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: May 18, 2023
Date Decided: September 5, 2023

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GLASSCOCK, Vice Chancellor

The Defendant, Takeda Pharmaceutical Company Limited ("Takeda"), is a producer of pharmaceutical drugs, including a drug used to treat cancer, Lupron Depot ("Lupron"). The Plaintiff, AbbVie Endocrine Incorporated ("AbbVie"), is a distributor of Lupron under a contract with the Defendant which requires Takeda to supply Lupron sufficient to meet Plaintiff's needs as expressed by AbbVie's "firm orders." In 2019, however, Takeda found it necessary, intermittently, to shut down one of the plants at which it manufactured Lupron, rendering it unable to supply the Plaintiff's requirements and creating a shortage for other distributors of the drug around the world.

AbbVie sued in this Court, seeking to invoke equity to order the Defendant to distribute such Lupron as it could manufacture to AbbVie, with priority over other distributors. AbbVie also sought contractual damages. Much litigation has followed.

This is my third Memorandum Opinion in the matter. In *AbbVie I*, I found that equity could not support the injunctive relief sought by the Plaintiff. In *AbbVie II*, I found that Takeda was in breach of its contract with AbbVie, and that its breach had caused AbbVie cognizable damages. The current Memorandum Opinion addresses, post-trial, the quantum of those damages.

I will not repeat here the extensive factual development pertinent to the issues in *AbbVie I* and *AbbVie II*. Interested readers should consult those opinions. What

follows is a brief statement of only those facts necessary to understand my damages analysis. I then address the quantum of those damages and how they were demonstrated at trial.

I. BACKGROUND[1]

Plaintiff AbbVie is a Delaware incorporated drug distributor.[2] One drug that AbbVie distributes is Lupron, whose applications include the treatment of prostate cancer.[3] AbbVie receives its entire supply of Lupron from Defendant Takeda, the drug's sole producer.[4] This supply relationship is governed by a requirements contract (the "Supply Agreement") under which Takeda fulfills AbbVie's firm orders.[5]

In late 2019, a piece of sterilization equipment failed its annual requalification test at one of Takeda's two Lupron-producing facilities.[6] This set into motion a chain of events that resulted in intermittent facility closures and, ultimately, a period

[1] For a more detailed statement of this case's factual background, see my memorandum opinions of September 7 and 22, 2021. *AbbVie Endocrine Inc. v. Takeda Pharm. Co. Ltd.*, 2021 WL 4059793, at *2–5 (Del. Ch. Sept. 7, 2021) ("*AbbVie I*"); *AbbVie Endocrine Inc. v. Takeda Pharm. Co. Ltd.*, 2021 WL 4302920, at *2–4 (Del. Ch. Sept. 22, 2021) ("*AbbVie II*"). Facts drawn from the exhibits jointly submitted by the parties are referred to by the numbers provided on the parties' joint exhibit list (cited as "JX __" unless otherwise defined). Phase II trial testimony is cited as "TT (Name) __:__."
[2] Joint Pre-Trial Stipulation and Order ("Phase II PTO") ¶ 2, Dkt. No. 411.
[3] *Id.* ¶ 4.
[4] *AbbVie I* at *1.
[5] *Id.*
[6] Joint Pre-Trial Stipulation and Order ("Phase I PTO") ¶ 38, Dkt. No. 156; JX 390.

in which Takeda was unable to fulfill AbbVie's firm orders.[7] A Lupron shortage resulted.[8]

AbbVie brought suit for breach of contract in November 2020,[9] together with motions for a preliminary injunction, which I denied, and for expedition, which I granted.[10] Following discovery, a four-day trial ("Phase I") was held on the issues of Takeda's liability under the Supply Agreement and the appropriateness of final injunctive relief.[11] In *AbbVie I*, I held that the injunctive relief Plaintiff sought would be unworkable.[12] In *AbbVie II*, I determined that Takeda was liable for breaching the Supply Agreement.[13]

A second, three-day, trial ("Phase II") was held in January 2023 to determine "the quantum of cognizable damages—if any[.]"[14] Post-trial oral argument for Phase II was held on May 18, 2023, and I consider the matter fully submitted as of that date.[15]

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[7] *See AbbVie I*.
[8] *Id.* at *4.
[9] Verified Compl. for Specific Performance, Dkt. No. 1.
[10] Telephonic Hr'g re: Pl.'s Mot. to Expedite and the Ct.'s Ruling, Dkt. No. 34.
[11] *See* Trial Tr., Dkt. Nos. 165–68.
[12] *AbbVie I* at *8–9.
[13] *AbbVie II* at *7.
[14] *Id.* at *4.
[15] Tr. of Post-Trial Oral Arg., Dkt. No. 448.

II. ANALYSIS

The principal question before me is whether AbbVie has carried its burden of presenting the Court with a responsible, non-speculative estimate of damages. I begin by dealing with a number of threshold legal questions, including the appropriate choice of law, measure of damages, and burden of proof. From there, I move to an assessment of AbbVie's damages estimation methodology, which is the focal point of the parties' Phase II disputes. Following a brief overview of that methodology, I delve one-by-one into the disputed inputs. Finally, I address Takeda's arguments that any recovery should be reduced, or even eliminated, due to AbbVie's purported failures to mitigate or show causation.

A. Legal Standard

1. Delaware Law Applies to Phase II

My decision in *AbbVie II* applied Illinois law in determining that Takeda had breached the Supply Agreement, the "validity and interpretation" of which is governed by that state's law.[16] The Supply Agreement also provides that:

> Except as otherwise provided in this Agreement, any and all disputes arising out of or relating to this Agreement shall be governed by Section 15.05 of the [Contribution and Exchange Agreement, dated as of March 19, 2008, and amended and restated as of April 30, 2008 (the "CEA")].[17]

[16] *See AbbVie II*; Phase I PTO ¶ 26. The parties further stipulate that the Contribution and Exchange Agreement is a valid and enforceable contract. *Id.* ¶ 13.

[17] Phase I PTO ¶ 27. The parties have further stipulated that the CEA governs the Supply Agreement. *Id.* ¶ 28.

The CEA contains a broad choice of law provision applying Delaware law to disputes, "except as otherwise explicitly provided[.]"[18] Reading the two agreements together, "all disputes arising out of or in connection with" the Supply Agreement are assessed under Delaware law unless an explicit carve-out, such as the one made for "validity and interpretation[,]" applies.[19] Accordingly, Delaware law governs this damages determination because no such carve-out applies.[20]

2. The Measure of Damages

"[U]nder Delaware law, the standard remedy for breach of contract is based on the reasonable expectations of the parties that existed before or at the time of the breach."[21] Expectation damages "require the breaching promisor to compensate the promisee for the promisee's reasonable expectation of the value of the breached contract, and, hence, what the promisee lost."[22] Lost profits are an accepted means of quantifying expectation damages in a breach of contract action.[23] However, "no

[18] JX 100 § 15.06.
[19] *Id*.
[20] Defendant's post-trial briefing does not discuss the choice of law issue and relies almost entirely on Delaware caselaw. *See* Def. Takeda Pharm. Co. Ltd.'s Corrected Post-Trial Opening Br. ("Takeda PTOB"), Dkt. No. 442; Def. Takeda Pharm. Co. Ltd.'s Answering Post-Trial Br. ("Takeda PTAB"), Dkt. No. 432. Therefore, to the extent Defendant disputes the application of Delaware law, such an argument is deemed waived. *See Emerald P'rs v. Berlin*, 726 A.2d 1215, 1224 (Del. 1999) ("Issues not briefed are deemed waived") (citations omitted).
[21] *Siga Techs., Inc. v. Pharmathene, Inc.*, 132 A.3d 1108, 1132–33 (Del. 2015), *as corrected* (Dec. 28, 2015) ("*Siga*") (citation omitted).
[22] *Duncan v. Theratx, Inc.*, 775 A.2d 1019, 1022 (Del. 2001).
[23] *See generally Siga*, 132 A.3d 1108 (discussing Delaware courts' approach to lost profits calculations).

recovery can be had for loss of profits which are determined to be uncertain, contingent, conjectural, or speculative."[24]

3. Burden of Proof

I noted in *AbbVie II* that the burden remains on AbbVie to prove "the quantum of cognizable damages[.]"[25] While a plaintiff must prove the fact of damages by a preponderance of the evidence, the "proof required to establish the *amount* of damage is not as great as that required to establish the fact of damage."[26] Indeed, showings of future lost profits need only meet the more relaxed "substantial evidence" standard,[27] requiring "such relevant evidence that a reasonable mind might accept as adequate to support a conclusion."[28]

Here, the fact of damages is established by my holding in *AbbVie II* "that AbbVie has experienced injury sufficient to sustain a finding of liability[.]"[29] As a result, AbbVie's showing of the amount of damages "can be an estimate, uncertain,

[24] *Id.* at 1131 (quotation omitted).
[25] *AbbVie II* at *4.
[26] *Beard Rsch., Inc. v. Kates*, 8 A.3d 573, 613 (Del. Ch. 2010), *aff'd sub nom. ASDI, Inc. v. Beard Rsch., Inc.*, 11 A.3d 749 (Del. 2010) ("*Beard Rsch.*") (quoting *Total Care Physicians, P.A. v. O'Hara*, 2003 WL 21733023, at *3 (Del. Super. July 10, 2003)) (emphasis added).
[27] *See Agilent Techs., Inc. v. Kirkland*, 2010 WL 610725, at *29 n.271 (Del. Ch. Feb. 18, 2010) ("*Agilent*").
[28] *See Standard Distrib., Inc. v. Hall*, 897 A.2d 155, 158 (Del. 2006) (citations omitted).
[29] *AbbVie II* at *4.

or inexact"[30] as long as it provides the Court with "a basis to make [] a responsible estimate"[31] that goes beyond "mere 'speculation or conjecture[.]'"[32]

a. The Wrongdoer Rule

AbbVie argues that, in addition to this reduced burden, "[a]ny uncertainty in the damages calculation that can be traced to Takeda's breaches is presumptively resolved against Takeda" under the so-called "wrongdoer rule."[33] For its part, Takeda contends that "the wrongdoer rule [only] applies to bad-faith or willful breaches."[34]

This Court has previously acknowledged the inherent imprecision involved in crafting a remedy based on a hypothetical "but-for" world in which no breach occurred.[35] This complex reality is reflected in the discretion afforded to trial courts in shaping remedies that reflect the facts and circumstances of a specific case.[36] The wrongdoer rule AbbVie articulates is, at its core, just one form this discretion can take.

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[30] *Siga*, 132 A.3d at 1122 (quotation and citation omitted).
[31] *Beard Rsch.*, 8 A.3d at 613 (citing *Del. Express Shuttle, Inc. v. Older*, 2002 WL 31458243, at *15 (Del. Ch. Oct. 23, 2002)).
[32] *Id.* (quoting *Medek v. Medek*, 2009 WL 2005365, at *12 n.78 (Del.Ch. July 1, 2009)).
[33] Pl.'s Post-Trial Answering Br. ("AbbVie PTAB") 12–13, Dkt. No. 431.
[34] Takeda PTAB at 17.
[35] *See, e.g.*, *Agilent*, 2010 WL 610725, at *24 (discussing the relationship between uncertainties and trial court discretion in the crafting of remedies).
[36] *Id.*

Previous cases in which the Court employed AbbVie's preferred approach to resolving uncertainty all involved either bad faith or willful[37] action on the part of the defendant.[38] My decisions in *AbbVie I* and *II* made no finding that Takeda breached the Supply Agreement willfully or in bad faith, nor has AbbVie subsequently made such a showing.[39] Accordingly, I decline to apply the wrongdoer rule as articulated by AbbVie. I do so because I find that the reduced burden of proof described above appropriately balances AbbVie's uncertainty concerns against Takeda's lack of wrongful intent.

B. The Damages Model

The next issue before me is the appropriateness of AbbVie's damages model. Takeda challenges the fundamentals of this model on two grounds: AbbVie's purported data manipulation and the overall methodology used to estimate damages. I examine both of these arguments below.

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[37] That is, intentional.

[38] *See Siga*, 132 A.3d at 1131 (explicitly discussing the trial court's findings of bad faith and willfulness in resolving uncertainties and determining damages); *Bandera Master Fund LP v. Boardwalk Pipeline P'rs, LP*, 2021 WL 5267734, at *88 (Del. Ch. Nov. 12, 2021) (finding that breach was willful and the wrongdoer rule applicable but exercising discretion not to apply), *rev'd and remanded on other grounds*, 288 A.3d 1083 (Del. 2022); *Great Am. Opportunities, Inc. v. Cherrydale Fundraising, LLC*, 2010 WL 338219, at *28 (Del. Ch. Jan. 29, 2010) (finding that defendant acted willfully and maliciously); *Agilent*, 2010 WL 610725, at *34 (finding that defendant acted willfully and maliciously); *see generally Beard Rsch.*, 8 A.3d 573 (mentioning Delaware courts' willingness to resolve uncertainty against wrongdoers but making no explicit application of this discretion).

[39] *See* Pl.'s Post-Trial Opening Br. ("AbbVie PTOB"), Dkt. No. 421; AbbVie PTAB.

1. AbbVie's Alleged Data Manipulation

Takeda contends that AbbVie intentionally inflated its Lupron orders during the course of litigation in order to maximize its eventual damages.[40] Per Takeda, this "matters because a significant percentage of AbbVie's claimed damages . . . depend on ***AbbVie's own*** projections of future Lupron sales and profits."[41] But Takeda entirely neglects to explain *how* inflated order volume impacts AbbVie's damages calculations.[42] Indeed, order volume is not a component of AbbVie's damages model.[43] To the best of my understanding, Takeda instead invites me to approach *all* AbbVie-generated data with skepticism, given AbbVie's allegedly underhanded approach to order volume. Such an inference, drawn post-trial, must be adequately supported by the record. As discussed above, Takeda cannot marshal sufficient arguments, let alone evidence, to support its desired inference. Accordingly, my assessment of AbbVie's model, including its inputs, is based solely on the evidence in the record, free of adverse inferences.

2. Methodology

AbbVie's damages estimate is drawn from the expert report of economist Dr. Christine Meyer.[44] While I address various contested components of Dr. Meyer's

[40] Takeda PTOB at 10–17.
[41] *Id.* at 1–2 (emphasis in original).
[42] *Id.* at 10–17.
[43] AbbVie PTAB at 17–19; *see generally* JX 5399 (the "Meyer Report"); JX 5533 (the "Meyer Supplement").
[44] *See* Meyer Report; Meyer Supplement.

damages model in greater detail below, I provide a generalized overview here in order to better address Takeda's critiques.

The model's central premise is that the Lupron shortage caused customers to jump to competitors' products, costing AbbVie sales and, in some cases, permanently eroding Lupron's market share due to market characteristics that make a switch back unlikely.[45] Dr. Meyer begins by breaking damages out into three categories based on Lupron's principal applications: urology ("URO"), pediatrics ("PED"), and gynecology ("GYN").[46] Both URO and PED are further divided into past and future damages, given AbbVie's allegations that the shortage's impacts will continue for years to come.[47]

a. Estimation of URO and PED Damages

Dr. Meyer calculates past damages for the URO and PED segments by taking the difference between an estimated pre-shortage baseline and the actual sales data for a given post-shortage month.[48] After making necessary adjustments, such as for the post-shortage launch of a new competitor drug, Dr. Meyer then multiplies this difference by the actual average selling price per unit for that year.[49] Finally, she

[45] Meyer Report at 0026–47.
[46] *See generally id.* at 0002–04 (laying out the general structure of Dr. Meyer's expert report).
[47] *Id.* at 0047–61, 0081–92, 0105–09.
[48] *Id.* at 0047, 0059, 0081, 0091.
[49] Where the data manipulations employed are identical for URO and PED, I cite only to the URO section of Dr. Meyer's report discussing those calculations. *See, e.g., id.* at 0054 (discussing this calculation for the URO segment). For 2022 calculations, Dr. Meyer used AbbVie's internal price projections. *Id.*

incorporates the incremental costs AbbVie would have incurred in selling those units.[50] This results in a dollar figure representing AbbVie's estimate of its lost profits due to lost sales in that segment through October 2022.[51]

AbbVie's estimate of future URO damages aims to quantify the difference between (a) the profits AbbVie would have earned from October 2022 through 2031 had there been no shortage and (b) the reduced profits it expects to earn in the real world during that same period.[52] The URO model incorporates sales and pricing projections from the expert report of Edward Buthusiem with data on that market segment's expected growth rate, yielding a dollar estimate of damages.[53] Dr. Meyer then discounts this figure to its present value using AbbVie's weighted-average cost of capital ("WACC").[54]

AbbVie projects that the impact of the shortage on future PED profits will have concluded in June 2023.[55] Per AbbVie, the shortage provided a timely boost to a new market entrant, Fensolvi, allowing that drug to capture a larger market share than it otherwise would have.[56] Dr. Meyer therefore begins calculating future damages by taking the difference between Lupron's pre-shortage PED market share,

[50] *Id.* at 0056 (describing the incorporation of cost for URO).
[51] *Id.* at 0058–59; *see* Meyer Supplement (bringing past damages data up to date through October 2022).
[52] *See* JX 5381 at 0042 ("Buthusiem Supplement"); Meyer Report 0059–61.
[53] Meyer Report at 0060.
[54] *Id.* at 0060–61.
[55] *Id.* at 0091–92.
[56] *Id.* at 0084–88.

adjusted downward to account for competition from Fensolvi but not the shortage-induced boost, and Lupron's post-shortage market share projected forward.[57] These lost sales figures are then combined with sales price projections, as well as estimated costs, before being discounted to the present value.[58]

b. Estimation of GYN Damages

AbbVie seeks only past damages for the GYN segment.[59] Because Lupron sales in the GYN market vary considerably from month to month, Dr. Meyer employs a three-month rolling average to smooth this volatility.[60] She then uses this smoothed data as a baseline against which to compare the post-shortage data, finding that AbbVie lost sales through October 2021.[61] Dr. Meyer then uses AbbVie's pricing and incremental cost data to convert those lost sales into a dollar figure damages amount.[62]

c. Incidental Damages

The final piece of AbbVie's damages estimate involves two additional categories of past damages not specifically associated with one of the three major Lupron applications. The first category involves additional testing fees that AbbVie incurred to ensure that certain shipments of Lupron received from the troubled

[57] *Id.*
[58] *Id.* at 0091–92.
[59] *Id.* at 0092–93.
[60] *Id.* at 0105–06.
[61] *Id.* at 0106–08.
[62] *Id.* at 0108–09.

manufacturing plant were safe for distribution.[63] AbbVie also claims to have incurred penalties from the federal government due to pricing penalties resulting from the shortage.[64]

d. Takeda's Critiques

Though Takeda's economic expert, Dr. Michal Malkiewicz, adopts Dr. Meyer's methodology in his own damages estimate,[65] Takeda contends that this does not constitute an endorsement and that "Takeda has conceded nothing with respect to the cause or amount of AbbVie's alleged lost profits."[66] Despite this explicit lack of concession, Takeda's arguments focus on the model's inputs and assumptions, leaving the overarching methodology untouched.[67] I find that the damages model employed by the parties is capable of producing a reliable, non-speculative estimation of damages. Accordingly, I adopt it.[68]

I address Takeda's critiques of various model inputs below.

C. Damages Calculation

Having found Dr. Meyer's damages calculation methodology fundamentally reliable, I turn now to the principal source of the parties' disputes: the model's

[63] *Id.* at 0110.
[64] *Id.* at 0110–13.
[65] *See generally* JX 5453 (the "Malkiewicz Report").
[66] Takeda PTAB at 16.
[67] *See* Takeda PTOB at 40–78; Takeda PTAB at 6–51.
[68] For the avoidance of doubt, the Court also adopts the numerous inputs and assumptions underlying this model. To the extent a given input or assumption is not addressed in this opinion, it is because I find it reasonable.

inputs. Below, I carefully assess each dispute, finding most of AbbVie's proposed inputs reasonable, with a key exception.

In the following brief paragraphs, I present an overview of the disputes between the parties before beginning a more detailed analysis. Finally, having adopted AbbVie's fundamental damages model and resolved the disputes as to inputs and application, I conclude by asking the parties to apply these rulings by computing the appropriate damages figure.

I begin with an analysis of the appropriate discount rate, finding it more sensible to apply AbbVie's overall WACC, as calculated by the market, than the company's internal "hurdle rate." Turning to the URO market segment, I find AbbVie's proposed 22-month benchmark credible in light of Lupron's stable market share pre-shortage. I further find that AbbVie's estimated growth rate for the URO market is reasonable in light of both the actual data and competitors' projections. While AbbVie has shown its 2022 pricing update succeeded in stabilizing Lupron URO's falling prices, the company fails to establish that the update will allow it to steeply increase prices through 2031 without losing sales as it contends.

The only adjustment I make to AbbVie's PED damages estimate is the removal of a disputed period of volatility immediately preceding the shortage. I find AbbVie's estimate of GYN damages reasonable and decline to make Takeda's requested adjustments. Turning to AbbVie's claims for incidental damages, I find

that it is entitled to some, but not all, of the damages it seeks. Finally, I find that, because Takeda's arguments on AbbVie's failure to mitigate or establish causation are unpersuasive, AbbVie is entitled to expectation damages as well as accompanying pre- and post-judgment interest.

My reasoning follows.

1. Discount Rate

Generally, a discount rate consists of a component representing the time value of money as well as a premium representing the risks associated with that specific investment.[69] Here, the risk premium represents the uncertainty associated with AbbVie's ability to achieve its projected profits.[70] As touched on briefly in Section II.2.A, the discount rate is used in the parties' damages models to discount estimates of future damages to their present value. A higher number will, all else equal, result in a correspondingly lower present value.

Both parties' experts use AbbVie's WACC as their discount rate, reflecting the average cost the company must pay its investors for their capital.[71] They differ in the source (and size) of the WACC. AbbVie proposes that the Court use the company's enterprise-level WACC of 6.6%, as calculated by Bloomberg.[72] In

[69] Jonathan Berk & Peter DeMarzo, Corporate Finance: The Core 241–42 (pages numbered sequentially based on PDF) (5th ed. 2020) ("Berk & DeMarzo").
[70] *See, e.g.*, Malkiewicz Report at 0050.
[71] Berk & DeMarzo at 731.
[72] AbbVie PTOB at 77–78.

contrast, Takeda argues that the Court should apply the 8.0% WACC AbbVie uses as its "hurdle rate," given that this is the figure AbbVie uses internally to calculate the net present value of potential future investments.[73] Per Takeda's expert,

> [The] [h]urdle rate is a minimum rate that a company expects to earn from its investment project. Thus, in order to be accepted, the estimated project's rate of return should exceed the company's hurdle rate. Hurdle rate is also used as a discount rate to calculate the net present value of investment. Hurdle rate can be adjusted up or down by a company to reflect relevant risks of the specific investment project. Therefore, it is a better measure of the discount rate for a specific project (the Lupron franchise) that incorporates all relevant risks.[74]

This assessment draws a tenuous conclusion from a correct, if incomplete, overview of its technical underpinnings. A company uses its internal hurdle rate as a benchmark against which to assess which projects it should prioritize given limited time and funds.[75] While a hurdle rate can be "adjusted up or down by a company to reflect relevant risks of the specific investment project[,]" that is not the case where, as here, a company uses a single company-wide hurdle rate that is only adjusted periodically.[76] Instead, a company may opt to adjust its hurdle rate upwards for various reasons unrelated to a given project's risk,[77] including a prioritization of the most profitable projects in a research and development intensive industry.

[73] Takeda PTOB at 56–58; Malkiewicz Report at 0050.
[74] Malkiewicz Report at 0050 n.174.
[75] TT (Meyer) 754:2–14.
[76] *Id.* at 839:11–841:13; JX 5357 160:25–164:18.
[77] TT (Meyer) 754:2–14.

I find that the evidence in the record supports a conclusion that the risks associated with AbbVie's Lupron profits through 2031 align more closely with the company's risk as a whole. I further find credible Dr. Meyer's testimony that AbbVie's proposed discount rate of 6.6% may *overstate* the risk for a mature drug like Lupron, given that Bloomberg's estimate of the company-wide WACC includes the risk of nascent drugs in development.[78] Combined with my determination, *infra*, that Lupron enjoyed a steady market share prior to the shortage, I conclude that AbbVie has carried its burden in showing that its proposed discount rate of 6.6% is an appropriate approximation.

2. URO – Past Damages

Takeda's principal dispute with AbbVie's estimate of past URO damages is the length of the benchmark period used to calculate Lupron's baseline market share.[79] As discussed above, this baseline is used to calculate the resulting post-shortage drop in sales for a given month. Here, Dr. Meyer's benchmark period runs from October 2018 through July 2020,[80] resulting in a stable baseline market share of 64.3%.[81]

[78] *Id.* at 752:20–754:1.
[79] Takeda PTOB at 60–63.
[80] Meyer Report at 0048.
[81] *Id.* at 0051.

While Takeda faults this benchmark for excluding nearly two years of data,[82] AbbVie presents compelling evidence in favor of the shorter period. AbbVie argues that "the oldest available data contains a subtle downward trend that is not present in later data."[83] Per AbbVie, that downward trend was replaced by the current stability.[84] As supporting evidence, AbbVie points to pre-shortage internal documents, as well as testimony.[85] Indeed, the stable baseline AbbVie projects is robust to adjustments of the benchmark period by up to one year (i.e., as short as 10 months or as long as 34 months).[86]

Takeda argues that this "'robustness analysis' was outcome driven" and obscures "Lupron's historically declining market-share due to growing competition."[87] Takeda bases this argument on select pieces of testimony from AbbVie employees and vague contentions that Dr. Meyer's exclusion of the oldest data was unjustified.[88] It has no real answer to the argument, borne out in the data,

[82] Takeda PTOB at 60.
[83] AbbVie PTOB at 54 (citing TT (Meyer) 725:15–21).
[84] *Id.* at 54–56.
[85] JX 448; TT (Lidtke) 137:2–16.
[86] TT (Meyer) 718:3–16, 717:22–718:2.
[87] Takeda PTAB at 32–33
[88] *Id.* I find credible Dr. Meyer's testimony that her model was not impacted by the anomalous pre-shortage drop in Zoladex's market share. TT (Meyer) 847:8–848:7. As a result, I decline Takeda's invitation to make an unspecified downward adjustment to AbbVie's estimated Lupron benchmark. *See* Takeda PTOB at 62–63; Takeda PTAB at 32 n.11.

that Lupron URO's market share had reached a stable equilibrium prior to the shortage.[89]

Accordingly, I find that AbbVie has carried its burden in showing that Lupron URO enjoyed a stable market share prior to the shortage and that a 22-month benchmark is appropriate.

3. URO – Future Damages

Turning to future URO damages, two disputed inputs remain before me: the market growth rate and AbbVie's "universal update" pricing changes.[90]

a. URO Market Growth Rate

AbbVie assumes an approximately 2.9% annual growth rate through 2030 for the relevant androgyn deprivation treatment ("ADT") market segment.[91] This figure is drawn from AbbVie's January 2020 Long-Range Plan[92] and is purportedly

[89] *See* Takeda PTAB at 31–33 (fielding only conclusory accusations that Dr. Meyer erred by excluding the "stale" data).

[90] Takeda contends that there is a third dispute: the impact of 2022 market entrants in the form of Camcevi and Lutrate, which it argues AbbVie's model fails to account for. Takeda PTOB at 63–64. This argument is too little, too late. Though Takeda argues that it "can illustrate AbbVie's mistakes without bearing the burden of soundly modeling their impact[,]" Takeda PTAB at 17, Takeda cannot credibly argue the materiality of these competitors or their impact on AbbVie's model without some quantifiable evidence, which was not presented at trial. Perhaps realizing this, on the eve of post-trial argument, Takeda filed a motion to supplement the trial record, which included amended models purporting to estimate impact of the new URO competitors. Defs.' Mot. to Suppl. the Trial R., Dkt. No. 419. Finding that the proposed supplement contained improper expert opinions, I granted AbbVie's motion to strike. Pl.'s Opp'n to Mot. to Suppl. the Trial R. and Cross-Mot. to Strike, Dkt. No. 427; Letter Op., Dkt. No. 438. Because Takeda's arguments here do not find sufficient support in the current record, such that they can move beyond mere speculation, I need not address them further.

[91] Buthusiem Supplement at 0046, Fig. 22. AbbVie assumes a growth rate of 1.9% for the target market for 2031, the final year of the future damages period at issue here. *Id.*

[92] *Id.*

consistent with the United Nations' growth projections for ADT's primary target demographic.[93] Takeda argues for a growth rate of 1.75% per year citing a 2019 GlobalData report on the ADT market,[94] further informed by expert testimony.[95]

AbbVie contends that the GlobalData report Takeda relies on is stale and has not been borne out by IQVIA's[96] ADT market data since 2019.[97] Indeed, outside of the shortage's impact in 2020, GlobalData's estimate underpredicts the actual data, as reported by IQVIA, by at least 2% for each year from 2018 to 2022.[98] While Takeda attacks AbbVie's use of United Nations' demographic data, which includes women, as an inappropriate proxy for the growth of the overwhelmingly male ADT market,[99] the data in question is merely one of a handful of sources AbbVie uses to validate its estimate.[100] Takeda declines to directly address the shortcomings of the GlobalData report.[101] Accordingly, I find that, absent credible evidence of an impending drop in demand for ADT, AbbVie's estimated growth rate of 2.9% is both consistent with recent data and reasonably conservative.

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[93] *Id*.
[94] Malkiewicz Report at 0102.
[95] Takeda PTOB at 58–60.
[96] IQVIA is a third-party, industry-standard data clearinghouse. AbbVie PTOB at 8.
[97] AbbVie PTOB at 65–69.
[98] JX 5592 at 0046; *see* AbbVie PTOB at 67.
[99] Takeda PTAB at 33–36.
[100] TT (Buthusiem) 453:16–456:1; JX 5592 at 0013–16.
[101] *See* Takeda PTOB at 58–60; Takeda PTAB at 33–36.

Takeda draws upon the opinion testimony of its expert medical oncologist, Dr. Marc Garnick, to argue "that the standard of care is shifting, and the relative use of ADT will decrease."[102] This impending decrease, per Takeda, merits a downward adjustment of the ADT market segment's future growth.[103] I found Dr. Garnick to be an inspirational and persuasive witness in his discussion of the future of treatment for prostate cancer. However, I find that Dr. Garnick's opinion testimony does not justify the adjustment Takeda seeks. Dr. Garnick, in both his expert report and trial testimony, discussed recent "leading-edge" advances in the identification and treatment of prostate cancer, concluding that ADT's "usage will diminish[.]"[104] However, Dr. Garnick's report offers very little explanation of *when* this change will occur and *how fast* it will take place.[105] Thus, I find that, even if I agree with Dr. Garnick's ultimate conclusion that ADT usage will eventually diminish, Takeda has not marshalled evidence showing that this diminution will occur by 2031, such that a significant downward adjustment of AbbVie's otherwise reasonable estimated growth rate for the ADT market is merited.

[102] Takeda PTOB at 59–60.
[103] Takeda PTAB at 33–36.
[104] TT (Garnick) 591:2–23; *see* JX 5382 ("Garnick Report") at 0056.
[105] *See, e.g.*, Garnick Report 0056–59 (stating overall conclusions, with only one of nine providing any sort of timeline).

b. Universal Pricing Update

The parties' next dispute centers on the impact of AbbVie's 2022 rollout of a new pricing structure impacting many of its Lupron URO sales channels. This update aims to increase the average sale price ("ASP") of future units of Lupron sold in the URO market, which would, obviously, increase the money damages arising out of lost sales per unit. This raises two issues: (1) whether the pricing update was a litigation-driven strategy and (2) whether AbbVie's estimates of post-update ASP are credible.

Takeda argues that "AbbVie's claim that this radical change to Lupron pricing was conducted in the ordinary course of business is suspect" because AbbVie had been aware of Lupron URO's declining profitability since at least 2015.[106] This, per Takeda, merits scrutiny of AbbVie's mid-litigation implementation of the strategy.[107] AbbVie retained Boston Consulting Group ("BCG") in October 2019 to evaluate its Lupron URO business.[108] BCG delivered its recommendations the following spring.[109] Per AbbVie, supply issues had already begun at that point and the company could not implement the recommendations until supply stabilized.[110] Takeda contends that the shortage did not start until August 2020, months after the

[106] Takeda PTOB at 65. Notably, Takeda does not actually argue that AbbVie would not have implemented a pricing update absent the shortage.
[107] Takeda PTAB at 37–41.
[108] TT (Lidtke) 139:22–140:21, 144:19–145:8.
[109] *Id.* at 151:12–16.
[110] *Id.* at 151:17–152:11.

recommendations were delivered.[111] However, the record shows that both parties were aware of problems at the Hikari plant by spring of 2019.[112] Accordingly, I find AbbVie's justifications for its delayed implementation of BCG's recommendations credible and that Takeda's contentions to the contrary lack sufficient supporting evidence.

AbbVie projects that the pricing update will reverse a decade of declining ASP in the URO segment. Mr. Buthusiem projects that the overall ASP will increase in each subsequent year, starting from a low of $141 in 2022 and reaching $177—or roughly 2015 levels—by 2031.[113] In order to rectify declining profitability in the indirect sales channel, purportedly borne out of an inconsistent patchwork of discounts and elevated wholesaler fees,[114] AbbVie moved its indirect contracted customers from fixed price contracts to pricing based on Lupron's wholesale acquisition cost ("AC").[115] Under this new formula, the uniform ASP for the indirect channel would be equal to the AC minus 91.75%, less a 2.05% returns and service fee.[116] AbbVie further plans to increase AC by 4.9% each year through 2031.[117]

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[111] Takeda PTAB at 38.
[112] *See, e.g.*, Takeda PTOB at 18–19 (discussing AbbVie's May 2019 audit of the Hikari plant).
[113] JX 5585 at 0030.
[114] Buthusiem Supplement at 0059–61.
[115] *Id.* at 0061–64. Wholesale acquisition cost refers to the price a drug company offers its medication to a wholesaler. This figure is *not* for a single dose of the drug. For instance, Lupron's 2022 wholesale acquisition cost is $1,854. *Id.* at 61.
[116] *Id.* at 0065.
[117] *Id.*

Because the channel subject to this pricing scheme accounts for 27.1% of AbbVie's URO sales, these changes are a major driver of the overall rebound in ASP that AbbVie projects.[118]

Takeda argues that AbbVie's projections lack support in both basic economic principles and reality. AbbVie's projections assume that the negative repercussions of its 4.9% annual price increases will be limited to a one-time drop in sales volume of 15% in the channel impacted by the pricing update.[119] This figure of 15% is based, it would appear, on a single email between AbbVie employees, rather than any economic analysis that has been explained in this case.[120] Nor does AbbVie explain how Lupron would maintain *both* increasing prices and a stable market share in the face of competition from both Eligard and new market entrants. Instead, AbbVie argues that evidence of the pricing update's initial success justifies the Court's adoption of Mr. Buthusiem's ASP projections.[121] Evidence that AbbVie's pricing update has not caused customer demand to drop is probative of the company's ability to stem price erosion in the indirect channel.[122] It does not, to my mind, justify AbbVie's argument that Lupron will maintain its market share despite compounding 4.9% price hikes every year through 2031. In short, customers'

[118] *See id.* at 0067, Fig. 44 (breaking out the various components of ASP).
[119] *Id.* at 0069; TT (Matthew Williams) 210:9–22; TT (Buthusiem) 524:23–528:13.
[120] Buthusiem Supplement at 0069; TT (Meyer) 773:14–774:4.
[121] AbbVie PTOB at 59–61.
[122] *See id.* at 59–60 (arguing that a post-update increase in indirect channel sales volume proves the pricing update successful).

tolerance for an indirect channel price of $114.95 in 2022, absent more, does not prove that they would maintain their purchasing habits in the face of a price of $176.80 in 2031.[123]

Accordingly, I find that, while AbbVie has shown that the pricing update stabilized the dropping price of Lupron in the indirect channel, it nonetheless fails to carry its burden of showing that the ambitious price increases it has planned will not have a negative impact on customer demand. Combined with my finding, *infra*, that Lupron URO's market share was stable with AbbVie's showing that a stabilized price has not resulted in customer flight, I therefore find it reasonable that AbbVie will maintain its 2022 pricing in the indirect channel through 2031.[124]

4. PED – Past Damages

Moving next to the pediatrics market for Lupron, the parties disagree over two aspects of the benchmark: the extent to which a volatile period from April to August 2020 should be included and the appropriate adjustment for a new competitor drug, Fensolvi.

[123] *See* Buthusiem Report at 0065, Fig. 42.
[124] *Id*. For the avoidance of doubt, the figure I reference is equal to $114.95. I decline to alter other components of the overall ASP pricing model because Takeda has not presented sufficient evidence that AbbVie will diverge from its pricing strategy.

a. The Appropriate Benchmark Period

Takeda accuses AbbVie of inflating the benchmark by including data from April 2020, "in which Lupron market-share was anomalously high."[125] Though AbbVie acknowledges that April 2020 saw a "spike in market share," it contends that both this spike and a subsequent "'valley' of lower-than-usual market share" are related to the drop, and subsequent recovery, in market share of a surgically-implanted competitor at the beginning of the COVID-19 pandemic.[126] Per AbbVie, by removing the spike and keeping the valley, Takeda "cherry-pick[s]" its data.[127] Takeda responds by pointing out that AbbVie's drop-and-recovery theory lacks evidentiary support and is further undermined by the fact that the valley "extends months beyond" the parties' benchmark period.[128] What Takeda fails to mention is that the mid-point of this extended valley also coincides with the start of backorders in August 2020, further confounding the analysis.[129]

I find that, during the period from April to August 2020, the PED market experienced a variety of disruptions that contributed to market share volatility, including both the pandemic and early impacts of the shortage.[130] Neither party's

[125] Takeda PTOB at 70.
[126] AbbVie PTAB at 30.
[127] AbbVie PTOB at 73.
[128] Takeda PTAB at 42.
[129] *See* Meyer Supplement at 0024 (graphing market share in the PED segment).
[130] TT (Meyer) 736:19–737:2 (acknowledging that some of the "valley" may be due to early impacts of shortages).

explanation convinces me that the additional market share information contained in these datapoints outweighs the noise they bring to the benchmark estimate. Accordingly, I find that the parties should exclude from the benchmark period all data from April 2020 onward.

b. The Impact of Fensolvi

The parties further dispute how Lupron PED's but-for market share should be adjusted to account for Fensolvi, a competing drug that was launched in June 2020.[131] AbbVie takes the position that, because Fensolvi "was launched contemporaneous with the peak of the [Lupron PED] shortage[,]"[132] it received a competitive boost that allowed it to achieve a larger market share than it otherwise would have.[133] AbbVie therefore models two but-for market share scenarios: one in which Fensolvi enjoyed no boost from the Lupron shortage, and a second in which the shortage caused Fensolvi to take some of Lupron's market share.[134] In order to isolate what piece of Fensolvi's market share is attributable to the shortage-induced boost, AbbVie's economic expert estimates the boost enjoyed by a third, established, competing PED drug, Triptodur.[135] She does so by comparing Triptodur's post-shortage market share to a pre-shortage baseline, finding a boost of approximately

[131] *See* Meyer Report at 0084 (discussing the launch of Fensolvi).
[132] *Id.*
[133] AbbVie PTOB at 36.
[134] Meyer Report at 0085, 0186–87, Exs. 37A–B.
[135] *Id.* at 0085–86.

62%.[136] She then applies this and other adjustments to Fensolvi's market share to determine what portion of this share would have gone to Lupron in a but-for world, resulting in an overall upward adjustment of Lupron's but-for market share compared with the "no boost" scenario.[137]

Takeda disputes two of the assumptions underlying this analysis: Triptodur's suitability as a proxy and the degree to which Fensolvi's growth can be attributed to the shortage.[138] In justifying her choice of Triptodur as a proxy, Dr. Meyer points out that, other than Fensolvi and Lupron, the main drugs on the market are Triptodur and Supprelin.[139] While Supprelin requires a surgical implant,[140] both Fensolvi and Triptodur are injectables that come in a six-month dose.[141] Additionally, Triptodur, which launched in October 2017, has a similar market share to Fensolvi.[142] Despite these similarities, Takeda argues that Triptodur is an inappropriate proxy because (1) Fensolvi's injection is subcutaneous, rather than intramuscular, and (2) Triptodur is made by Tolmar, the producer of Eligard, which, per Takeda, makes it "a more potent threat to Lupron-PED than Triptodur."[143] Takeda's implied argument is that

[136] *Id.* at 0086.
[137] *Id.* at 0086–88. For an illustration, *compare id.* at 0186, Ex. 37A *with id.* at 0187, Ex. 37B.
[138] Takeda PTOB at 71–74.
[139] TT (Meyer) 730:1–23.
[140] Pl.'s Pre-Trial Br. ("AbbVie Pre-Trial Br.") 50, Dkt. No. 405; Takeda PTOB at 70–71.
[141] TT (Meyer) 730:4–15.
[142] *See* Meyer Report at 0180, Ex. 35 (showing comparative market shares of Lupron, Supprelin, Triptodur, and Fensolvi).
[143] Takeda PTOB at 72–73.

I should decline any proxy estimation as overly speculative because it is based on a good but not perfect comparison. I disagree. Because I find Triptodur to be a reliable proxy for the purposes of calculating Fensolvi's market share boost, I adopt it.

Takeda's second quarrel with Dr. Meyer's treatment of Fensolvi is that her projections fall within AbbVie's own *pre-shortage* predictions of Fensolvi's market share.[144] Per Takeda, this undermines AbbVie's contention that AbbVie lost market share to Fensolvi due to the shortage.[145] However, while AbbVie's internal projections are helpful, they are not dispositive.[146] Here, I find credible the testimony by AbbVie's Vice President of Endocrinology, Metabolics, and Women's Health that AbbVie will routinely "project ambitiously on behalf of" new competitors for planning purposes, only to "make the correction backwards once the actuals come in."[147] I therefore find that AbbVie's pre-shortage predictions do not fatally undermine the argument that Lupron PED lost market share to Fensolvi as a result of the shortage.

Finally, Takeda argues that Fensolvi's capture of market share is at least partly attributable to a COVID-driven preference for longer-acting PED formulations.[148]

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[144] *Id.* at 73.
[145] *Id.*
[146] Indeed, Takeda itself argues as much on numerous occasions. *See, e.g., id.* at 2, 9 n.12, 38–42 (arguing at times that AbbVie's internal projections are untrustworthy, overly rosy, etc.).
[147] TT (Medgar Williams) 5:16–22, 115:2–22.
[148] Takeda PTOB at 73–74.

Lupron, as the dosage with the shortest duration, would be on the losing end of this preference.[149] However, other than testimony from Dr. Meyer acknowledging this trend and stating that she *accounted for it in her model*,[150] Defendants can point to no evidence in the record supporting an alternative adjustment.[151] I therefore decline to diverge from my finding that Dr. Meyer's adjustments for Fensolvi were appropriate.

5. PED – Future Damages

AbbVie claims future damages in this segment through June 2023, which it calculates as the difference between the but-for baseline and Lupron PED's post-shortage market share, projected forward.[152] AbbVie's expert opines that the real-world data from December 2021 to October 2022 exhibits no linear trend, suggesting that Lupron's share of the PED market post-shortage has flattened.[153]

Takeda's remaining argument boils down to a contention that, by ignoring favorable data on new patient/therapy starts ("NTS"), AbbVie's expert underestimates Lupron's recovery of market share.[154] Per Takeda, NTS data indicating that 70% of new PED patients are going to Lupron confirms Takeda's

[149] *Id.*
[150] TT (Meyer) 804:7–806:5.
[151] *See* Takeda PTOB at 73–74 (citing only to Meyer's testimony); *see also* Takeda PTAB at 41 (citing the same).
[152] Meyer Report at 0091–92. Though June 2023 came and passed prior to the publication of this opinion, the record that I rely upon was closed far earlier, necessitating projections.
[153] TT (Meyer) 741:5–742:9; AbbVie PTOB at 74.
[154] Takeda PTOB at 74.

higher projections of actual market share.[155] However, Takeda's argument ignores the fact that NTS data, which is limited to prescriptions at retail pharmacies, undercounts Supprelin, Lupron's surgically-implanted competitor, by almost two thirds and excludes Triptodur entirely.[156] I therefore find that the NTS data does not undermine AbbVie's evidence that a steady post-shortage PED market share is reasonable.[157]

6. GYN

Takeda contends that AbbVie's calculation of past damages in the GYN segment is flawed because it (1) uses an incorrect endpoint and (2) ignores "cannibalization" of Lupron GYN market share by competing AbbVie drugs.[158] Using three-month rolling averages to smooth the extreme volatility of monthly Lupron GYN sales, AbbVie's economic expert bases her past damages endpoint on an assessment of when average sales returned to or exceeded benchmark levels.[159] The use of trailing averages, by design, carries a risk of overestimating the length of the shortage.[160] This is because a given month's average combines the data from

[155] *Id.* at 75.
[156] TT (Medgar Williams) 49:4–52:6.
[157] Takeda also argues that AbbVie's theory of a stable post-shortage Lupron PED market share of 50.3% is belied by a single month in which that market share reached 52%. Takeda PTOB at 74–75 (citing Meyer Supplement at 0028). This argument ignores both the historical volatility of PED market shares and the basic math of averages.
[158] *Id.* at 75.
[159] Meyer Report at 0106.
[160] Malkiewicz Report at 0067.

that month as well as the two previous months, giving more weight to the past than the present.[161] This weighting could therefore cause the impact of the shortage to appear to persist a month or two after it had, in fact, ended. However, I find that, given the volatility of the monthly sales data, this methodology is the best available to provide the Court with a reasonable, non-speculative endpoint for past damages calculation.

Without challenging the propriety of Dr. Meyer's rolling average methodology, Takeda argues that only "actual monthly data" can reveal the appropriate endpoint for the past damages period.[162] Per Takeda, the damages period should end in January 2021 because its economic expert "performed a regression analysis on monthly sales, which shows no significant differences between" the benchmark period and post-January 2021 damages period.[163] But the fact that "it's really hard to ascertain trends in noisy data" is precisely why AbbVie's expert employed rolling averages,[164] a methodological decision that Takeda's expert voiced no quibbles with.[165] Other than a more favorable result (to Takeda), Takeda presents no argument for why the trends its expert now pulls from this noisy data allay these

[161] *Id.*
[162] Takeda PTOB at 75–76.
[163] *Id.* at 76.
[164] TT (Meyer) 747:3–11.
[165] *See* Malkiewicz Report at 0064–68 (expressing no critiques of the rolling average methodology other than the potential to overestimate shortage length).

concerns or are reliable.[166] Further, Takeda declines to respond to AbbVie's argument that Takeda's expert ends the past damages calculation in the middle of ongoing instances of Lupron GYN customer orders exceeding available inventory.[167] Accordingly, I find that Takeda has presented no evidence to impugn the reliability of AbbVie's calculation of the Lupron GYN damages endpoint.

Takeda next argues that AbbVie overstates its Lupron GYN damages by ignoring market share cannibalization from two competing AbbVie drugs: Orilissa and Oriahnn.[168] Most of Takeda's evidence indicates that these are *possible* alternatives to Lupron.[169] Takeda's sole piece of evidence that these drugs *actually* eroded Lupron's market share comes from Mr. Buthusiem's rebuttal report of March 15, 2021, in which he acknowledges that "[i]t appears that Orilissa did erode a portion of Lupron sales."[170] What Takeda declines to address is that, consistent with AbbVie's position that there has been no substitution *post-shortage*,[171] Mr. Buthusiem concluded that Orilissa's market share growth and, presumably, any cannibalization occurred "*prior to the July 2020 shortage*[.]"[172] Takeda's cannibalization argument therefore is not persuasive.

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[166] *Id.* at 0067–68; Takeda PTOB at 76.
[167] TT (Malkiewicz) 914:16–917:17; *see* Takeda PTAB at 44–45 (failing to address the stockout argument raised in AbbVie's opening brief).
[168] Takeda PTOB at 75–77.
[169] JX 2225 at 0016; JX 2449 36:21–37:16, 42:1–14, 23:19–24:3, 69:5–23; JX5455 at 0002.
[170] Takeda PTOB at 76–77 (quoting JX 2522 at 0024).
[171] Meyer Report at 0095–96.
[172] JX 2522 at 0025 (emphasis added).

7. Incidental Damages

In addition to the lost profits analyzed above, AbbVie also claims damages arising from additional testing costs and pricing penalties necessitated by the shortage.[173] I find that, while AbbVie fails to carry its burden of proof with regard to the testing costs, it may recover damages for the pricing penalties incurred as a result of Takeda's breach.

Pre-trial, AbbVie argued that it was owed $1.3 million for testing costs it incurred after it "told the FDA it would perform additional oversight and testing on each lot of Lupron coming from [Takeda's production facility at] Hikari."[174] Post-trial, AbbVie is curiously vague when it comes to specifics.[175] Dr. Meyer's expert report notes that $1,187,289 of this testing cost "is the amount that AbbVie paid Takeda for the Lupron products that were tested."[176] However, AbbVie cites no evidence indicating that the testing was destructive, or that this cost was not

[173] AbbVie PTOB at 40.
[174] AbbVie Pre-Trial Br. at 66–67.
[175] AbbVie PTOB at 40.
[176] Meyer Report at 0110.

otherwise recouped.[177] AbbVie therefore fails to carry its burden with regard to these purported costs.[178]

AbbVie claims that it suffered an additional $4,341,604 in incidental damages as a result of "penny pricing" penalties triggered by the shortage.[179] The following is a simplified version of the causal chain alleged: Under the Veterans Healthcare Act (the "VHA"), AbbVie sells Lupron to federal agencies, at a discount, through wholesalers.[180] Also pursuant to the VHA, AbbVie must report an annual Non-Federal Average Manufacturer's Price ("non-FAMP") to the government based on a subset of Lupron sales.[181] The VHA imposes a pricing penalty if the year-on-year increase in non-FAMP exceeds the consumer price index.[182]

Due to the shortage, Lupron sales in the third quarter of 2020 were depressed.[183] However, chargebacks,[184] which typically lag sales data by a month

[177] *See id.* at 0110 (describing Dr. Meyer's understanding only that the figure represents what AbbVie paid); JX 5146 144:13–145:5 (confirming only that testing took place); AbbVie Pre-Trial Br. at 66–67 (citing only to the previous two sources); AbbVie PTOB at 40 (citing only to JX 5146); AbbVie PTAB at 36 (citing only to Meyer Report at 0110).
[178] AbbVie's claim to the remaining $140,887 also fails as speculative. Even Dr. Meyer admitted that she could not identify what the cost corresponds to. *See* Meyer Report at 0110 (admitting that some or all of the figure may represent an allocation of overhead at AbbVie's testing facility).
[179] AbbVie PTOB at 40; Meyer Report at 0110–13.
[180] Meyer Report at 0110.
[181] *Id.* at 0110–11.
[182] *Id.* at 0111–12.
[183] *See, e.g.*, Fig. 1, *infra*.
[184] Per AbbVie, a chargeback is "[a] cost issued by a wholesaler to AbbVie, which AbbVie pays, for Lupron units sold by that wholesaler. The amount is equal to the difference between [wholesale acquisition cost] and the contracted price paid to the wholesaler by the end customer." AbbVie Pre-Trial Br., Table of Definitions.

or two,[185] continued to roll in. This artificially deflated the 2020 non-FAMP.[186] One year later, Lupron sales had begun to recover, causing a pronounced rise between the 2020 and 2021 non-FAMP.[187] This triggered discounts under the VHA, which caused the Federal Ceiling Price, which is calculated as a 24% discount to a drug's previous year's non-FAMP,[188] to turn negative in 2022,[189] allowing federal agencies to purchase certain Lupron formulations at a price of one penny per syringe.[190] Dr. Meyer calculates the economic loss due to these additional discounts by assuming that the discounts AbbVie would have provided to these agencies, but for the shortage-induced pricing, would have been the same as they were in 2020.[191]

Though AbbVie explicitly raises this category of damages in both its pre- and post-trial briefing,[192] Takeda's declines to address the issue directly,[193] waiving the argument.[194] Thus, the only question is whether AbbVie has carried its burden with regard to the penalty pricing damages. I find that it has, and that Dr. Meyer's

[185] JX 5329 at 261:3–264:3.
[186] Meyer Report at 0111.
[187] *Id.* at 0111–12 n.310.
[188] *Id.* at 0112 n.311.
[189] *Id.* at 0112 n.312.
[190] *Id.* at 0112.
[191] *Id*. at 0112–13.
[192] AbbVie Pre-Trial Br. at 67–68; AbbVie PTOB at 40.
[193] *See* Def. Takeda Pharm. Co. Ltd.'s Pre-Trial Br., Dkt. No. 406 (making no mention of incidental damages); Takeda PTOB at 77 (addressing only the $1.3 million in testing costs); Takeda PTAB at 51 (mentioning penalty costs only in the context of rejecting AbbVie's argument that Takeda's expert had conceded the point).
[194] *Emerald P'rs*, 726 A.2d at 1224 ("Issues not briefed are deemed waived") (citations omitted).

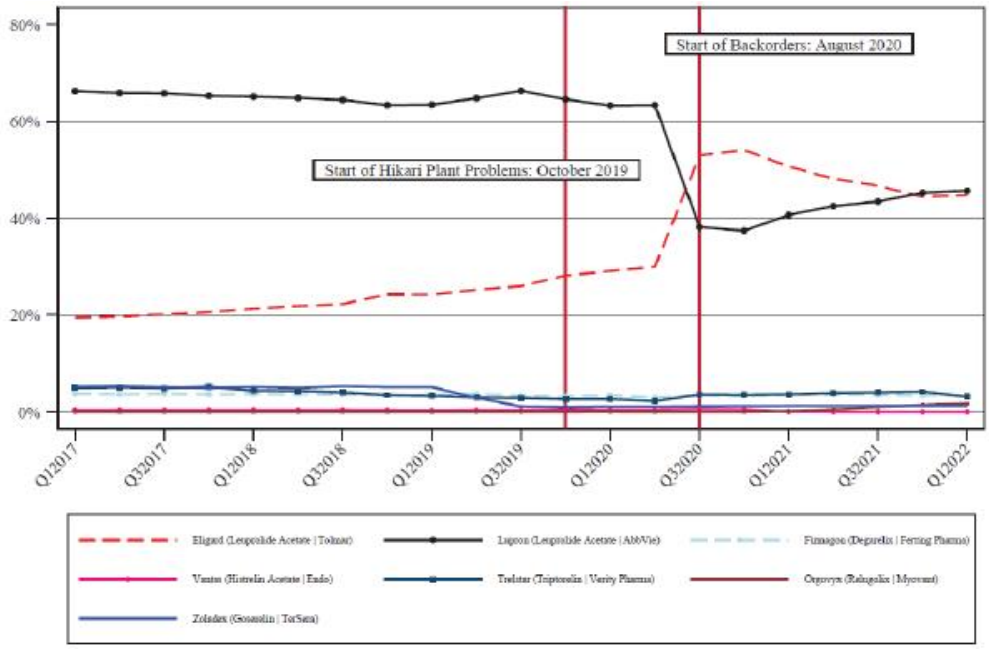
calculation provides the Court with a reasonable estimate of the quantum of damages.[195]

D. Causation, Mitigation

1. Causation

It is indisputable that AbbVie suffered lasting damages as a result of the Lupron shortage. The impact of the shortage is perhaps best demonstrated graphically:

Figure 1: U.S. ADT Market Share, Q1 2017 to Q1 2022[196]



[195] I find that AbbVie has proven both the fact of damages, as well as causation, by a preponderance of the evidence.
[196] Meyer Report at 0145.

The shortage sent Lupron URO's market share crashing down, with limited recovery even a year later. As discussed above, AbbVie also suffered damages in the PED and GYN markets.

While Takeda acknowledges that AbbVie suffered *some* damages as a result of the shortage,[197] it argues that AbbVie simply assumes causation and thus fails to "sufficiently isolate damages caused by the breach alone[.]"[198] Per Takeda, this alleged failure to show causation means that "'no damages may be awarded.'"[199] Because Takeda's position on causation largely repackages arguments that I addressed in Section II.C,[200] I limit my analysis here to the non-duplicative contentions.

Takeda's principal argument on causation is that AbbVie failed to account for customers that, for reasons *unrelated* to the shortage, switched away from Lupron during the damages period.[201] As evidence, Takeda points to a survey in which its economic expert reached out to the "physicians, pharmacists, practice managers, and purchasing/procurement managers, who were affiliated or employed with an

[197] *See, e.g.*, Takeda PTAB at 6–7 (acknowledging, albeit impliedly, that the shortage caused some of AbbVie's losses).
[198] *Id.* at 6.
[199] *Id.* (quoting *Deville Ct. Apts, L.P. v. Fed. Home Loan Mortg. Corp.*, 39 F. Supp. 2d 428, 433 (D. Del. 1999)).
[200] *Compare* Takeda PTOB at 21–22 *with* Takeda PTOB at 60–63 (offering the same arguments about Lupron URO's declining market share).
[201] *Id.* at 22–27.

institution" that AbbVie reported had stopped or decreased Lupron purchases because of the shortage.[202] Takeda pays particular attention to three former Lupron customers—Mayo Clinic, Huntington Internal Medicine Group, and Urologic Specialists of Oklahoma—that reported in the survey that they switched away for reasons unrelated to the shortage.[203] Per Takeda, the inclusion of these accounts in the damages calculation "is unjustified, and evidence of a much broader error."[204]

Takeda, I think, fundamentally misunderstands the underlying damages methodology used by both parties' experts. In estimating damages for the URO segment,[205] both experts calculate a baseline market share against which shortage-induced damages can be assessed.[206] Changes to Lupron's market share in the form of routine losses and gains of customer accounts are "baked in" to this baseline. For example, the loss of a customer to Eligard in May 2019 would be reflected in a drop in Lupron's market share from that month onward. Similarly, the gain of a customer in July 2019 would bring with it a corresponding increase in market share, all else equal. A pervasive pattern of customer losses pre-shortage would present itself as a

[202] Malkiewicz Report at 0082 n.305.
[203] Takeda PTOB at 24–25.
[204] *Id.*
[205] I limit my discussion to URO because that is the segment from which Takeda's examples are drawn and that dominates the list of accounts AbbVie claims to have lost. Takeda PTOB at 24; JX 5087 at 0017–27.
[206] *See* Section II.B.2.a; *see also* Meyer Report at 0048–49.

downward slope in the baseline.[207] Thus, absent evidence of confounding trends not accounted for in the model, AbbVie's damages methodology adequately demonstrates causation by isolating the impact of the shortage from the but-for world conditions incorporated in the market share baseline.

In order to show a lack of causation, Takeda would need to point to more than anecdotal evidence that specific switches were unrelated to the shortage. Instead, Takeda must show a pattern of post-shortage customer behavior that deviates from the pre-shortage behavior reflected in the damages model. For example, if, from October 2021 onward, price-based switches to Eligard accelerated vis-à-vis the baseline for reasons unrelated to the shortage, AbbVie would not be entitled to damages for the loss of sales associated with that new trend. Takeda's survey-based causation argument reflects no such trend or pattern absent from the baseline. Instead, it represents an attempt to argue via anecdote what Takeda has failed to prove with data.

2. Mitigation

Takeda argues that AbbVie's damages must be reduced because of its failure to mitigate the damages resulting from Takeda's breach.[208] Specifically, Takeda

[207] In fact, this is precisely the adjustment that Takeda's economic expert advocated for in response to alleged price competition from Eligard. Malkiewicz Report at 0047–49. I rejected that adjustment as based on stale data. *See* Section II.C.2.
[208] Takeda PTOB at 18–21; Takeda PTAB at 46–51.

contends that AbbVie knew of the breach in May 2019 and could have mitigated starting then by (1) exercising its contractual rights to audit Takeda's manufacturing process more closely, (2) stockpiling additional Lupron, and (3) *not* implementing a plan—"Operation Phoenix"[209]—that purportedly shifted Lupron supply towards lower-profit sales channels.[210] Even assuming that Takeda is correct as to AbbVie's knowledge of the breach in May 2019, Takeda's arguments fail.

Takeda argues that, because AbbVie had joint responsibility for current good manufacturing practices violations at the Hikari plant, it could have exercised its rights to "audit Takeda every two years, inspect documents, attend regulatory inspections, and put a 'person in the plant' to inspect manufacturing."[211] Takeda's implied argument, as I understand it, is that it would have complied with these steps, potentially averting or mitigating the supply shortage. This argument strains credulity, given that, in June 2019, as Takeda's manufacturing woes became visible, Takeda repeatedly downplayed the concerns of AbbVie's auditor and denied requests for further information.[212] I therefore find that the record does not support Takeda's argument that AbbVie could have mitigated via the exercise of its contractual rights.

[209] This was a mitigation effort by AbbVie aimed at maintaining core URO customers in the direct channel until the shortage passed. Buthusiem Supplement at 0013–20.
[210] Takeda PTOB at 18–21.
[211] *Id.* at 20.
[212] JX 339; JX 351 at 0002.

Takeda next argues that, had AbbVie stockpiled Lupron starting in May 2019, "[e]very week of additional inventory AbbVie had on-hand would have reduced the shortage by a week."[213] In addition to benefiting from a healthy dose of hindsight, this argument ignores the reality that Takeda has no "best efforts" duty when it comes to fulfilling orders exceeding 120% of previously projected requirements.[214] Therefore, even if AbbVie had attempted to increase its orders in the hopes of creating a stockpile, Takeda would have had little obligation to cooperate.[215] Finally, Takeda also turns a blind eye to the fact that AbbVie submits its firm orders to Takeda five months in advance,[216] which means that hypothetical stockpile shipments ordered in May 2019 would have run into the FDA-ordered hold on Lupron shipments.[217]

Finally, Takeda argues that AbbVie's shortage-response plan, Operation Phoenix, "drove volume away" from profitable sales channels in order to preserve supply in other, less profitable, channels.[218] This argument attacks AbbVie's mitigation attempts merely because they do not comport with what Takeda now believes would have been the best course of action. Other than labelling Operation

[213] Takeda PTAB at 50.
[214] JX 1849 at 0063, Section 9.2(b).
[215] Given Takeda's response to AbbVie's auditor, I conclude that the record does not support a finding Takeda would have complied with stockpiling efforts, absent some contractual duty.
[216] Phase I TT (Laegeler) 14:20–16:16.
[217] *See AbbVie I* at *7–8.
[218] Takeda PTOB at 21.

Phoenix "a failure[,]" Takeda does not present evidence that the plan was unreasonable.[219] Accordingly, Takeda's speculative mitigation arguments lack both legal and factual support.

E. Pre- and Post-Judgment Interest

In its post-trial briefing, AbbVie makes an unopposed request for pre- and post-judgment interest.[220] I find that an award of interest at the legal rate is appropriate given the facts of the case and that such an award is consistent with Delaware caselaw.[221]

III. CONCLUSION

I find that AbbVie's damages methodology is reliable and appropriate, subject to the foregoing adjustments. I instruct the parties to submit an adjusted damages calculation consistent with this decision.

To the extent the foregoing requires an order to take effect, IT IS SO ORDERED.

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[219] *See id.*; Takeda PTAB at 50–51; *see also W. Willow-Bay Ct., LLC v. Robino-Bay Ct. Plaza, LLC*, 2009 WL 458779, at *8 (Del. Ch. Feb. 23, 2009) (holding that the injured party need only make reasonable mitigation efforts, even if they are ultimately unsuccessful).
[220] AbbVie PTOB at 83–84; AbbVie PTAB at 38; *see* Takeda PTAB (failing to contest the issue).
[221] *See, e.g., Gholl v. eMachines, Inc.*, 2004 WL 2847865, at *18 (Del. Ch. Nov. 24, 2004) (explaining the rationale behind an award of interest).