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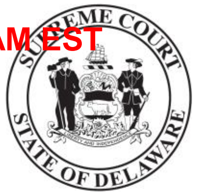


**IN THE**
**SUPREME COURT OF THE STATE OF DELAWARE**

BTG INTERNATIONAL INC.,
*Plaintiff, Counterclaim Defendant—Appellant,*

*v.*

WELLSTAT THERAPEUTICS CORPORATION,
*Defendant, Counterclaim Plaintiff—Appellee.*

**No. 509, 2017**

On appeal from the November 2, 2017 Final Order and Judgment of the Court of Chancery of the State of Delaware (Laster, V.C.), C.A. No. 12562-VCL.

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# CORRECTED APPELLANT'S OPENING BRIEF

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## NATURE OF PROCEEDINGS

This breach-of-contract appeal arises from a Court of Chancery decision that awarded Wellstat Therapeutics Corporation ("Wellstat") over $71 million, including pre- and post-judgment interest that accrues at the rate of 12% per year, compounded monthly. After a bench trial, the court found that BTG International Inc. ("BTG") breached the Exclusive Distribution Agreement (the "Agreement"), under which BTG was to promote, distribute, and sell Wellstat's drug Vistogard, by failing to promote and market Vistogard with the degree of diligence required by the Agreement. BTG timely appealed the court's November 2, 2017 Final Order on December 1, 2017. A1941 (Supr. Ct. D.I. 1).

While BTG disagrees with many of the trial court's conclusions, this appeal addresses damages and interest only.[1] It is a fundamental principle of contract law that remedies for a breach should compensate for lost expectation caused by the breach, but go no further. *See, e.g.*, *E.I. DuPont de Nemours & Co. v. Pressman*, 679 A.2d 436, 445 (Del. 1996). Contract remedies must not overcompensate or punish. *Id.* Unfortunately, the trial court disregarded this principle in at least four separate ways—and in so doing awarded super-compensatory and improperly punitive damages and interest.

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[1] BTG thus does not appeal the court's liability determination, not because it accepts the court's factual findings, which it does not, but because of the applicable appellate standard of review.

*First*, the court erred as a matter of law by disregarding BTG's absolute right to terminate the Agreement five years after Vistogard's FDA approval. Where, as here, the breaching party bargained for an escape-hatch right to terminate the contract at its sole discretion, courts may not multiply damages by forcibly extending the term of the contract beyond the date that termination becomes possible. The trial court awarded damages for a period twice as long as it should have—on the premise that BTG would not have exercised its termination right because doing so would have been "economically irrational." That holding contradicts this Court's longstanding rule that such termination provisions must "be given effect" by limiting lost profits to the length of the contract's assured existence, notwithstanding any argument that it would be "unrealistic to suppose that [the breaching party] would enforce the provision." *Chrysler Corp. v. Quimby*, 144 A.2d 885, 886 (Del. 1958). In light of this purely legal error, the case should be remanded for the court to recalculate damages using the correct analysis.

*Second*, the trial court permitted Wellstat to base its lost profits on speculation rather than competent evidence. The court correctly recognized that lost profits could not lawfully be based on a patient population that included patients to whom Vistogard could not legally be marketed (given federal law's ban on "off-label" promotion of prescription drugs). Yet, the trial court improperly allowed Wellstat do just that, excusing fundamental errors in the survey of medical

practitioners that Wellstat used to estimate Vistogard's potential patient population. Because of the survey's many flaws, Wellstat's damages model improperly included an extremely large amount of projected off-label sales, and yet the trial court largely permitted those sales' inclusion based on nothing more than conjecture as to how physicians would have parsed the survey's errors. The trial court's efforts to repair Wellstat's thoroughly flawed damages model on the back-end improperly inflated the damages award by more than $50 million, requiring remand.

*Third*, the court ignored the bedrock rule that damages calculations must take into account not just the revenues the plaintiff did not receive, but also the losses it was able to avoid. In this case, Wellstat demanded the return of Vistogard's distribution rights because it believed, as its witness testified at trial, that it could achieve higher Vistogard sales selling Vistogard itself. Wellstat has gotten that which it demanded: the contract is now terminated, and Wellstat is free to sell Vistogard in the future. By avoiding what Wellstat asserted were BTG's suboptimal sales—to say nothing of the large revenue percentage that BTG otherwise would have been entitled to retain under the Agreement—the product return will avoid future loss. Yet, Wellstat's damages model made no effort to account for this valuable return of the distribution rights, but rather calculated future damages based upon the counterfactual premise that *BTG* continued to

market the product and retain a portion of the sales revenues. By not factoring in its own increased sales and avoided expenses after this return of the Vistogard distribution rights, Wellstat failed to provide competent proof of its damages and received a windfall recovery.

*Fourth* and finally, the trial court's interest calculation was based on (1) an excessive interest rate not provided for in the Agreement, and (2) an undisputedly incorrect start date. As a matter of law, Delaware's statutory interest rate governs the rate of pre- and post-judgment interest unless the parties' contract states otherwise or equity so requires. Although the court recognized that the Agreement's termination provisions do not provide an interest rate for contract damages, the court resorted to an unrelated provision of the contract governing late payments to impose a general interest rate of 1% per month, compounding monthly. While this alone constituted error, the trial court then committed a second error by setting the interest start date six months before Wellstat's evidence of damages, six months before the first Vistogard sale, and six months before the date Wellstat itself requested.

Contract law prohibits double recoveries and punitive damages. Under long-established doctrines designed to effectuate those prohibitions, the trial court's damages and interest awards should be reversed.

## SUMMARY OF ARGUMENT

I. BTG had a unilateral right under the Agreement to terminate the Agreement for convenience after five years. The trial court erred as a matter of law in rejecting BTG's argument that damages should have been cut off at the five-year termination date.

II. The FDA declined to approve Vistogard for patients suffering from "moderate" chemotherapy toxicities. The trial court exceeded its discretion by including prescriptions for such patients in its damage award based on improper speculation about the faulty and misleading survey proffered by Wellstat's experts.

III. Wellstat's damages model failed to account for the relief that Wellstat demanded and received in this lawsuit—the return of Vistogard's distribution rights. That model estimated Wellstat's damages based on BTG's projected future Vistogard sales rather than the purportedly higher sales that Wellstat will be able to achieve now that the Vistogard rights have been returned. By adopting Wellstat's flawed damages model, the trial court abused its discretion and committed legal error in awarding Wellstat a windfall that will result in double recovery.

IV. The trial court applied an inappropriate rate of interest and an incorrect starting date for the interest calculation. It erred as a matter of law in both respects, causing BTG to pay an inflated amount of pre- and post-judgment interest.

## STATEMENT OF FACTS

Vistogard is an orally administered antidote for overdose or excessive toxicity caused by the chemotherapy drug 5-fluorouracil ("5-FU") and the related drug capecitabine. A877 (§ II(7)). 5-FU is a cancer drug commonly used to treat solid cancerous tumors. A875-76 (§ II(4)).[2]

In 2011, BTG and Wellstat entered the Agreement, which provided that BTG would promote, distribute, and sell Vistogard in the United States for a default ten-year term, to begin on the date of Vistogard's FDA approval. A168 (§ 12.1). But the Agreement included several termination provisions, including an unconditional right that allowed either party to terminate for convenience just five years after FDA approval. *Id.* (§ 12.2).

The Agreement required BTG to exercise "Diligent Efforts" in promoting, distributing, and selling Vistogard. A156 (§ 8.1). As part of its Diligent Efforts, BTG was to provide Wellstat an Initial Commercialization Plan before Vistogard's commercial launch. *Id.* BTG did so in mid-September 2015. A191-247.

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[2] 5-FU is listed on the World Health Organization's List of Essential Medicines, a compilation of the most important medicines needed in a basic health system. A875-76 (§ II(4)). 5-FU has been used for approximately 50 years and severe reactions to 5-FU are very uncommon. A1115 (Cartwright 565:14-18), A1117 (Cartwright 574:13-22). Physicians have long used inexpensive alternatives, such as mouthwashes, analgesics, and IV fluid, to treat most cases of 5-FU over-exposure. A1118 (Cartwright 578:7-16); *see also* Trial Court Opinion ("Op.") at 49 (citing "cheap and widely available alternative therapeutic treatments" in excluding mild toxicity patients from forecast) (attached hereto as Exhibit A).

On December 11, 2015, the FDA approved Vistogard for use. A265-68. Although Wellstat sought approval for the treatment of *moderate* 5-FU toxicity in addition to *severe* toxicity, the FDA only approved Vistogard for the more limited range of cases—specifically, "early-onset, severe or life-threatening toxicity" from 5-FU. *Id.*; A1268 (Bamat 912:5-21) (noting FDA specifically declined indication for moderate patients).[3]

Vistogard became commercially available on March 2, 2016, and was launched in April 2016. A892 (§§ II(75)-(76)). Both before and after the launch, the parties disagreed about BTG's level of commercial activity. A893-94 (§§ II(85)-(91)). That disagreement led to Wellstat's demand for the return of the distribution rights and ultimately to this lawsuit, which BTG initiated in the Court of Chancery on July 15, 2016. A294-327 (BTG's Verified Complaint for Declaratory and Injunctive Relief). BTG sought, among other things, a declaration that it was not in breach of its contractual obligations under the Agreement and that Wellstat had no right to terminate the Agreement at the time. *See generally id.*

Wellstat responded with a Notice of Termination, which it served on BTG on July 18, 2016. A328-30. Wellstat asserted that BTG had failed to exercise

[3] As contrasted with otherwise "severe" or "life-threatening" toxicities, "early onset" toxicities are those that "occur[ ] very soon after beginning, [or] in the first cycle or so of a treatment with 5-FU or with capecitabine." A1224 (Bamat 881:10-15). Such toxicities may be caused by factors such as genetic mutations, genetic dysfunctions, and metabolic dysfunctions. *Id.* at 881:16-20.

Diligent Efforts to promote, distribute, and sell Vistogard and that the Agreement would be terminated as of September 16, 2016. *Id.* In its Answer and Counterclaims, Wellstat repeated its demand for a return of the distribution rights. A384, A409.

The case was tried before the Honorable J. Travis Laster over five days in May 2017. A18. Before trial, the parties agreed that any challenges to the relevance or admissibility of expert testimony would be addressed at trial or through post-trial briefing. A830.

In support of its damages claims, Wellstat relied upon an expert report authored by Howard Brock and Neel Patel. A605-760. The Brock and Patel report offered a market assessment, forecast, and commercialization model to calculate what Vistogard sales would have been if BTG had exercised Diligent Efforts. *E.g.*, A608-12 (summarizing opinions). To develop this model, Patel prepared and conducted a survey to determine the population of patients whom physicians would treat with Vistogard. A269-93. The key question in the survey, Question 50, asked respondents to estimate the percentage of patients to whom they would prescribe Vistogard, for three separate levels of toxicity—"mild," "moderate," and "severity" [sic]. A283. Based on the answers to this question, Brock and Patel projected a Vistogard patient population that included patients suffering from all three groups, including those suffering from "mild" and "moderate" toxicities,

even though the FDA did not approve Vistogard for use in treating patients with non-severe toxicity levels. *E.g.*, A1568 (Patel 1236:6-19).

Wellstat's economic damages expert, Christopher Gerardi, used the Brock and Patel model to calculate the net present value of Wellstat's damages. *See generally* A540-604. Assuming a ten-year contract term, without regard for BTG's absolute right to terminate the Agreement after five years, A1586 (Gerardi 1308:22-24), Gerardi calculated the "difference between expected royalty and manufacturing profits that would be owed to Wellstat from the commercial sale of Vistogard® had BTG used Diligent Efforts to commercialize and promote Vistogard® and the expected royalty and manufacturing profits that would be owed to Wellstat if BTG continues to commercialize Vistogard according to its current forecasts." A545. Gerardi thus ignored the real-life scenario in which Wellstat took over Vistogard's commercialization. A1583 (Gerardi 1293:22-1294:2). At trial, however, Wellstat principal David Wohlstadter testified that he thought Wellstat would itself be able to earn substantially more from Vistogard than what BTG projected. A1530-31 (D. Wohlstadter 1174:4-1175:18); A1539 (D. Wohlstadter 1183:9-19); A184-90 (Wellstat Vistogard model).

After trial and post-trial briefing on both liability and damages, the trial court issued the post-trial Memorandum Opinion on September 19, 2017, finding that BTG breached the Agreement by (1) not exercising Diligent Efforts with

respect to launching Vistogard, and (2) failing to provide a satisfactory Initial Commercialization Plan. *See generally* Exhibit A. In the Final Order dated November 2, 2017, the court awarded Wellstat $55,749,152.03 in damages. *See* Final Order and Judgment (attached hereto as Exhibit B). It also imposed accrued pre-judgment interest in the amount of $15,745,059.67, through October 14, 2017, an additional $446,595.76 up to the date of the Final Order, post-judgment interest until payment is made on the judgment, and costs in the amount of $12,548.25, for a total judgment as of November 2, 2017, of $71,953,355.71. *Id.* The rate of pre- and post-judgment interest was set at 1% per month (i.e., 12% per year), compounded monthly, *id.*, a rate the trial court selected based on a provision in the Agreement addressing late payment of amounts "due under [the] Agreement." Op. at 57-58; A144 (§ 4.8) (establishing Late Payment interest rate).

In calculating the significant interest award, the trial court selected as its start date from which interest would run the date on which BTG provided the Initial Commercialization Plan—September 15, 2015. Op. at 58. It did so even though no damages began accruing on that date, which was nearly six months before Vistogard was first available for sale—March 2, 2016. A892 (§ II(75)). Wellstat recognized this fact in its post-trial brief and proposed the product's commercial availability date as the interest start date. *E.g.*, A1787 (Wellstat Opening Post-Trial Brief ("WOB") (pointing to Gerardi's calculations dating to

March 2, 2016)). The court thus awarded Wellstat six months' worth of interest that Wellstat did not even request.

BTG timely appealed on December 4, 2017. A1941 (Supr. Ct. D.I. 1).

# ARGUMENT

## I. THE CHANCERY COURT ERRED AS A MATTER OF LAW IN FAILING TO ENFORCE THE AGREEMENT'S FIVE-YEAR TERMINATION PROVISION.

### A. Question presented.

Did the trial court err in awarding damages for the full ten-year term of the Agreement, when BTG had bargained for the right to terminate after five years?

This claim was presented in BTG's Opening Post-Trial Brief ("BOB") at 72 (A1714) and BTG's Post-Trial Reply Brief ("BRB") at 29-30 (A1822-23). The trial court addressed it at pages 53 and 54 of its Memorandum Opinion.

### B. Scope and standard of review.

This Court reviews *de novo* "claims that [a] disputed remedy was erroneous as a matter of law, because the trial court erred in formulating or applying legal principles." *Berger v. Pubco Corp.*, 976 A.2d 132, 139 (Del. 2009) (internal quotation marks omitted); *cf. Hill Int'l, Inc. v. Opportunity Partners L.P.*, 119 A.3d 30, 37 (Del. 2015) ("Although a trial court's decision to grant or refuse injunctive relief is generally reviewed for an abuse of discretion, this Court does 'not defer to the trial court on embedded legal conclusions and reviews them *de novo*.'") (quoting *N. River Ins. Co. v. Mine Safety Appliances Co.*, 105 A.3d 369, 380–81 (Del. 2014)).

### C. Merits of argument.

The Court of Chancery erred as a matter of law by awarding damages for a ten-year period because that award failed to give effect to BTG's absolute right to terminate the Agreement five years after the FDA approved Vistogard. A168 (§ 12.2).[4] The trial court rejected BTG's argument that Wellstat's damages should end pursuant to a termination date of December 11, 2020 (five years after Vistogard's FDA approval, *see* A265-68), to account for this right.[5] The court did not dispute that BTG was entitled to terminate on that date, but surmised that BTG would never have exercised that right because doing so would have been "economically irrational." Op. at 54. This error improperly increased Wellstat's

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[4] Specifically, the Agreement provided in relevant part:

> 12.2 **Termination for Convenience**. Subject to Section 6.4(b)(iv), either Party may elect to terminate this Agreement beginning five (5) years after FDA Approval of the Subject Product at any time by providing six (6) months prior written notice to the other Party . . . .

A168 (§ 12.2). Upon termination under this provision, Wellstat may elect for BTG to continue to sell its existing inventory for a period of six additional months. A170-71 (§ 12.11(a)(iii)).

[5] The Agreement permitted both parties to terminate at five years. It is inconsistent for the court to say that it would be economically irrational for BTG to terminate after five years, but not consider the potential incentive for Wellstat to terminate at five years.

damages by tens of millions of dollars[6] and directly conflicts with long-established Delaware law.

In *Chrysler Corp. v. Quimby*,[7] this Court explained that, in circumstances like those involved here, bargained-for termination rights should "be given effect." 144 A.2d 885, 886 (Del. 1958). The jury found defendant Chrysler liable for breaching a promise to restore the plaintiff's auto dealership franchise, which Chrysler had terminated due to a change in ownership. *See Chrysler Corp. v. Quimby*, 144 A.2d 123, 126-28 (Del. 1958). Although this Court upheld the jury's finding that Chrysler was liable for failing to restore the franchise, *id.* at 128-132, it nevertheless found the plaintiff entitled to only those "profits that might reasonably have been expected during a period of 90 days," because the original franchise agreement gave Chrysler the unilateral right to terminate the franchise upon 90

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[6] Taken alone, without any other modification to the award, crediting the Termination for Convenience provision would result in a damages award of approximately $21.3 million to Wellstat. This number may be calculated from Wellstat's own expert reports by excluding the "mild" patients identified within Brock & Patel's Forecast (A761, "Vistogard Summary" and "Vistogard Forecast" tabs) from the patients calculated in Gerardi's Rebuttal Report (A776). Once the mild sales are excluded, the total net present value of damages for years one through five, plus the prorated portion of year six (until June 10, 2021, pursuant to the inventory sales period of Section 12.11(a)(iii) (A170-71)), results in a total award of approximately $21.3 million.

[7] This Court first considered the case in April 1958. *See Chrysler Corp. v. Quimby*, 144 A.2d 123 (Del. 1958). It subsequently denied reargument in a separate September 1958 opinion. *See Chrysler Corp. v. Quimby*, 144 A.2d 885 (Del. 1958). Both decisions are referred to collectively as *Chrysler*.

days' notice. *Id.* at 134. The plaintiff petitioned for reargument, contending "that his claim in respect of loss of profits was not limited to . . . 90 days." 144 A.2d at 886. According to the plaintiff, it was "unrealistic to suppose that Chrysler would enforce the [termination] provision" immediately after restoring the franchise, as Chrysler was obliged to do. *Id.* In addressing the plaintiff's argument, the Court held that "[t]his argument misses the point": the provision gave Chrysler "an absolute right to terminate," and there was "no reason why it should not be given effect." *Id.* Therefore, the Court found that the "loss of profits must be confined to a period of 90 days." *Id.* at 887.

This rule is now established in Delaware law. *See, e.g., Reiver v. Murdoch & Walsh, P.A.*, 625 F. Supp. 998, 1010 (D. Del. 1985) ("Delaware courts have held, as a matter of law, that a ninety day notice provision in a termination clause limits the terminated party's damages to the benefits he is entitled to receive under the contract during the notice period.") (citing *Chrysler*); *see also J.E. Rhoads & Sons, Inc. v. Ammeraal, Inc.*, 1988 WL 32012, at *9 (Del. Super. Mar. 30, 1988) ("Since the purpose of damages is to put plaintiff in as good a position as he would have been in without the breach, the Delaware law does not allow future profits as damages for a period beyond the termination date of the contract sued upon."); *cf.* 25 C.J.S. Damages § 166 ("Where a contract provides for its termination by either

party on notice of a specified number of days, profits may be recovered for only that length of time.") (citing *Chrysler*).

The trial court's holding violates this rule. BTG's bargained-for "Termination for Convenience" right was a key term of the contract,[8] and that right entitled BTG to end the Agreement in December 2020. *See* A168 (§ 12.2); *see also Garner's Dictionary of Legal Usage* 882 (3d ed. 2011) (characterizing "termination for convenience" as "essentially equivalent to 'termination for any reason at all—or no reason'"). Notwithstanding that the record does not support the court's finding, it is irrelevant whether it would have been "economically irrational," as the Court of Chancery stated, for BTG to exercise the termination right, just as it was irrelevant whether it would have been "unrealistic" to expect Chrysler to do so. Contracting parties bargain for termination provisions like these to guard against a wide range of risks, foreseen and unforeseen—not the least of which is exposure in potential litigation with one's counterparty. By forcing BTG to pay Wellstat ten years' worth of damages rather than only five, the trial court effectively wrote BTG's termination right out of the contract.

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[8] The particular importance of BTG's termination right is evidenced by the fact that BTG bargained for an absolute right to terminate the Agreement at five years, whereas Wellstat's right to termination included financial obligations to BTG in the event it terminated under this provision. A168 (§ 12.2).

This error of law was significant. Limiting Wellstat's damages to five years rather than ten would reduce the award by tens of millions of dollars. A1587 (Gerardi 1310:6-1311:1); *see also supra* n.6. This Court should therefore reverse the trial court's damages award and remand for the trial court to limit damages consistent with BTG's right to terminate the Agreement for convenience.

## II. THE CHANCERY COURT IMPROPERLY INCLUDED PATIENTS SUFFERING "MODERATE" TOXICITIES IN ITS DAMAGES AWARD BASED ON A FAULTY AND MISLEADING SURVEY.

### A. Question presented.

Did the trial court err by including patients suffering from "moderate" 5-FU toxicities in its assessment of Vistogard's patient population?

The appropriateness of Brock's and Patel's *post hoc* "correction" of their report in light of the error in their survey was directed to the court in the Pre-Trial Order. A908-09. The court overruled BTG's objection at oral argument. A853. BTG asserted that moderate patients should be excluded as a result in its briefing. A1703-08; A1817-22. The trial court addressed the claim in its Memorandum Opinion at pages 45 through 49.

### B. Scope and standard of review.

This Court reviews the award of damages for abuse of discretion, and will uphold related factual determinations absent clear error. *See SIGA Techs., Inc. v. PharmAthene, Inc.*, 132 A.3d 1108, 1128 (Del. 2015).

### C. Merits of argument.

The Chancery Court abused its discretion in relying on projections from a deeply flawed survey conducted by Wellstat's expert, Neel Patel. In an effort to identify the size of Vistogard's potential patient population, that survey asked physicians to estimate the percentages of patients for whom they would prescribe Vistogard, based on whether the patients suffered from mild, moderate, or severe

5-FU toxicities. Although the trial court correctly excluded patients suffering from mild 5-FU toxicity out of recognition that Vistogard could not lawfully be marketed for such patients under the terms of the FDA's approval of the drug, the court failed to apply the same logic for patients in the moderate category, even though federal law equally prohibits marketing Vistogard for them. The trial court ostensibly concluded that physicians estimating their prescription percentages for "moderate" patients actually meant to be estimating their prescription percentages for "severe" patients—based on terminology used *incorrectly* in a *different* part of the survey. That was an abuse of discretion, without which Wellstat's damages would have been reduced to approximately $1.7 million.[9]

[9] Although the trial court observed in its opinion that excluding both "mild" and "moderate" patients "would reduce Wellstat's damages to no more than $19.2 million" (Op. at 46), this assumed that the court accepted Wellstat's "investor update" forecast as the basis for future sales, which the court ultimately rejected. *Id.* at 51-52. Under the BTG revised forecast, which the trial court accepted and applied, damages without "moderate" patients are reduced to roughly $1.7 million. *See* A1634 (Revised Decision Tree Demonstrative).

The key question in Patel's survey was Question 50:

50. To what percent of your 5-FU/capecitabine toxicity patients in each of the following segments would you prescribe Product X (Note to survey taker: please assume that all early-onset toxicity patients presented within the 96 hour window following end of 5-FU/capecitabine administration?

| | | | |
|---|---|---|---|
| Early-onset toxicity patients segmented by severity of toxicity symptoms | Mild | Moderate | Severity |
| | % | % | % |
| Early-onset toxicity patients segmented by DPD-deficiency status (assuming DPD information is available) | DPD-deficiency positive patients NOT presenting with any 5-FU/ capecitabine toxicity symptoms | DPD-deficiency positive patients presenting with some level of 5-FU/ capecitabine toxicity symptoms | DPD-deficiency negative patients presenting with some level of 5-FU/ capecitabine toxicity symptoms |
| | % | % | % |
| 5-FU/capecitabine overdose patients | Overdose patients presenting WITHOUT any 5-FU/ capecitabine toxicity symptoms | | Overdose patients presenting WITH any 5-FU/ capecitabine toxicity symptoms |
| | % | | % |

A283. These descriptions of different levels of toxicity—mild, moderate, and severe—partly track Vistogard's FDA-approved label, which states that Vistogard is approved to treat early onset or "severe or life-threatening toxicities" from 5-FU. A250.

Patel used the responses to Question 50 to estimate the number of patients that would be treated for mild, moderate, and severe 5-FU toxicities, and included all three categories in his projected patient population. *E.g.*, A1568 (Patel 1236:6-20), A1569 (Patel, 1238:10-21).

Compounding this error, another of Wellstat's experts, Christopher Gerardi, premised his estimation of Vistogard's expected sales (assuming BTG had

exercised Diligent Efforts as required by the Agreement) on Patel's patient population, including patients with mild and moderate toxicities. A1586 (Gerardi 1306:21-1307:21); A1591-92 (Barry 1328:24-1330:15) (noting mild and moderate toxicities account for roughly 59% of projected sales).

But because Vistogard received FDA approval only for "early-onset, severe or life-threatening toxicity," A250, it was wrong for Wellstat's experts to base damages on "off-label" prescriptions for patients suffering from less than severe toxicity. Generally speaking, federal law allows doctors to engage in off-label uses of prescription drugs and devices but prohibits companies like Wellstat and BTG from promoting off-label uses or from selling such products with the intent that they be used for off-label purposes. *See, e.g.*, *Wash. Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000). The trial court correctly noted that BTG could not market for off-label use (and could not be responsible for doing so), and it excluded "mild" patients from the damages calculation for that very reason. Op. at 46, 48-49 & n.184 (citing 21 U.S.C. § 355(a); 82 Fed. Reg. 2193 (Jan. 9, 2017) (to be codified at 21 C.F.R. §§ 201, 801, 1100)); *see also, e.g.*, A1268 (Bamat 912:12-21) (Wellstat's chief scientist noting FDA rebuke regarding approval for "moderate" patients); A1360-63 (Boghigian 1004:11-15, 1007:7-18) (agreeing, *inter alia*, that for company to size sales force in expectation of off-label sales would be potentially incriminating, and that companies accordingly do not factor

off-label sales in projections); A1458-59 (Gianchetti 1102:22-1103:14) (similar); A1202 (Suvari 801:7-14) (similar).

But the trial court refused to treat "moderate" patients the same way and excused Wellstat's inclusion of them in its forecast. The court seemed to conclude that physicians answering Question 50 interpreted "moderate" to mean "severe" based on other questions in the survey. Unlike Question 50 itself, other questions (but not all) characterized toxicity levels using four numeric grades. For example, Question 25 states:

25. For the patients experiencing 5-FU/capecitabine toxicity within the first week following 5-FU/capecitabine treatment initiation, please segment them by severity of toxicity. (Note to survey taker: The percentage of patients from all the groups should add up to 100%)

| Segments by Severity of Toxicity | | |
|---|---|---|
| Mild (Grade 1-2) | Moderate (Grade 3) | Severe (Grade 4) |
| % | % | % |

A274.

However, as the trial court noted, Patel's four grades do not match the most "widely used" four-tier grading system in the industry, the Common Terminology Criteria for Adverse Events (the "Common Terminology"):

| **Common Terminology** | | **Patel Terminology** | |
|---|---|---|---|
| Grade | Description | Grade | Description |
| 1 | Mild | 1-2 | Mild |
| 2 | Moderate | 3 | Moderate |
| 3 | Severe | 4 | Severe |
| 4 | Life Threatening | No Grade | Life Threatening |

*Compare* Op. at 46, *with* A274. Crucially, whereas Patel characterizes "moderate" toxicity as Grade 3, standard terminology uses "Grade 3" to refer to *severe* toxicity.

Although Patel's curious departure from usual terminology should only *weaken* its credibility, the court used this discrepancy in an effort to fix Question 50's evident flaws. It is beyond dispute that Question 50 contained no reference to numeric toxicity grades. Yet, the court grafted Patel's incorrect numeric grading terminology from questions like Question 25 onto Question 50. The court apparently presumed that physicians estimating "moderate" prescriptions in Question 50 had in mind the grading tiers set off in parentheticals in Question 25 (which idiosyncratically characterizes "moderate" toxicity as "Grade 3"). Then, since the correct industry-wide terminology uses "Grade 3" to refer to "severe" toxicity, the court guessed that physicians must have concluded that the word "moderate" in Question 50 actually meant "severe." *See* Op. at 45-49

(superimposing grading terminology onto Question 50 despite the fact that the question did not mention grades). Moreover, the court engaged in this flawed interpretation of "moderate" without bothering to address the effect on the categories "mild," "severe," or "life threatening."

This convoluted effort to make up for Wellstat's experts' errors goes too far. To be sure, plaintiffs often get the benefit of the doubt in damages calculations, but still they may not obtain recovery "for loss of profits which are determined to be uncertain, contingent, conjectural, or speculative." *SIGA Techs.*, 132 A.3d at 1131; *cf. Gannet Co. v. Kanaga*, 750 A.2d 1174, 1188 (Del. 2000) ("While the plaintiff is entitled to the benefit of reasonable inferences from established facts, the jury cannot supply any omission by speculation or conjecture."). The trial court correctly understood that the fundamental premise of Wellstat's damages analysis was legally unsound because it factored in sales that BTG was legally forbidden to pursue, and that should have ended the discussion.

Instead, the court tried to fix the problem with speculation about how the physicians interpreted the relationship between industry-standard terminology and Patel's confusing, non-standard terminology. Then, when BTG objected that Patel got his four grades *wrong*, the court hypothesized that the error somehow helped BTG. But the only basis the court could identify for this hypothesis was BTG's own, slightly higher internal estimates of the likely patient population. Op. at 48 &

n.183. Wellstat, however, bore the burden of supporting its damages calculations with credible expert testimony. *See, e.g.*, *PJ King Enters., LLC v. Ruello*, 2008 WL 4120040, at *3 (Del. Super. Jul. 1, 2008) ("Delaware law consistently holds that economic and financial damages require expert testimony."). Far from credible, Wellstat's expert testimony was flawed legally and factually.

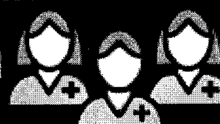
That is why Patel, over BTG's objection, A908-09, ultimately sought to amend his expert report to obscure its errors and inflate Wellstat's damages. Patel knew the correct Common Terminology grading methodology when he authored his original expert report, since he accurately described the methodology in a slide attached to that report. A435. His initial expert report did not even include numeric grading, but instead used only symptom descriptions. *E.g.*, A421; A467. After BTG's expert pointed out Patel's errors, Wellstat amended its expert report to substitute the symptom descriptions for the mislabeled grades. *Compare* A681 (revised report using numerical grades), *with* A467 (original report using symptom descriptions). In addition, Patel initially reported only on the "severe" responses, but then in his revised report expanded the results to include both "Grade 3" and "Grade 4."

*Compare*:

**What the Interviewed HCPs Reported**

- An average of 18% incidence of any level of early-onset 5-FU/capecitabine toxicity, of which only an average of 7% cases are classified as severe

A421, *with*:

**What the Interviewed HCPs Reported** 

- An average of 18% incidence of any level of early-onset 5-FU/capecitabine toxicity, of which only an average of 7% cases are classified as grade 4 and 21% are grade 3

A635; *compare also* A425, *with* A639.[10]

BTG objected to these supposed "corrections" in the Pre-Trial Order, A908-09, but those objections were overruled at the Pre-Trial Conference. A853.

[10] The "amended" report also adds a misleading definition slide. A630. It states that "when conducting our market research, respondents were given these definitions" and that "to avoid confusion, whenever the report uses the terms 'severe,' 'moderate,' or 'mild,' it will indicate the corresponding Grade that is intended, which corresponds to how it was used when conducting our market research." *Id.* This is not true; Question 50 has *no* such grades (nor do many other questions in Patel's survey). This is not the only misleading statement within this new slide. This slide also states that "according to the National Institute of Health and National Cancer Institute 'severe' toxic reactions equates to Grade 3 or 4 symptoms." *Id.* This statement cites to the NCI Common Terminology grading chart, which does *not* state that "severe" equates to Grade 3 or 4 symptoms.

Setting aside the impropriety of these amendments, the fact remains that the critical Question 50 used words like "moderate," not numeric grades that depart from the industry standard professional lingo. Had the court properly awarded damages for severe patients only, in accordance with the FDA-approved label, Wellstat's damages would total $1.7 million. *See* A1634 (Revised Decision Tree Demonstrative); A1594 (Barry 1338:1-6). Awarding Wellstat more than this amount resulted in a windfall, and that award should be reversed.

## III. WELLSTAT'S DAMAGES MODEL LIKEWISE FAILED TO ACCOUNT FOR FUTURE SALES ON VISTOGARD'S RETURN TO WELLSTAT.

### A. Question presented.

Did the trial court err in accepting damages projections premised on BTG's continued distribution of Vistogard, even though Wellstat requested, and received, return of the distribution rights in this lawsuit?

This claim was presented to the trial court in BTG's briefing. *See* BOB at 72 and 73 (A1714-15); BRB at 30-32 (A1823-25). The trial court addressed it at pages 54 and 55 of its Memorandum Opinion.

### B. Scope and standard of review.

As noted above, this Court reviews the overall award of damages for abuse of discretion, *SIGA Techs.*, 132 A.3d at 1128, but "claims that [a] disputed remedy was erroneous as a matter of law, because the trial court erred in formulating or applying legal principles," are reviewed *de novo*, *Berger*, 976 A.2d at 139 (internal quotation marks omitted).

### C. Merits of argument.

Wellstat's damages model made no attempt to account for the termination and return of Vistogard's distribution rights to Wellstat, which Wellstat requested in its Notice of Termination (A328-30) and later in its counterclaim and in the Pre-Trial Order (A384, A409; A897). Although the court's Final Order granted Wellstat's request (*see* Exhibit B), the trial court rejected BTG's argument that

Wellstat's damages model should have accounted for the rights return. Specifically, Wellstat should have calculated the difference between what it would have earned had BTG not breached and what it will earn having recovered the distribution rights. Instead, Wellstat calculated the difference between what it would have earned had BTG not breached and "the expected royalty and manufacturing profits that would be owed to Wellstat if *BTG continues to commercialize Vistogard® according to its current forecasts*." A545 (emphasis added).

Those two calculations are very different. Upon the return of the distribution rights, Wellstat no longer receives mere royalties from BTG—ranging from 20% to 40% of net sales (A138-39 (§ 4.3(a))—but *all* of the distribution revenue, minus its costs and expenses. Wellstat presented no evidence on what its profits would be under this scenario and failed even to establish that it would suffer *any* net injury with the return of the distribution rights. In fact, as Wellstat principal David Wohlstadter admitted at trial, he believes Wellstat will recoup substantially more revenue after Vistogard's return than BTG projected it could achieve. A1530-31 (D. Wohlstadter 1174:4-1175:18); A1539 (D. Wohlstadter 1183:9-19) & A188 (noting belief that if properly marketed and sold, the net present value of the Vistogard royalty stream would be of the magnitude of $771

million; a value Wellstat "would hope" to achieve when it commercializes Vistogard on return).

The trial court excused Wellstat's inexplicable failure to factor those profits into its damages model based on a legal mistake: it concluded that BTG's argument was *solely* an argument about Wellstat's obligation to mitigate its damages, on which BTG supposedly bore the burden of proof. Op. at 55. But as BTG argued below, Wellstat's "failure to base its damage calculation on what it would sell upon return of Vistogard® is a basic and fundamental failure of proof." A1715; *see also* A1824 ("This is not simply a mitigation issue; it is a failure to prove damages.").

Under blackletter contract law, expectation damages are calculated by adding the losses the plaintiff suffered due to the breach and then subtracting "any cost or other loss that he has avoided by not having to perform." Restatement (Second) of Contracts § 347 (1981); *accord WaveDivision Holdings, LLC v. Millennium Dig. Media Sys., L.L.C.*, 2010 WL 3706624, at *20 (Del. Ch. Sept. 17, 2010) (Strine, V.C.). "If [the plaintiff] makes an especially favorable substitute transaction, so that he sustains a smaller loss than might have been expected, his damages are reduced by the loss avoided as a result of that transaction." Restatement (Second) of Contracts § 347 cmt. e. Contract "damages should not act as a windfall." *Paul v. Deloitte & Touche, LLP*, 974 A.2d 140, 146 (Del. 2009).

Wellstat clearly viewed the return of the Vistogard rights and its future commercializing of those rights as a "favorable" development—that is why Wellstat demanded that relief. As a consequence, its damages calculations had to take that substitute relief into account. Contrary to the trial court's conclusion, Wellstat, not BTG, bore the burden of proof. *VICI Racing, LLC v. T-Mobile USA, Inc.*, 87 F. Supp. 3d 697, 699 (D. Del. 2015) ("A defendant seeking to offset a damages award due to avoided costs must move forward by pointing out the costs it believes the plaintiff avoided because of its breach. The burden then shifts to the plaintiff to incorporate those saved costs into its formulation of a plausible but-for world.") (citations, brackets, and quotation marks omitted).

By failing to account for its future sales of Vistogard now that the product has been returned to it, as repeatedly demanded, Wellstat failed to prove the measure of its damages. The trial court exceeded its discretion by fashioning a damages award based on Wellstat's fundamentally flawed damages projections.

## IV. THE COURT APPLIED AN ARBITRARY RATE OF PRE- AND POST- JUDGMENT INTEREST FOUNDED ON AN INAPPLICABLE PROVISION IN THE AGREEMENT.

### A. Question presented.

Did the trial court err as a matter of law in applying the rate of interest applicable to late payments and choosing an inappropriate date from which interest should run?

Wellstat requested the trial court impose pre- and post-judgment interest at the rate of 12%. WOB at 65-67 (A1786-88). BTG objected. BRB at 32-33 (A1825-26). The trial court addressed this issue in its Memorandum Opinion at pages 57-58.

### B. Scope and standard of review.

"[W]hen the Court of Chancery's interest award involves questions of law, that award will be subject to a *de novo* standard of review." *Cede & Co. v. Technicolor, Inc.*, 884 A.2d 26, 42 (Del. 2005). The date on which pre-judgment interest begins to accrue is also reviewed *de novo*. *E.g.*, *Delphi Petroleum, Inc. v. Magellan Terminal Holdings, L.P.*, 2017 WL 6371162, at * 2 (Del. Dec. 12, 2017).

## C. **Merits of argument.**

### 1. The Chancery Court arbitrarily applied an excessive interest rate with no basis in the applicable contractual provisions.

On top of the errors in the trial court's damages calculation, the trial court also erred by ordering BTG to pay an exorbitant interest rate that applies to late payments under the contract, not expectation damages for a material breach.

As the trial court recognized, where parties do not contract for a particular rate of interest, the default legal rate set forth in 6 *Del. C.* § 2301(a) should be applied unless equity demands otherwise.[11] Op. at 57-58; *see also, e.g.*, *Watkins v. Beatrice Cos., Inc.*, 560 A.2d 1016, 1023 (Del. 1989). But rather than applying that statutory rate, the trial court arbitrarily applied a rate over twice as severe, drawing upon the Agreement's Late Payments provision, which states:

> 4.8 **Late Payments**. BTG shall pay interest to Wellstat on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of (a) one percent (1%) per month, or (b) the highest rate permitted by applicable law, calculated on the number of days such payments are paid after the date such payments are due. In addition, in any payment dispute, the prevailing party shall reimburse the other Party for all costs and expenses, including without limitation

[11] 6 *Del. C.* 2301(a) provides that "[w]here there is no expressed contract rate, the legal rate of interest shall be 5% over the Federal Reserve discount rate including any surcharge as of the time from which interest is due …." *Id.* Between March 2016 and present, the Federal Reserve discount rate for primary credit has ranged from 1% to 2%. *See* Federal Reserve Board Discount Window, Historical Rates, https://www.frbdiscountwindow.org/~/media/Documents/primarysecondary.ashx?la=en (last visited Jan. 11, 2018).

attorney fees and legal expenses, incurred in the collection of late payments under dispute.

A144 (§ 4.8).

On its face, this provision has no application here. It is expressly self-limiting to "payment dispute[s]" over "payments . . . due under this Agreement." *Id.* Thus, it is triggered only when one of the parties fails to make a timely payment to the other, and helped to ensure that missed payments would be addressed promptly. Wellstat's damages award, by contrast, is based on future expectation damages from a material breach, not past-due payments. The parties understood the difference between a "material breach" and "payment breach," as evidenced in the "Termination For Breach" provision, which expressly distinguished between a "Payment Breach" and a "material breach." A169 (§ 12.4). The material breach provision articulates the procedure that would be followed in the event of a material breach but is completely silent about what interest rate might apply. *Id.* The parties could have inserted interest-rate language in this provision similar to the language in Section 4.8, related to late payments, but they did not.

Alternatively, the parties could have used interest language similar to what they used in Section 14.5(b), which addresses expedited arbitration of any disputes arising out of their Joint Development and Commercialization Committee. A176 (§ 14.5(b)) ("Any award shall include interest at the maximum rate allowable by

law[.]"). The fact that the parties chose different interest rates for different contingencies underscores the impropriety of the trial court's decision to conscript the Late Payments interest rate into service for a material, non-payment breach. Picking that rate instead of the arbitration rate was simply arbitrary.

The trial court attempted to justify its use of the Late Payment interest rate by citing cases involving "[s]imilar language." Op. at 58 & n.215. But the underlying *disputes* in those cases were critically different: although each case awarded interest using the rate from the contract's late-payment provision, liability in each case was actually premised, in whole or in part, on *late payments*. *See Miller v. Silverside*, 2016 WL 4502012, at *9 (Del. Super. Aug. 26, 2016) (failure to pay nursing home fees); *Bridev One, LLC v. Regency Ctrs., L.P.*, 2017 WL 3189230, at *5 (Del. Super. July 20, 2017) (failure to pay rent due under commercial lease); *Millcreek Shopping Ctr. LLC v. Jenner Enters., Inc.*, 2017 WL 1282068, at *2 (Del. Super. Mar. 31, 2017) (similar). None of these cases shoehorned a dispute about interest due on lost profits—awarded as expectation damages for a non-payment breach—into language addressing late payments under the contract.

This case was not about damages from a late payment. It was and always has been about expectation damages in the form of lost future profits. The trial court made no effort to explain its application of the Late Payment provision's

interest rate when the contract had multiple interest rate provisions. While prejudgment interest is meant to provide "compensation" for the plaintiff's inability to access the damages awarded, *Moskowitz v. Mayor & Council of Wilmington*, 391 A.2d 209, 210 (Del. 1978), the trial court's imposition of the Late Payment interest rate in this case can only be described punitive.

2. The Chancery Court overcompensated Wellstat by choosing an interest start date six months earlier than Wellstat's damages.

Finally, to make matters worse, the trial court also reversibly erred in determining when that interest would begin to run, choosing a date that has no evidentiary support and was six months earlier than even Wellstat requested.

The trial court found that interest would run from the date of the first breach it found—i.e., the perceived failure to provide the Initial Commercialization Plan on September 15, 2015. Op. at 58. Wellstat, on the other hand, sought interest only as of March 2, 2016—"when the product was launched" and "damages beg[a]n to run." A1924 (Post-Trial Argument Tr. 96:9-17); *see also* A1787.[12] Wellstat never claimed to have suffered damages at the time of the Initial Commercialization Plan's provision but later, when BTG purportedly began to sell Vistogard using less than Diligent Efforts. Indeed, Wellstat's own damages expert

[12] Although Wellstat's counsel referred to March 16, 2016, as the correct interest start date during oral argument, Wellstat's briefing treated March 2, 2016, as the correct date. *Compare* A1924 (Post-Trial Argument Tr. at 96:91-10), *with* A1787. BTG therefore believes that counsel's reference to March 16, 2016, was an inadvertent misstatement.

used March 2, 2016 as the start date for calculating interest, since that was the moment at which Wellstat claimed it began suffering monetary harm. A597 & A598 n.1.

That was the correct approach to this question. "Generally, pre-judgment interest accumulates from the date payment was due to a party, or alternatively when the plaintiff first suffered a loss at the hands of the defendant." *Delphi*, 2017 WL 6371162, at *2. That is because interest is meant to compensate the plaintiff for the temporary loss of the use of its property. *See Moskowitz*, 391 A.2d at 210. The authorities invoked by the trial court are not to the contrary. *See* Op. at 58 n.213. In fact, they agree that prejudgment interest does not begin until the plaintiff's loss becomes concrete. *See Citadel Holding Corp. v. Roven*, 603 A.2d 818, 826 (Del. 1992) ("Such interest is to be computed from the date *payment* is due.") (emphasis added); *Wilson v. Pepper*, 1995 WL 562235, at *2 & *6 (Del. Super. Aug. 21, 1995) (computing interest from date septic tank began to leak).

There was therefore no basis in law or fact for the trial court's decision to begin pre-judgment interest on September 15, 2016. That decision, too, should be reversed.

## CONCLUSION

For the foregoing reasons, BTG respectfully requests this Court to reverse the award of damages and interest to Wellstat and find that Wellstat failed to provide adequate proof of its damages or, in the alternative, to reverse and remand for further calculation of damages and interest consistent with the Court's determination, including recalculation of pre- and post-judgment interest at the legal rate, and commencing March 2, 2016.

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