality control program.[89] Takeda predicts that, should the Court order performance, even the more modest mandatory injunctive relief sought would end in failure and non-compliance.[90] These failures would likely result in a series of contempt hearings at which Takeda defends based upon impossibility.[91]

In response, AbbVie posits that Takeda is "choosing" to deny AbbVie reliable supplies of Lupron,[92] and suggests that with a Court order and Court supervision Takeda could comply with any requirement so ordered. At oral argument, AbbVie posited that the current employees simply lacked the "will"

[87] Laegeler Decl., Ex. A, 1 n.1.
[88] Trial Tr. 656:1–5, Dkt. No. 167.
[89] *Id.* at 636:20–638:2.
[90] Def.'s Post-Trial Answering Br. 37–38.
[91] *Id.* at 3.
[92] Pl.'s Post-Trial Answering Br. 46.

required to overcome Takeda's production problems.[93] Presumably, it sees injunctive relief as necessary to generate sufficient willpower to overcome Takeda's Lupron shortfalls. At the same oral argument, AbbVie's counsel pointed out that a late July FDA inspection revealed that the Hikari plant remained out of compliance,[94] despite the extensive efforts to the contrary which Takeda demonstrated at trial.[95]

Mandatory injunction is an extraordinary remedy. Nonetheless, as AbbVie correctly points out, requirements contracts like the one at issue here, where the buyer has no alternative source for the product, are the quintessential business contract subject to specific performance.[96] In such a situation, the lack of an alternative source for an essential product threatens irreparable harm, so that allowing an efficient breach remedied by damages is insufficient in equity.[97] If Takeda were sitting on a mountain of Lupron suitable to the Supply Agreement, specific performance would be an attractive remedy. I note, however, that the existence of a requirements contract, the breach of which threatens irreparable harm,

[93] Posttrial Tr. 57:12–19. In trial testimony, one of AbbVie's witnesses suggested that changes in leadership of Takeda might be beneficial to the remediation efforts. *See* Trial Tr. 1093–94, Dkt. No. 168.
[94] Posttrial Tr. at 56:6–10.
[95] *See supra* notes 60–66 and accompanying text.
[96] UCC § 2-716 cmt. 2 ("[R]equirements contracts involving a particular or peculiarly available source or market present today the typical commercial specific performance situation. . . .").
[97] *See Equitable Trust Co. v. Gallagher*, 102 A.2d 538, 546 ("It is elementary that the remedy of specific performance is designed to take care of situations where the assessment of money damages is impracticable or somehow fails to do justice.").

is not sufficient to support injunctive relief where compliance is impossible or unworkable without extraordinary Court intervention, as the following hypotheticals attempt to make clear.[98]

Consider a case where buyer, a bullet-proof vest manufacturer, had entered a contract with a seller of a new metal, Vibranium. The seller touts the quality of its product, which is uniquely suited to the task, able to deflect the largest-caliber projectiles. The parties enter a requirements contract, and buyer makes a large down payment; subsequently, it enters contracts to supply Vibranium vests to a number of customers. Seller breaches, and buyer seeks specific performance.

Once it proves that the seller is a fraudster who developed the concept of Vibranium from reading comic books, a number of remedies are possible. It is readily apparent, however, that, despite threatened reputational harm to the buyer, the Court will not attempt to enforce a mandatory injunction to provide the fictional Vibranium. Equity will not impose a meaningless order or mandate impossible performance.

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[98] *See, e.g.*, *Wholesale Janitor Supply Co., Inc. v. Diamond Motor Sports, Inc.*, 1979 WL 6167, at *1 (Del. Ch. Mar. 1, 1979) ("[P]laintiff does not have the absolute right to seek specific performance . . . because such form of relief would, in effect, constitute specific performance of a building contract which a court of equity should not generally have to supervise"); *see also In re Diet Drugs (Phentermine/Fenfluramine/Dexenfluramine) Prods. Liab. Litig.*, 369 F.3d 293, 315 (3d Cir. 2004) ("[I]njunctions must be enforceable, workable, and capable of court supervision."); *Lemon v. Kurtzman*, 411 U.S. 192, 200 (1973) ("[E]quitable remedies are a special blend of what is necessary, what is fair, and what is workable."); Richard A. Lord, 25 *Williston on Contracts* § 67:22 (4th ed. 2021).

Next, consider another example, one closer to the instant facts. A supplier of automobiles for movies and resorts wishes to provide historically accurate Model B Fords to its customer for a new series of "Depression Parks" where visitors get to "vacation like it's 1939." It contracts with a manufacturer of replica cars, which shows the supplier an example of its work, a handmade Model B. The parties enter a requirements contract for 100 cars per month. But the manufacturer proves completely incapable of scaling up, and struggles to deliver five per month. The buyer points out that it will suffer irreparable reputational harm if it cannot supply its own customers with the promised Model Bs, and also argues that, with a sufficient expenditure of funds for plant and equipment and labor, the contract is performable. It seeks specific performance.

The result here will be the same as with the Vibranium case. Although the contract is theoretically performable, the Court would be unable practically to enforce an order of specific performance. The complexity of the business judgments involved, and the involvement of the Court required to differentiate contemptuous from non-contemptuous failures to comply, would involve the Court in the seller's business far beyond the boundaries of equity. Such a request for unworkable injunctive relief would be denied.

AbbVie, no doubt, would point out that unlike the small replica car manufacturer, Takeda is a large drug company that has proven capable in the past of

supplying Lupron without problems. True. But it became clear at trial that Takeda has thus far been unable to overcome both the production problems and the bottlenecks caused by vigorous third-party oversight of the complex production process, which oversight is required to satisfy FDA concerns and permit shipment of product to the U.S. market.

In *Northern Delaware Industrial Development Corporation v. E.W. Bliss Company,* this Court was asked to grant an order of specific performance that would have required the defendant to hire 300 workmen to advance the completion of a construction project which had fallen behind schedule.[99] The Court noted that enforcement would require the Court to become "deeply involved" in the supervision of a complex project located on the plaintiff's property, which would be impracticable, if not impossible.[100] As such, the *Bliss* court declined to grant the requested relief, reasoning that courts of equity "should not order specific performance of any building contract in a situation in which it would be impractical to carry out such an order."[101]

Although the case before me today deals with drug production rather than construction, the factual posture is similar enough for *Bliss* to be instructive. AbbVie argues that the production of Lupron has fallen behind schedule and seeks injunctive

[99] *See N. Del. Indus. Dev. Corp. v. E. W. Bliss Co.*, 245 A.2d 431 (Del. Ch. 1968).
[100] *Id.* at 433.
[101] *Id.* at 434 (citing Restatement (First) of Contracts § 371 (Am. Law Inst. 1932)).

relief that will require, as in *Bliss*, "speeding up of work at the site by means of a court-ordered requisitioning."[102] I conclude that, just as this Court in *Bliss* found it impractical to supervise the hiring and progress of 300 laborers in order to fulfill a building contract,[103] it would be similarly impractical to supervise and enforce the detailed and precise work of drug manufacturing overseas. AbbVie suggests that Takeda could meet its contractual obligations, if only it was ordered to do so,[104] but the facts at trial indicate otherwise.[105] If Takeda is objectively unable to produce Lupron in the amounts AbbVie requests while remaining in compliance with the applicable quality assurance and quality control metrics, ordering them to produce and deliver Lupron per AbbVie's firm orders will not magically resolve the compliance issues and attendant delays.

The complex nature of the production of Lupron, as complicated by FDA requirements and the addition of outside quality control monitors (as agreed to by AbbVie and as promised to the FDA) makes Takeda's ability to supply AbbVie with the requested amounts of Lupron, in the short term, problematic. As such, it may be impossible for Takeda to comply with an affirmative injunction to produce Lupron. The most likely scenario, should mandatory relief issue, and assuming supply delays

[102] *Bliss*, 245 A.2d at 432.
[103] *See generally id.*
[104] Trial Tr. 867:17–24, Dkt. No. 167.
[105] *Id.* at 822:7–823:1.

continue, is that a series of contempt hearings would ensue, in which I would be asked to second-guess Takeda's operation of its manufacturing process, and to determine whether any failure to supply Lupron in a timely fashion was contemptuous or non-contemptuous in nature. This type of relief, requiring as it would intensive Court oversight and enforcement, is unworkable, and unavailable in equity.

I note that I have assumed here both contractual breach and resulting irreparable harm. The latter element is clearly present, as AbbVie's inability to comply with demand from its own customers has no doubt caused some quantum of reputational damage beyond my ability to quantify as damages. Nonetheless, if I find Takeda in breach of the Supply Agreement, AbbVie is hardly without remedy. Much of the loss it has suffered may be addressed in damages after the next phase of trial.

III. CONCLUSION

The Plaintiff's Request for Injunctive Relief is DENIED. The parties should submit a form of order consistent with this Memorandum Opinion.