



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.

APPELLANT'S REPLY BRIEF

OF COUNSEL:

Richard L. Scheff
Lathrop B. Nelson, III
**Montgomery, McCracken,
Walker & Rhoads, LLP**
123 South Broad Street, 28th Floor
Philadelphia, PA 19109
(215) 772-1500

Dated: March 2, 2018

**MONTGOMERY McCracken
WALKER & RHOADS, LLP**

Lisa Zwally Brown (No. 4328)
1105 North Market Street
Suite 1500
Wilmington, DE 19801
(302) 504-7800

*Attorneys for BTG International Inc.
Plaintiff Below-Appellant*

TABLE OF CONTENTS

| | Page |
|---|-------------|
| ARGUMENT | 1 |
| I. WELLSTAT CANNOT ESCAPE THE CHANCERY COURT’S LEGAL ERROR IN FAILING TO ENFORCE THE AGREEMENT’S FIVE-YEAR TERMINATION PROVISION. | 1 |
| A. BTG FAIRLY PRESENTED THIS ARGUMENT BELOW..... | 1 |
| B. CHRYSLER IS “THE MOST RELEVANT DELAWARE AUTHORITY,” AND IT SQUARELY FORECLOSES WELLSTAT’S ARGUMENTS. | 4 |
| C. A REMAND IS NECESSARY..... | 9 |
| II. THE FLAWS IN THE PATEL SURVEY, UPON WHICH THE COURT OF CHANCERY FOUNDED ITS INCLUSION OF PATIENTS SUFFERING FROM OFF-LABEL “MODERATE” TOXICITY, CANNOT BE EXPLAINED AWAY AS A MERE “AMBIGUITY.” | 10 |
| A. THE CRITICAL FLAW IN PATEL’S SURVEY WAS MORE THAN AN “AMBIGUITY.” | 10 |
| B. WELLSTAT IS WRONG TO ASSERT THAT THERE IS “NOTHING WRONG WITH” OFF-LABEL SALES BEING INCLUDED IN ITS PROJECTED VISTOGARD PATIENT POPULATION..... | 13 |
| III. WELLSTAT’S DAMAGES MODEL LIKewise FAILED TO ACCOUNT FOR FUTURE SALES ON VISTOGARD’S RETURN TO WELLSTAT. | 15 |
| A. WELLSTAT HAS LONG UNDERSTOOD THAT BTG’S ARGUMENT WAS NOT A MERE “MITIGATION” DEFENSE. | 15 |
| B. WELLSTAT’S DAMAGES MODEL FAILED TO ACCOUNT FOR THE RELIEF REQUESTED. | 16 |
| IV. THE COURT’S INTEREST RATE WAS PURPORTEDLY A CONTRACT RATE, BUT HAD NO BASIS IN THE AGREEMENT. | 19 |

TABLE OF CONTENTS

(continued)

Page

| | | |
|----|---|----|
| A. | THE TRIAL COURT SAID IT WAS APPLYING A CONTRACTUAL INTEREST RATE, NOT THAT IT HAD DISCRETIONARILY CHOSEN A PUNITIVE 12% INTEREST RATE THAT COMPOUNDED MONTHLY. | 19 |
| B. | HAVING REQUESTED THE INTEREST START DATE BTG ASKS FOR, WELLSTAT CANNOT CLAIM BTG'S REQUEST IS WAIVED. WELLSTAT DOES NOT DISPUTE BTG'S REQUEST ON THE MERITS. | 21 |
| | CONCLUSION..... | 24 |

TABLE OF AUTHORITIES

| | Page(s) |
|--|----------------|
| Cases | |
| <i>Amarin Pharma., Inc. v. U.S. Food & Drug Admin.</i> , 119 F. Supp. 3d 196 (S.D.N.Y. 2015) | 14 |
| <i>Bridev One, LLC v. Regency Ctrs., L.P.</i> , 2017 WL 3189230 (Del. Super. Ct. Jul. 20, 2017)..... | 21 |
| <i>Carestream Health, Inc. v. M & G Polymers USA, LLC</i> , 9 A.3d 475 (Del. 2010) | 5 |
| <i>Charlotte Broad., LLC v. Davis Broad. Of Atlanta, LLC</i> , 2015 WL 3863245 (Del. Super. Ct. June 10, 2015)..... | 8 |
| <i>Chevrolet Motor Co. v. McCullough Motor Co.</i> , 6 F.2d 212 (9th Cir. 1925) | 6, 8 |
| <i>Chrysler Corp. v. Quimby</i> , 144 A.2d 885 (Del. 1958) | <i>passim</i> |
| <i>Clark v. Clark</i> , 47 A.3d 513 (Del. 2012) | 3 |
| <i>Comcast Corp. v. Behrend</i> , 569 U.S. 27 (2013)..... | 17 |
| <i>Crowell Corp. v. Himont USA, Inc.</i> , 1994 WL 762663 (Del. Super. Ct. Dec. 8, 1994) | 4 |
| <i>Dalton Properties, Inc. v. Jones</i> , 683 P.2d 30 (Nev. 1984)..... | 6, 7 |
| <i>Debakey Corp. v. Raytheon Serv. Co.</i> , 1999 WL 35024516 (Del. Ch. Oct. 15, 1999) | 7 |
| <i>J.E. Rhoads & Sons, Inc. v. Ammeraal, Inc.</i> , 1988 WL 32012 (Del. Super. Ct. Mar. 30, 1988)..... | 5, 8, 9 |
| <i>Kerbs v. Cal. E. Airways</i> , 90 A.2d 652 (Del. 1952) | 3 |

TABLE OF AUTHORITIES

(continued)

| | Page(s) |
|--|----------------|
| <i>Koufakis v. Carvel</i> , 425 F.2d 892 (2d Cir. 1970) | 7 |
| <i>LeMond Cycling, Inc. v. PTI Holding, Inc.</i> , 2005 WL 102969 (D. Minn. Jan. 14, 2005) | 7 |
| <i>M & G Polymers USA, LLC v. Carestream Health, Inc.</i> , 2009 WL 3535466 (Del. Super. Ct. Aug. 5, 2009) | |
| <i>M & G Polymers USA, LLC v. Carestream Health, Inc.</i> , 2010 WL 1611042 (Del. Super. Ct. Apr. 21, 2010) | 5, 7 |
| <i>Millcreek Shopping Ctr. LLC v. Jenner Enters., Inc.</i> , 2017 WL 1282068 (Del. Super. Ct. Mar. 31, 2017)..... | 21 |
| <i>Miller v. Silverside</i> , 2016 WL 4502012 (Del. Super. Ct. Aug. 26, 2016)..... | 21 |
| <i>N. River Ins. Co. v. Mine Safety Appliances Co.</i> , 105 A.3d 369 (Del. 2014) | 3 |
| <i>Osborn v. Commanche Cattle Industries, Inc.</i> , 545 P.2d 827 (Okla. Ct. App. 1975)..... | 6 |
| <i>PJ King Enters., LLC v. Ruello</i> , 2008 WL 4120040 (Del. Super. Ct. July 1, 2008)..... | 12 |
| <i>Reiver v. Murdoch & Walsh, P.A.</i> , 625 F. Supp. 998 (D. Del. 1985)..... | 4 |
| <i>Ring Bros. Co. v. Martin Bros. Container & Timber Prods. Corp.</i> , 438 F.2d 420 (9th Cir. 1971) | 7, 8 |
| <i>Salamone v. Gorman</i> , 106 A.3d 354 (Del. 2014) | 20 |
| <i>Siga Techs., Inc. v. PharmAthene, Inc.</i> , 132 A.3d 1108 (Del. 2015) | 12 |

TABLE OF AUTHORITIES

(continued)

| | Page(s) |
|--|----------------|
| <i>Smalley Transp. Co. v. Bay Dray, Inc.</i> , 612 So. 2d 1182 (Ala. 1992)..... | 5 |
| <i>Smith v. Delaware State University</i> , 47 A.3d 472 (Del. 2012), refused | 3 |
| <i>Tanner v. Exxon Corp.</i> , 1981 WL 191389 (Del. Super. Ct. July 23, 1981)..... | 4 |
| <i>Telxon Corp. v. Meyerson</i> , 802 A.2d 257 (Del. 2002) | 3 |
| <i>VICI Racing, LLC v. T-Mobile USA, Inc.</i> , 763 F.3d 275 (3d Cir. 2014) | 16 |
| <i>Watkins v. Beatrice Cos.</i> , 560 A.2d 1016 (Del. 1989) | 3 |
| <i>Zoller v. Rowe Mfg. Co.</i> , 1978 WL 215749 (Ohio Ct. App. June 15, 1978) | 5 |
| Statutes | |
| 6 <i>Del. C.</i> § 2301(a)..... | 19 |
| Other Authorities | |
| <i>Corbin on Contracts</i> § 68.9 (rev. ed. 2003)..... | 8 |
| Federal Judicial Center, Reference Manual on Scientific Evidence (3d ed. 2011) | |

ARGUMENT

I. WELLSTAT CANNOT ESCAPE THE CHANCERY COURT'S LEGAL ERROR IN FAILING TO ENFORCE THE AGREEMENT'S FIVE-YEAR TERMINATION PROVISION.

Unable to distinguish this Court's squarely on-point decision in *Chrysler Corp. v. Quimby*, 144 A.2d 885 (Del. 1958), Wellstat diverts attention to cases from other jurisdictions, which do not address or even acknowledge *Chrysler*, and cases that confront materially different circumstances. It also belabors that BTG waived its principal argument on this topic because BTG responded to a separate legally flawed argument made by Wellstat, the first of several instances in which Wellstat raises baseless procedural arguments to excuse its failure to materially grapple with the merits of BTG's claims.

Wellstat is wrong about waiver and wrong about the law. The trial court's damages decision improperly inflated Wellstat's award based on demonstrably incorrect legal principles, warranting a remand.

A. BTG fairly presented this argument below.

Below, BTG's main argument was that it was improper for Wellstat to obtain lost profits through 2025 because BTG had a "*right* to terminate without penalty in 2020." BTG's Post-Trial Reply Brief ("BRB") at 29 (A1822) (emphasis added). It was enough, on BTG's view, that "BTG *can* terminate . . . in December 2020." BTG's Opening Post-Trial Brief ("BOB") at 72 (A1714) (emphasis added). Wellstat's damages expert was obligated to take that termination right into

account. He did not. *Id.*; A1586-A1587 (Gerardi 1308:7-1311:1). The trial court understood BTG’s argument, stating, “BTG claims that Wellstat’s damages should be limited by the fact that BTG has the *right* to terminate.” Post-Trial Memorandum Opinion (“Op.”) at 53 (emphasis added).

Wellstat disagreed with that argument and insisted that the termination right lacked significance unless BTG could prove, factually, that it would exercise that right in 2020—in a hypothetical world in which the parties proceeded happily with their agreement. To be sure, BTG challenged Wellstat’s argument by contesting Wellstat’s factual assumption that BTG would not terminate. BRB at 29-30 (A1822-A1823). But that was a rebuttal, not BTG’s main contention, and as such it was not a concession that Wellstat’s legal premise was correct.¹

Apart from confusing the record, Wellstat misreads Rule 8’s requirement that issues be fairly presented below. Contrary to Wellstat’s presentation, BTG is not limited to the exact formulation it offered below. This Court’s caselaw demonstrates that appellants may change their “focus[]” on appeal so long as they

¹ Wellstat’s reliance on the post-trial oral argument is misplaced. There, BTG took the same approach as in its briefing: it faulted Wellstat for failing to “take into consideration that BTG had the right to terminate after five years” and then argued against Wellstat’s factual arguments in the alternative. A1861-A1862 (Tr. 33:18-34:20). Nor does Wellstat’s effort later at argument to put words into BTG’s mouth change the nature of BTG’s principal objection to the ten-year projection. *See id.* at A1919-A1920.

sufficiently raised the “broader issue,” *N. River Ins. Co. v. Mine Safety Appliances Co.*, 105 A.3d 369, 383 (Del. 2014), and may cite previously uncited authorities as “an additional reason in support of a proposition urged below,” *Kerbs v. Cal. E. Airways*, 90 A.2d 652, 659 (Del. 1952). The Court has permitted appellants to press theories that were only “implicitly raised below,” *Telxon Corp. v. Meyerson*, 802 A.2d 257, 263 (Del. 2002), and stated “that the mere raising of the issue is sufficient to preserve it for appeal,” *Watkins v. Beatrice Cos.*, 560 A.2d 1016, 1020 (Del. 1989).

Wellstat’s two main cases do not suggest otherwise. In *Clark v. Clark*, 47 A.3d 513, 517-18 (Del. 2012), the appellant made a passing reference to her appellate issue during oral argument on an unrelated motion where the issue was “irrelevant to the issue at hand.” The Court in *Smith v. Delaware State University*, 47 A.3d 472, 479 (Del. 2012), refused to consider an argument that was completely different from the argument made in the trial court. The appellant had argued below that she could prove two elements of her claim, but on appeal argued that she need not prove those elements. *Id.*

Unlike the appellants in those cases, BTG advanced, and the trial court rejected, the argument that Wellstat’s lost profits calculation had to account for BTG’s termination right. BTG therefore satisfies Rule 8’s requirements.

B. *Chrysler* is “the most relevant Delaware authority,” and it squarely forecloses Wellstat’s arguments.

Wellstat has failed to call *Chrysler* into doubt or demonstrate its inapplicability. The case unequivocally rejects Wellstat’s argument that a termination right is insignificant to the lost profits inquiry absent factual proof that termination would occur. Just like Wellstat, the plaintiff there “argue[d] that it is unrealistic to suppose that [the breaching party] would enforce the [termination] provision.” 144 A.2d at 886. This Court held that “[t]his argument misses the point.” *Id.* The point, in the Court’s (and BTG’s) view, is that the contract “confer[red] upon either party an absolute right to terminate,” and there is “no reason why it should not be given effect” in the lost profits calculation. *Id.* The way to do that is by recognizing “that loss of profits must be confined to [the] period” in which the breaching party had no power to terminate the contract. *Id.* at 887.

Although *Chrysler* applied Michigan’s law of promissory estoppel, nothing in its analysis turned on issues specific to Michigan law or promissory estoppel. The case has been followed on exactly this point by courts applying Delaware contract law. *Tanner v. Exxon Corp.*, 1981 WL 191389, at *3 (Del. Super. Ct. July 23, 1981); *Reiver v. Murdoch & Walsh, P.A.*, 625 F. Supp. 998, 1010 (D. Del. 1985). It is consistent with other Delaware decisions on the subject, e.g., *Crowell Corp. v. Himont USA, Inc.*, 1994 WL 762663, at *3 (Del. Super. Ct. Dec. 8, 1994);

J.E. Rhoads & Sons, Inc. v. Ammeraal, Inc., 1988 WL 32012, at *10 (Del. Super. Ct. Mar. 30, 1988), and has been cited approvingly by courts in other jurisdictions as an example of “the majority rule in this country.” *Smalley Transp. Co. v. Bay Dray, Inc.*, 612 So. 2d 1182, 1188 & n.3 (Ala. 1992); *see also, e.g., Zoller v. Rowe Mfg. Co.*, 1978 WL 215749, at *3 (Ohio Ct. App. June 15, 1978).

Instead of acknowledging these cases, Wellstat implausibly argues that this Court’s *Chrysler* decision is less relevant than the Superior Court’s rulings in *M & G Polymers USA, LLC v. Carestream Health, Inc.*, 2009 WL 3535466, at *9 (Del. Super. Ct. Aug. 5, 2009), 2010 WL 1611042, at *38-*41 (Del. Super. Ct. Apr. 21, 2010), *aff’d sub nom. Carestream Health, Inc. v. M & G Polymers USA, LLC*, 9 A.3d 475 (Del. 2010) (TABLE). But that case did not involve the effect of a bargained-for, absolute termination right on the proper duration for lost profits damages. Unsurprisingly, the *M & G* defendant appears never to have invoked *Chrysler* or advanced the argument BTG makes, nor did the court address them either.

Equally baseless is Wellstat’s assertion that *Chrysler* only applies where the party in breach “unequivocally indicat[ed] an intent to discontinue the contractual relationship.” Appellee’s Br. at 21 n.6. That is just another question-begging invocation of Wellstat’s incorrect theory that what matters is whether BTG wanted

to terminate. The rationale for *Chrysler's* rule has nothing to do with that question, as can be seen from cases Wellstat cites.

For example, *Osborn v. Commanche Cattle Industries, Inc.*, 545 P.2d 827, 830 (Okla. Ct. App. 1975), pithily stated and applied *Chrysler's* rule despite the court's conclusion that the breaching party had *never* given "advance notice" of its intent to terminate:

[T]he only legally protectable expectation interest in the party to a contract terminable by either party upon notice is the prospect of profit over the length of the notice period. Since his assurance of performance never extends beyond the length of the notice period neither does his prospect of net gain.

Id. at 831. The court derived this principle from another case Wellstat cites, *Chevrolet Motor Co. v. McCullough Motor Co.*, 6 F.2d 212, 214 (9th Cir. 1925), which justifies the *Chrysler* rule by reasoning that a plaintiff cannot, "by reason of the defendant's breach, acquire rights greater than those which the contract gave it." That is what Wellstat has been permitted here by forcing payment of lost profits after 2020 and effectively writing BTG's termination right out of the contract.

Other cases demonstrate that *Chrysler's* lost profits limitation applies even when the parties' contractual relationship is affirmatively expected to continue. In *Dalton Properties, Inc. v. Jones*, 683 P.2d 30, 30 (Nev. 1984), a subcontractor was barred from the job site, but later allowed to *resume work* on the project. The court

still held that, during the interim, the subcontractor was not entitled to lost profits in light of the contract's termination provision because that would place him "in a better position than the terms of the contract allowed." *Id.*

It cannot be disputed that Delaware follows these principles. In fact, Wellstat's law firm has previously advanced this very view of Delaware law: "It is well established that where a party possesses a contractual termination right, the proper measure of damages is . . . the lost profits (if any) achievable during the time that the contract was assured of legal existence." Raytheon's Post-Trial Brief at § I.F.1, *Debakey Corp. v. Raytheon Serv. Co.*, 1999 WL 35024516 (Del. Ch. Oct. 15, 1999) (citing, *inter alia*, *Chrysler*, 144 A.2d at 887).

Trying to avoid the overwhelming precedent, Wellstat falls back on inapposite cases. Several did not involve a bargained-for absolute right of termination. *See M & G Polymers*, 2009 WL 3535466, at *9; *LeMond Cycling, Inc. v. PTI Holding, Inc.*, 2005 WL 102969, at *1 (D. Minn. Jan. 14, 2005); *Koufakis v. Carvel*, 425 F.2d 892, 908 (2d Cir. 1970). Another is a federal case that has *never* been cited for the proposition advanced by Wellstat. *See Ring Bros. Co. v. Martin Bros. Container & Timber Prods. Corp.*, 438 F.2d 420, 422-23 (9th Cir. 1971). Even if that case had some persuasive value, notwithstanding *Chrysler*, it stands only for the proposition that different rules may apply (at least in some jurisdictions) where the defendant misled the plaintiff into "continu[ing] to commit

its . . . resources to the project on the expectation that it would be allowed to complete performance on the contract” and failed to “alert[] the [plaintiff] to search for other . . . jobs.” *Id.* at 423. Wellstat cannot claim that here because it affirmatively concluded on its own that BTG was not complying with the contract, terminated the contract, and had years to arrange a substitute distributor before 2020.²

Finally, Wellstat has failed to demonstrate that BTG’s termination right should be eliminated because of some “good faith” condition. The primary case cited, *Charlotte Broad., LLC v. Davis Broad. Of Atlanta, LLC*, 2015 WL 3863245, at *7 (Del. Super. Ct. June 10, 2015), did not involve an absolute termination right, but a contract permitting termination only for one specific reason; and there were factual issues as to whether plaintiffs terminated for that or a separate impermissible reason. *Id.* at *8. BTG’s termination right was subject to no such limitation.³

² Wellstat’s contracts treatise cited does not support its position. *See* Appellee’s Br. at 16 (citing *Corbin on Contracts* § 68.9 (rev. ed. 2003)). That section does not address the recoverability of lost profits past a date on which termination becomes contractually possible. On that question, the weight of authority firmly rejects the view that a defendant’s “total breach of contract” eliminates the breaching party’s contractual “right to terminate.” *Chevrolet*, 6 F.2d at 213.

³ The reference to “equity and good conscience” in *J.E. Rhoads*, 1988 WL 32012, at *10, if not *dictum*, does not support Wellstat. The court found it sufficient that
Footnote continues....

C. A remand is necessary.

Wellstat makes a last-ditch effort to excuse this legal error by arguing (for the first time) that a ten-year term is needed to “adequately compensate Wellstat for [its] continued loss.” Appellee’s Br. at 25. The problem, apart from its inconsistency with *Chrysler* and other authorities discussed above, is that this argument lacks record support. Wellstat’s only effort to quantify its loss was through the contrary-to-law assumption that the contract would continue past 2020. At trial, Wellstat’s expert was candid about assuming a ten-year period. *See* A1587 (Gerardi 1310:19-1311:1). Without the improper assumption, there is no foundation for the damages awarded.

there was “no indication that either party was mistaken or uninformed as to the meaning of the [termination provision’s] language.” *Id.* The same is true here.

II. THE FLAWS IN THE PATEL SURVEY, UPON WHICH THE COURT OF CHANCERY FOUNDED ITS INCLUSION OF PATIENTS SUFFERING FROM OFF-LABEL “MODERATE” TOXICITY, CANNOT BE EXPLAINED AWAY AS A MERE “AMBIGUITY.”

Wellstat discounts as mere “ambiguity” the errors in the survey of its expert, Neel Patel, and ignores the after-the-fact revision of Patel’s report designed to conceal them. Appellee’s Br. at 28. Wellstat’s rosy description of Patel’s blatant mistakes understates their impact on Wellstat’s damages. It also conflicts with the trial court’s holding that BTG could not be deemed responsible for promoting Vistogard off-label, Op. at 49, which is likely why Wellstat repudiates that holding on appeal. As the trial court appropriately excluded off-label patients suffering from “mild” toxicities, it should have done the same with off-label patients suffering from “moderate” toxicities. Instead, it attempted a back-end fix for Patel’s survey by supposing that physician-respondents would have read the word “moderate” to mean “severe,” based on incorrect terminology used sporadically in other parts of the survey. This was an abuse of discretion.

A. The critical flaw in Patel’s survey was more than an “ambiguity.”

Wellstat does not dispute that the central survey question, Question 50, used the descriptive terms “mild,” “moderate,” and “sever[e]” to describe toxicity levels (A283), and that these terms are consistent with the FDA-approved label’s similarly descriptive indication as being for early onset or “severe or life-

threatening toxicities” from 5-FU overexposure (A250). Matching the terms in Question 50 with the FDA-approved label would indisputably require excluding “moderate” patients from Wellstat’s model.

Yet Wellstat asserts that this is “[a]t most” an “ambiguity” in Patel’s survey that merely requires “interpretation” of the results. Appellee’s Br. at 29. By “interpretation,” Wellstat means “manipulation,” using numerical grading that was not included in the key question and also was wrong. *See* Appellant’s Br. at 22-24. Wellstat is incorrect that Patel’s prior questions referenced grades “each time” (Appellee’s Br. at 10); although Patel used grading in certain questions, such as Question 25, he did not in other critical questions, including the first question that distinguished levels of symptoms (Question 23), the primary question (Question 50), Question 50’s lead-in question (Question 49), and Question 50’s follow-up questions (Questions 50a, 51). A274, A283-84.

Where Patel did reference grades, he got them wrong. Wellstat argues that there is a lack of “consensus” over toxicity grading, but the trial court acknowledged that Patel’s grading system was inconsistent with the “widely used industry standard” terminology. Op. at 46-47. Patel’s own report described the correct National Cancer Institute grading scale, though his survey did not. A649, A435. Wellstat—and the FDA—also recognized the difference between

“moderate” and “severe” toxicity when Wellstat sought but was denied FDA approval for “moderate” toxicity. A1268 (Bamat 912:5-21).

This is just the type of “uncertain, contingent, conjectural, [and] speculative” guesswork that cannot support lost-profits damages. *Siga Techs., Inc. v. PharmAthene, Inc.*, 132 A.3d 1108, 1131 (Del. 2015). It is no answer to suppose that the survey’s errors might have helped BTG, using BTG’s slightly higher internal patient estimates. Op. at 48. That does not excuse Wellstat’s failure to support its damages calculations with credible expert testimony.⁴ *E.g., PJ King Enters., LLC v. Ruello*, 2008 WL 4120040, at *3 (Del. Super. Ct. July 1, 2008) (“Delaware law consistently holds that economic and financial damages require expert testimony.”).

Wellstat ignores its deliberate attempts to alter Patel’s survey results by offering an “amended” report, which removed the original severity descriptions and replaced them with numeric gradations. *See* Appellant’s Br. at 25-27; *compare also* A416 (defining “Moderate” as “Grade 2-3”), *with* A629 (removing “Moderate” and changing “Grade 2-3” to only “Grade 3” in the amended report). Put simply, Wellstat submitted an initial expert report that sought to include all “mild,” “moderate,” and “severe” patients in Vistogard’s patient population. When

⁴ Contrary to Wellstat’s assertion, BTG did not “ignore[]” this issue in its opening brief. Appellee Br. at 29; *see* Appellant’s Br. at 24-25.

BTG's expert identified the error in Wellstat's report, rather than explain it, Wellstat sought to *change it*. The "amended" report demonstrates that the irregularities were not mere "ambiguities" that required "interpretation," but errors so important that Wellstat tried to alter them. The fact remains that the Court held that BTG was not responsible for off-label sales, Op. at 49, Wellstat has not challenged that holding by way of a cross-appeal, and "moderate" patients are off label. They should have been excluded.

B. Wellstat is wrong to assert that there is "nothing wrong with" off-label sales being included in its projected Vistogard patient population.

Wellstat cannot justify including off-label moderate patients by insisting, that "[e]ven if" some off-label sales were included, "there is nothing wrong with that." Appellee's Br. at 31. For one thing, Wellstat's argument is irreconcilable with the trial court's decision, which Wellstat did not cross-appeal. The court excluded patients suffering from mild toxicities exactly because such sales are off-label, out of recognition that "pharmaceutical companies generally do not include off-label prescriptions in their sales forecasts." Op. at 49.

For another, Wellstat's own witnesses explained the basis for this conclusion: off-label promotion is illegal. *See, e.g.*, Appellant's Br. at 21-22. Moderate toxicities were off-label, as Wellstat knows, since it sought but did not

receive FDA approval for treatment of moderate toxicities. A1268 (Bamat 912:12-21).

Wellstat relies on *Amarin Pharma., Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 200 (S.D.N.Y. 2015), to note that off-label sales “are inevitable in the drug industry, especially in the oncology field.” Appellee’s Br. at 31. Even if this is so (there is no record support for this statement), as the trial court observed, it is no reason to require pharmaceutical companies to include off-label uses when projecting future sales, and *Amarin* does not suggest otherwise. Because the federal prohibition on off-label promotion tracks the company’s “intended use” of the drug, *Amarin*, 119 F. Supp. 3d at 203, Wellstat’s suggestion regarding off-label sales effectively demands that companies run the risk of significant civil and criminal liability. There is no legal support for this.

The trial court should have applied the same logic to off-label moderate patients as it did to off-label mild patients by excluding them from Wellstat’s damages.

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

A. Wellstat has long understood that BTG's argument was not a mere "mitigation" defense.

There is no merit to Wellstat's forfeiture accusations concerning Wellstat's failure to account for its future sales of Vistogard. BTG's argument was not, as Wellstat claims, a classic "mitigation defense." Appellee's Br. at 33-34. In challenging Wellstat's damages as violating the ban on speculative damages, BTG asserted that Wellstat's expert erred by using "*BTG's* projected sales, rather than *Wellstat's* projected sales on return of the product." BOB at 68 (A1710). Later, BTG asserted that "Wellstat's damages calculations ignore ... [its] mitigation obligations," *id.* at 72 (A1714), explaining that Wellstat's damages expert "did not take into account Wellstat's sales, should Vistogard® be returned ... despite [Wellstat principal] David Wohlstadter's testimony that Wellstat would employ more resources and obtain more sales." *Id.* This failure, BTG argued, was "a basic and fundamental failure of proof." *Id.* at 73 (A1715). BTG's post-trial reply advanced similar arguments. *E.g.*, BRB at 30-31 (A1823-A1824).

BTG's argument has always been that Wellstat's damages projections have failed to account for the relief requested—Vistogard's return to Wellstat—which will, no doubt, trigger Wellstat's duty to mitigate its future losses by doing that which it has asserted that it will, *i.e.*, selling Vistogard. This is not the classic

mitigation defense about what efforts Wellstat could have taken between breach and judgment (but did not) to avoid losses.

Wellstat's superficial argument and fixation on the word "mitigation" below is designed to mask Wellstat's failure to account for the relief that it requested. BTG's argument about this fundamental failure of proof is clear on the record and preserved for review.

B. Wellstat's damages model failed to account for the relief requested.

Though Wellstat repeatedly demanded that Vistogard's distribution rights be returned in this litigation, *see* Appellant's Br. at 28, Wellstat's damages expert did not account for what Wellstat would do with Vistogard once returned, despite Wellstat's stated intention to sell more Vistogard than BTG.

VICI Racing, LLC v. T-Mobile USA, Inc., 763 F.3d 275, 294 (3d Cir. 2014), cited by Wellstat, is indeed relevant, but not for the reasons Wellstat says. Most instructive is the court's explanation of the proper measure of expectation damages, including the requirement that the plaintiff "lay a basis for a reasonable estimate of the extent of his harm, measured in money." *Id.* (internal quotation marks and citation omitted). Wellstat failed to adhere to this requirement because it failed to model its damages on its requested relief. True, Wellstat's model calculated the amount of royalties it would have earned had BTG not breached the contract, but, as Wellstat admits, that is just half of the equation to prove the harm

caused by the breach. What it deducted was not what it requested in this case—return of the product—but rather “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). Not only are the two concepts—return of the product to Wellstat and BTG’s continued sale of it—diametrically opposed, but Wellstat’s damages model contemplates that it will receive only some portion of BTG’s future sales—between 20%-40% (A138-A139)—rather than all of the revenue now that it has full distribution rights.

It is a fundamental principle that “[t]he first step in a damages study is the translation of the legal theory of the harmful event into an analysis of the economic impact of that event.” Federal Judicial Center, Reference Manual on Scientific Evidence 432 (3d ed. 2011); *cf. Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013) (noting the “unremarkable premise” that “a model purporting to serve as evidence of damages . . . must measure only those damages attributable” to the theory of relief pursued on liability). Here, the economic impact of the material breach was the termination of the Agreement and the return of the distribution rights. Wellstat never presented what its damages would be under that scenario.

It is irrelevant that BTG retained the distribution rights through the litigation, since Wellstat has long known that if it prevailed, it would get the product back. Despite Wellstat’s claims to the contrary (Appellee’s Br. at 34

n.10), David Wohlstadter testified that Wellstat intends to sell Vistogard with enhanced efforts that left him hopeful that Wellstat will achieve far greater profits than those projected by BTG. A1539 (Wohlstadter 1183:3-19). Wellstat will not only double recover if allowed both the ten years' worth of royalties and also the ability to sell Vistogard now and in the future, but it is just as conceivable (based on Wohlstadter's projections) that Wellstat may suffer *no* net injury given the return of the distribution rights.⁵ The answer is unknown, and that is the point BTG has made since trial. By offering a damages model inconsistent with reality, Wellstat failed to prove its damages. The trial court acted outside of its discretion in awarding Wellstat damages that failed to account for the relief Wellstat received.

⁵ Even if, as Wellstat claims, its expert—who specifically testified that he was not asked to, and did not, look at what would happen if Wellstat retained the distribution rights—testified that BTG's forecasts are the “most reliable estimates of long term sales potential of Vistogard” (A1580, A1585 [Gerardi 1282:8-1283:9, 1302:15-21]), Wellstat's expert deducted only the royalty owed under the Agreement (topping out at 40%), and not the full amount of the “long term sales potential of Vistogard.” *Id.*; A545 (Gerardi's expert report); A138-A139 (contractual royalty provision).

IV. THE COURT'S INTEREST RATE WAS PURPORTEDLY A CONTRACT RATE, BUT HAD NO BASIS IN THE AGREEMENT.

Finally, Wellstat asserts that the trial court set the rate of interest in its discretion (when the court said it was applying a contract rate), portrays the Late Payments provision as something other than what it is, and raises yet another preservation argument regarding when interest began to accrue that is contrary to its own prior positions. None of these attempts to save the court's erroneous interest award succeeds.

A. The trial court said it was applying a contractual interest rate, not that it had discretionarily chosen a punitive 12% interest rate that compounded monthly.

Wellstat says that the trial court “expressly invoked” its discretion in “select[ing] an interest rate different from the legal rate.” Appellee’s Br. at 39. That is *not* what the court said. Rather, the court wrote: “Unless the parties have specified another rate by contract or the court determines that a different rate is warranted by the equities, the statutory rate of interest governs.” Op. at 57-58 (citing, *inter alia*, 6 Del. C. § 2301(a)). It then incorrectly applied the rate from Section 4.8 of the Agreement. Nothing in the court’s opinion suggests this rate was chosen for equitable reasons.

But Section 4.8 has nothing to do with damages for material breach. It contemplates a missed payment by BTG while performing under the Agreement. A144 (§ 4.8).

Wellstat runs from this common-sense understanding of Section 4.8's purpose, claiming that the provision means other than what it says. Appellee's Br. at 41. Delaware, however, "adheres to the objective theory of contracts, *i.e.*, a contract's construction should be that which would be understood by an objective, reasonable third party ... construing the agreement as a whole." *Salamone v. Gorman*, 106 A.3d 354, 367-68 (Del. 2014) (citation omitted). A reasonable third party would not pick Section 4.8 apart, as Wellstat attempts to do, but would read it as intending to address "payment dispute[s]" regarding "payments ... due under this Agreement," and how Wellstat could go about "collect[ing]" them in the event BTG missed such a payment. A144 (§ 4.8).

It makes sense both that the parties would contract for a significantly escalated interest rate to ensure timely payments of royalties and that they would contract for a rate of interest in the event of a JDCC dispute. A176 (§ 14.5(b)). But having established specific interest rates for those circumstances, it makes no sense that the parties would intend a court someday to impose the Late Payments rate in a dispute over termination for material, non-payment breach—particularly when the parties addressed termination in a different Article of the Agreement (Article XII), which is silent about interest. A168-A172. None of the authorities

on which the trial court relied in misapplying the Late Payments provision are to the contrary—a point Wellstat does not dispute in its brief.⁶

This case had nothing to do with untimely “payments ... due under this Agreement.” A144 (§ 4.8). The trial court’s decision to deviate from the applicable legal rate based on an inapposite Late Payments provision was without support and punitive. That award should be reversed.

B. Having requested the interest start date BTG asks for, Wellstat cannot claim BTG’s request is waived. Wellstat does not dispute BTG’s request on the merits.

Wellstat does not dispute that the trial court improperly awarded Wellstat six months’ worth of interest Wellstat did not ask for, and which had no record support. Rather, Wellstat rolls out yet another waiver argument, claiming that BTG addressed Wellstat’s interest request for the first time in its post-trial reply brief, “and said nothing at oral argument” about it. Appellee’s Br. at 42. This argument is specious.

There was *never* any dispute as to whether interest should start to run before March 2, 2016. Wellstat’s own expert used March 2, 2016 as the date Wellstat began suffering monetary harm. A597 & A598 n.1.

⁶ See *Miller v. Silverside*, 2016 WL 4502012 (Del. Super. Ct. Aug. 26, 2016); *Bridev One, LLC v. Regency Ctrs., L.P.*, 2017 WL 3189230 (Del. Super. Ct. Jul. 20, 2017); *Millcreek Shopping Ctr. LLC v. Jenner Enters., Inc.*, 2017 WL 1282068 (Del. Super. Ct. Mar. 31, 2017).

Even more surprising is Wellstat’s argument that BTG “said nothing at oral argument.” Appellee’s Br. at 42. Wellstat’s counsel specifically requested *at that argument* that interest accrue starting “when the product was launched”—March 2, 2016—and “damages began to run.” A1924 (Post-Trial Argument 96:9-17); *see also* A1787.⁷ Because Wellstat *asked* for the same date BTG now requests, there was nothing to be “said” in response.

Wellstat’s position then was correct. On appeal, however, Wellstat attempts revisionist history, incorrectly claiming that the trial court “adopted Wellstat’s legal position that interest runs from the ‘date of breach.’” Appellee’s Br. at 42-43. At no point at trial did Wellstat claim to have suffered any damages from the trial court’s date—September 15, 2015, *i.e.*, when BTG submitted the Initial Commercialization Plan—instead asserting that it began to suffer harm when BTG began selling Vistogard with less than Diligent Efforts. This was, as Wellstat conceded, when “damages began to run,” A1924 (Tr. 96:9-17), and when the trial court should have started interest. *See* Appellant’s Br. at 37. Wellstat knows that

⁷ As BTG noted in its opening brief, Wellstat’s counsel referred to March 16, 2016, as the start date; however, Wellstat’s briefing treated March 2, 2016, as the correct date. *Compare* A1924 (Tr. 96:9-10), *with* A1787. Wellstat does not answer this point, and has not challenged BTG’s belief (Appellant’s Br. at 36 n. 12) that counsel made an inadvertent misstatement.

the trial court's early start date has no legal basis, and its effort to profit from that clear error should be summarily rejected.

CONCLUSION

BTG thus respectfully requests that this Court reverse the award of damages and interest to Wellstat and find that Wellstat failed to provide adequate proof of its damages or, alternatively, reverse and remand for further calculation of damages and interest, including recalculation of pre- and post-judgment interest at the legal rate, and commencing March 2, 2016.

OF COUNSEL:

Richard L. Scheff

Lathrop B. Nelson, III

Montgomery McCracken

Walker & Rhoads, LLP

123 South Broad Street, 28th Floor

Philadelphia, PA 19109

(215) 772-1500

Dated: March 2, 2018

MONTGOMERY McCracken
WALKER & RHOADS, LLP

/s/ Lisa Zwally Brown

Lisa Zwally Brown (No. 4328)

1105 North Market Street

Suite 1500

Wilmington, DE 19801

(302) 504-7800

Attorneys for BTG International Inc.
Plaintiff Below-Appellant