

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

BTG INTERNATIONAL, INC., )  
 )  
Plaintiff/Counterclaim Defendant, )  
 )  
v. ) C.A. No. 12562-VCL  
 )  
WELLSTAT THERAPEUTICS )  
CORPORATION, )  
 )  
Defendant/Counterclaim Plaintiff. )

**MEMORANDUM OPINION**

Date Submitted: June 26, 2017  
Date Decided: September 19, 2017

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**LASTER, Vice Chancellor.**

Pursuant to an Exclusive Distribution Agreement dated July 1, 2011 (the “Distribution Agreement”), BTG International, Inc. (“BTG”) agreed to promote, distribute, and sell Vistogard,<sup>1</sup> a drug owned by Wellstat Therapeutics Corporation (“Wellstat”). At trial, Wellstat proved that BTG breached the Distribution Agreement, and BTG did not prove a prior breach by Wellstat that would have excused BTG’s breach. Wellstat is entitled to damages of \$55.8 million, pre- and post-judgment interest at the rate specified in the Distribution Agreement, costs, and a limited award of attorneys’ fees.

## **I. FACTUAL BACKGROUND**

Trial lasted five days. The parties introduced over 1,300 exhibits and lodged twenty-nine depositions. Nine fact witnesses and seven experts testified live. The two sides presented starkly different stories, and it was not possible to reconcile all of the witness testimony and documentary evidence. This decision has relied most heavily on the contemporaneous documents. Having weighed the evidence and evaluated the credibility of the witnesses, this decision finds that the following facts were proven by a preponderance of the evidence.

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<sup>1</sup> The parties used several different names for the drug before its commercial launch. For simplicity, this decision consistently refers to the drug as “Vistogard.”

## **A. Vistogard**

Vistogard is an orally administered antidote for 5-fluorouracil (“5-FU”), a commonly used chemotherapy drug. 5-FU toxicity can be severe, even fatal. Vistogard was the first commercially available drug to address 5-FU toxicity.

Wellstat developed Vistogard, but Wellstat lacked a sales team. Wellstat needed a partner to launch Vistogard commercially and to market and distribute the drug.

In fall 2009, Wellstat began discussions with BTG. On paper, the fit seemed strong. BTG’s corporate objective at the time was to “become a significant player in the field of specialty pharmaceuticals,”<sup>2</sup> a category that includes Vistogard. BTG had a dedicated specialty pharmaceuticals business unit (the “Pharmaceuticals Division”), which already marketed antidotes. BTG’s portfolio included Voraxaze, a drug that treats toxicity from another chemotherapy agent.

BTG was eager to secure the rights to Vistogard. BTG’s CEO, Louise Makin, called Vistogard “a great opportunity” for BTG and wanted to add the drug to BTG’s portfolio.<sup>3</sup>

## **B. The Distribution Agreement**

After several years of negotiations, Wellstat and BTG entered into the Distribution Agreement.<sup>4</sup> Wellstat granted BTG “the exclusive right and license . . . to promote,

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<sup>2</sup> JX 100 at 1.

<sup>3</sup> JX 126.

<sup>4</sup> JX 152.

distribute and sell” Vistogard for ten years following FDA approval.<sup>5</sup> BTG paid Wellstat a distribution rights fee of \$7.5 million and agreed to pay two milestone payments of \$1 million.<sup>6</sup> BTG also agreed to pay royalties on the sales of Vistogard at rates ranging from 20-40% of the revenue attributable to the drug.<sup>7</sup>

The Distribution Agreement divided responsibility for commercializing Vistogard between Wellstat and BTG. Wellstat was required to “use Diligent Efforts, at Wellstat’s sole cost and expense, to develop [Vistogard] in order to obtain, and subsequently maintain, FDA Approval for [Vistogard] . . . , including to conduct pre- and post-FDA Approval studies necessary to obtain and maintain FDA Approval.”<sup>8</sup> BTG was required to “use its Diligent Efforts to and be responsible for, at BTG’s sole cost and expense, all promotion, distribution and sales activities with respect to [Vistogard] . . . .”<sup>9</sup> The Distribution Agreement defined “Diligent Efforts” as follows:

Diligent Efforts means, with respect to a Party, the carrying out of obligations specified in this Agreement in a diligent, expeditious and sustained manner using efforts and resources, including reasonably necessary personnel and financial resources, that specialty pharmaceutical companies typically devote to their own internally discovered compounds or products of most closely comparable market potential at a most closely comparable stage in their development or product life, taking into account the following factors to the

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<sup>5</sup> *Id.* § 3.1(a).

<sup>6</sup> *Id.* §§ 4.1, 4.2.

<sup>7</sup> *Id.* § 4.3.

<sup>8</sup> *Id.* § 6.3(a).

<sup>9</sup> *Id.* § 8.1.

extent reasonable and relevant: issues of safety and efficacy, product profile, competitiveness of alternative products in the marketplace, the patent or other proprietary position of the Subject Product, and the potential profitability of the Subject Product. Diligent Efforts shall be determined without regard to any payments owed by a Party to the other Party (excluding the transfer price for supply of such Subject Product).<sup>10</sup>

As part of its responsibilities under the Distribution Agreement, BTG was required to “prepare in good faith the initial commercial plan and budget” for Vistogard (the “Commercial Plan”).<sup>11</sup> The Commercial Plan had to “include minimum commitments of resources, personnel and financing for pre-launch and launch activities with respect to, and subsequent promotion and distribution of” Vistogard.<sup>12</sup> The Commercial Plan was “subject to good faith discussions between the Parties” and was to be “mutually agreed upon by the parties . . . .”<sup>13</sup> Once the parties reached agreement, BTG was required to “promote and distribute [Vistogard] . . . in material compliance with such Commercial Plan.”<sup>14</sup>

The Distribution Agreement further called for the establishment of a joint development and commercialization committee (the “Committee”) to “manage and oversee the development and commercialization” of Vistogard.<sup>15</sup> The Committee consisted

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<sup>10</sup> *Id.* § 2.11.

<sup>11</sup> *Id.* § 8.1.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* § 5.1(a).

of four Wellstat representatives and four BTG representatives. The Committee's responsibilities included to

review and recommend amendments to the Commercial Plan, provided that no amendment to the Commercial Plan shall materially reduce the level of efforts required under the initial Commercial Plan agreed by the parties pursuant to Section 8.1 unless reasonably justified by changes in [Vistogard's] product lifecycle stage or changes in the market . . . .<sup>16</sup>

### **C. BTG's New Strategic Plan**

When BTG signed the Distribution Agreement, it had high hopes for Vistogard. Makin touted Vistogard as "an excellent fit" with BTG's existing business that would "enable [BTG] to leverage the sales team and back office support infrastructure which [it] already [had] in place."<sup>17</sup> BTG executives prepared an investor Q&A announcing that Vistogard "could generate up to \$60 m[illion] peak sales per annum."<sup>18</sup>

But after BTG executed the Distribution Agreement, Makin shifted BTG's corporate strategy away from specialty pharmaceuticals and towards interventional medicine.<sup>19</sup> In 2013, BTG adopted a new strategic plan called the "BTG – 2020/2021 Vision." It called for BTG to become "a leader in interventional medicine in oncology and

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<sup>16</sup> *Id.*

<sup>17</sup> JX 155.

<sup>18</sup> JX 153.

<sup>19</sup> "Interventional medicine is the use of minimally invasive image guided techniques to diagnose and treat diseases." JX 295 at 12.

vascular . . . .”<sup>20</sup> Between 2011 and 2014, BTG built a portfolio of interventional medicine products, primarily through acquisitions.<sup>21</sup> BTG’s revenue from interventional medicine grew astronomically, increasing from £5.6 million in 2011 to £79.1 million in 2014.<sup>22</sup> BTG expected that its revenue from interventional medicine would continue to increase, reaching £642.6 million by 2021 and comprising 75% of BTG’s total revenue.<sup>23</sup>

BTG’s strategic shift towards interventional medicine came at the expense of the Pharmaceuticals Division. Specialty pharmaceuticals could not generate the same rate of growth as interventional medicine, and BTG chose to allocate capital to the areas that promised the fastest growth. Between 2011 and 2014, BTG made no acquisitions in the specialty pharmaceuticals space.<sup>24</sup> The new role of the Pharmaceuticals Division was to generate cash to fund BTG’s investments in higher-growth areas.<sup>25</sup>

Makin emphasized the implications of BTG’s new strategic plan in her communications with BTG’s senior management team. In February 2015, Makin emailed the heads of BTG’s business units with guidance on preparing their annual budgets for the

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<sup>20</sup> *Id.* at 6.

<sup>21</sup> *Id.* at 3-6; *see also* Tr. (Higham) 661:9-14.

<sup>22</sup> JX 295 at 14.

<sup>23</sup> *Id.* at 7.

<sup>24</sup> Tr. (Makin) 943:8-12.

<sup>25</sup> *See, e.g.*, JX 543 at 4 (describing Pharmaceuticals Division’s goal as “[o]ptimising cash . . . and investing proceeds in high-growth areas of Interventional Medicine.”).

coming fiscal year. Makin explained that, although BTG previously had maintained “a nurturing/experimental mindset where we have been able to invest in most of the opportunities we thought worthwhile,” the company now had “a portfolio” of opportunities and therefore had “choices to make about where we invest.”<sup>26</sup> In her email, Makin ranked BTG’s five business units in order of priority for further investment. At the top was interventional vascular medicine, which was “the highest priority for investment.”<sup>27</sup> Last was the Pharmaceuticals Division, which “[n]eed[ed] to continue to execute smarter and smarter.”<sup>28</sup> Makin wrote that the “[c]hallenge is to run at constant cost base whilst keeping people motivated and deliver sustained mid to high single digit revenue growth. Ensure [Vistogard] launch is in line with our risk appetite and delivered cost neutrally. Low priority for additional investment.”<sup>29</sup>

At trial, Makin and other senior BTG representatives claimed that Makin’s challenge was not a directive, but rather an aspirational goal that the Pharmaceuticals Division could push back on and did not have to follow.<sup>30</sup> That testimony was not credible.

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<sup>26</sup> JX 361 at 1.

<sup>27</sup> *Id.* at 2.

<sup>28</sup> *Id.* at 3.

<sup>29</sup> *Id.*

<sup>30</sup> *See, e.g.*, Tr. (Lewis) 309:3-311:16; Tr. (Makin) 958:8-959:23.



In reality, the Pharmaceuticals Division heard Makin's message loud and clear. Its leadership promptly reduced the budget for the commercial group by \$825,000.<sup>31</sup>

**D. The Sales Force For Vistogard**

In early 2015, Wellstat began a rolling submission of a New Drug Application for Vistogard to the FDA. The submission started the countdown to the commercial launch.

Internally, BTG began considering the sales force it would need. At the time, the Pharmaceuticals Division had nineteen full-time sales representatives. All of them sold both oncology products and snake venom antidotes. Facing Makin's directive to run at constant cost, the Pharmaceuticals Division considered whether the same number of employees could market the oncology products better if the sales force split into two teams, one dedicated to oncology products and the other dedicated to snake venom antidotes. TGaS Advisors ("TGaS"), a consulting firm that the Pharmaceuticals Division had retained, recommended against splitting the existing team. TGaS advised that the "creation of a new sales force should only [be] considered with a significant . . . expansion" in the number of full-time sales representatives.<sup>32</sup> TGaS also told the Pharmaceuticals Division that BTG needed "to 'invest' to generate revenues and prepare for [Vistogard's] launch."<sup>33</sup>

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<sup>31</sup> JX 368.

<sup>32</sup> JX 353 at 7.

<sup>33</sup> JX 382.

In other words, BTG needed to add more sales representatives. TGaS recommended a substantial increase: “[A]t a minimum, you need to double your sales organization . . . .”<sup>34</sup>

Makin’s directive about the role of the Pharmaceuticals Division and the need for it to be “cost neutral” and run at a “constant cost base” meant that the TGaS recommendations were nonstarters. In March 2015, the constraints on the Pharmaceuticals Division tightened further when Anthony Higham took over. He was a Makin disciple who sought to impress his boss by exceeding her cost-control mandate. He immediately initiated “Project DJ,” which called for across-the-board cost reductions of 5%.<sup>35</sup> Higham told his staff: “I request all established products are prioritized ahead of [Vistogard], we cannot afford to be distracted from achieving the budget through ongoing [Vistogard] dialogue and activity.”<sup>36</sup>

In April 2015, BTG engaged a new consultant, ZS Associates, for advice on its sales team. BTG did not permit ZS Associates to do an independent assessment. Instead, BTG instructed ZS Associates to assume as an “immutable factor” for its analysis that the entire Pharmaceuticals Division sales force would remain fixed at nineteen.<sup>37</sup> Even with this

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

<sup>35</sup> Tr. (Higham) 634:1-635:12. DJ stood for “donkey jacket,” an English term that refers to “a type of coverall that you would wear if you’re cleaning up outside.” *Id.* This suggests Higham believed his job was to “clean up” excessive spending in the Pharmaceuticals Division.

<sup>36</sup> JX 424.

<sup>37</sup> A draft of BTG’s request for proposal set the “immutable factor” at seventeen. JX 387 (Carolyn Lewis, General Manager of the Pharmaceuticals Division, advising her team that the request for proposal “should call out that we want to increase [Vistogard] and

direct instruction, ZS Associates signaled that the Pharmaceuticals Division needed to hire more full-time sales representatives to launch Vistogard successfully. ZS Associates wrote, “If sales force is expected . . . to achieve the [Vistogard] forecast of \$9.5M net sales in FY 2017, we estimate that BTG will need **19-20 Oncology focused [full-time equivalents]**.”<sup>38</sup> Because the Pharmaceuticals Division had only nineteen sales representatives devoted to all of its products, the ZS Associates report necessarily contemplated more staff. Moreover, ZS Associates explained that adding more sales representatives would be highly profitable for BTG. According to ZS Associates, “[u]p to 22 Oncology [full-time equivalents] would still provide a marginal [return on investment] over 100% for Voraxaze and [Vistogard].”<sup>39</sup> ZS Associates noted that the estimated returns were “higher than [the] industry average.”<sup>40</sup>

But Higham was not interested in expanding the sales team. He was focused on cutting costs through Project DJ.

Constrained by Makin’s directives and Higham’s impassioned implementation of her strategy, the Pharmaceuticals Division went against the recommendations from TGAs and ZS Associates. In July 2015, BTG split the Pharmaceuticals Division sales force into

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Voraxaze sales without expanding the footprint in any way and the same applied to rolling in [Vistogard]”). The final request for proposal increased the cap to nineteen. JX 388; *see also* Tr. (Lewis) 335:19-337:1 (clarifying the change).

<sup>38</sup> JX 462 at 6.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

two teams, creating an oncology sales force with just seven representatives.<sup>41</sup> BTG planned for these representatives to split their time equally between Vistogard and Voraxaze.

#### **E. The Commercial Plan For Vistogard**

Under the Distribution Agreement, BTG was obligated to prepare the Commercial Plan so it could be implemented once the FDA approved Vistogard for launch. On July 10, 2015, Wellstat formally completed the filing of its New Drug Application with the FDA. BTG understood that the FDA could approve the application as soon as January 2016, which meant that BTG needed to be ready to launch Vistogard as early as April 2, 2016.<sup>42</sup>

Despite its obligation to prepare the Commercial Plan, BTG did nothing. Not until September 10, 2015, after Wellstat asked BTG to present the Commercial Plan at the next Committee meeting, did BTG spring into action.<sup>43</sup> BTG employees hastily assembled a PowerPoint presentation, which they dubbed the “Initial Commercialization Plan.”

On September 17, 2015, BTG presented the plan to the Committee. It was woefully inadequate. The bulk of the sixty-one slides consisted of generic information about how BTG would market Vistogard.<sup>44</sup> Only the last three slides addressed BTG’s obligation

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<sup>41</sup> JX 465 at 5.

<sup>42</sup> JX 478 at 4.

<sup>43</sup> JX 514. It appears that BTG forgot about its obligation to create the Commercial Plan. *See* JX 519 (BTG employee forwarding Higham relevant language of the Distribution Agreement).

<sup>44</sup> JX 523; *see also* Tr. (Schneider) 33:9-34:3 (acknowledging slides “look[] simple and . . . obvious”).

under the Distribution Agreement to provide “minimum commitments of resources, personnel and financing for pre-launch and launch activities.”<sup>45</sup> The content of these slides shows that BTG’s hastily constructed presentation did not offer a viable marketing strategy and did not meet the requirements for a Commercial Plan.

To address its obligation to provide a minimum commitment of resources, BTG claimed it would spend \$4.7 million on Vistogard in the coming year.<sup>46</sup> BTG represented that \$2.1 million of that total would be spent on advertising and promotion. BTG allocated the money among eight high-level categories, such as “market research,” “print and production,” and “industry events and seminars.”<sup>47</sup> BTG did not allocate the money based on any study of Vistogard’s specific marketing needs. Rather, BTG took the percentage allocated to each category in the Pharmaceuticals Division’s budget from the prior year, multiplied that percentage by \$2.1 million, and used the resulting figure for each category.<sup>48</sup>

To address its obligation to provide a minimum commitment of personnel, BTG represented that it would use its existing oncology sales force of seven representatives for pre-launch activities. BTG did not say definitively how many representatives it would use for launch. BTG suggested it could assign up to forty representatives from its Interventional

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<sup>45</sup> JX 152 § 8.1.

<sup>46</sup> JX 523 at 61.

<sup>47</sup> *Id.* at 60.

<sup>48</sup> JX 942 at 5-6; Tr. (Lewis) 373:2-375:15.

Oncology business unit,<sup>49</sup> but BTG had rejected that idea internally two months earlier.<sup>50</sup> In reality, BTG did not have a plan for its sales force or for a commercial launch. The most candid aspect of the presentation admitted that BTG’s plans were still “[u]nder development.”<sup>51</sup>

The Wellstat representatives were unimpressed. They began to suspect that BTG was not making the commitment required by the Distribution Agreement. Wellstat told BTG that it wanted “a more detailed commercialization plan . . . .”<sup>52</sup> The next month, Wellstat hired a consultant to assess whether BTG’s efforts were adequate.<sup>53</sup>

**F. The Pharmaceuticals Division Pleads For Resources.**

In October 2015, the Pharmaceuticals Division again engaged ZS Associates, this time to develop a plan for Vistogard’s post-launch sales force. BTG again imposed constraints on the analysis.<sup>54</sup> BTG told ZS Associates to build a model that would show the return on investment from placing representatives in thirty territories, splitting their

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<sup>49</sup> JX 523 at 61.

<sup>50</sup> *See* JX 472 at 5.

<sup>51</sup> JX 527 at 3; *see also* Tr. (Bamat) 907:5-16 (“[BTG] told us, ‘The seven sales reps is just a start. Don’t worry, there’s going to be more.’”).

<sup>52</sup> JX 527 at 3.

<sup>53</sup> JX 551.

<sup>54</sup> *See* Tr. (Lewis) 326:17-327:3.

time equally between Voraxaze and Vistogard.<sup>55</sup> BTG instructed ZS Associates to use a profit margin that was net of the royalty owed to Wellstat when calculating return on investment.<sup>56</sup> This instruction ran flatly contrary to the terms of the Distribution Agreement, which obligated each party to fulfill its duties “without regard to any payments owed by a Party to the other Party . . . .”<sup>57</sup>

Even with BTG’s revenues improperly depressed by the inclusion of the royalty, ZS Associates still concluded that putting one sales representative in each of the thirty territories would render all thirty territories immediately profitable.<sup>58</sup> ZS Associates further concluded that twenty-two of the territories would produce a 100% return on investment in the first year and twenty-seven would produce a 100% return on investment by the second year.<sup>59</sup>

But the Pharmaceuticals Division knew that Makin would reject any request to add twenty-three new employees to a division she had designated as a “[l]ow priority for additional investment.”<sup>60</sup> The Pharmaceuticals Division decided that the most it could ask

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<sup>55</sup> JX 828; Tr. (Lewis) 354:6-356:6.

<sup>56</sup> JX 555; Tr. (Lewis) 350:4-351:10.

<sup>57</sup> JX 152 § 2.11.

<sup>58</sup> JX 828.

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

<sup>60</sup> JX 361 at 3.

for was nine additional sales representatives, resulting in an oncology sales team of sixteen representatives. The Pharmaceuticals Division planned to place the representatives in the markets that would generate a 300% return on investment for BTG. ZS Associates had previously told BTG a 300% return was many times the average return on investment in the industry.<sup>61</sup>

On November 5, 2015, Phil Moody, the Pharmaceuticals Division's Vice President of Finance for the United States, approached Rolf Soderstrom, BTG's CFO, about expanding the oncology sales team. Moody tried to frame the request softly, stressing that the Pharmaceuticals Division "ha[d] heard you and [Makin] loud and clear that we need to drive efficiency to allow for investment."<sup>62</sup> But Moody emphasized that adding the sales representatives "will strongly bolster the launch of Vistogard and will be crucial to achieve optimal top line revenues. The return on investment here is significant."<sup>63</sup>

On November 18, 2015, the Pharmaceuticals Division presented its proposal for additional sales representatives to Makin. The presentation emphasized the need to have additional sales representatives for Vistogard at the outset: "Long term performance will be set in the first 6 months[.] *Must Get It Right . . . Early!*"<sup>64</sup> The presentation also stressed

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<sup>61</sup> See JX 462 at 6.

<sup>62</sup> JX 594 at 1.

<sup>63</sup> *Id.*

<sup>64</sup> JX 607 at 18.



that having more sales representatives in more local markets “generates incremental national lift due to robust, dynamic oncology networks.”<sup>65</sup>

Makin was skeptical and asked for more details. Higham read between the lines and received her message. The next day, November 19, 2015, he told his subordinates that he was “very disappointed” in the presentation.<sup>66</sup> He instructed his staff to prepare a new plan that would phase in the nine additional representatives over an extended period of time.<sup>67</sup> The Pharmaceuticals Division had previously considered and rejected this idea because it would provide lower returns to BTG in the long-run than hiring them immediately.<sup>68</sup>

Meanwhile, Makin’s corporate team put more pressure on the Pharmaceuticals Division to reduce costs. On November 22, 2015, Soderstrom instructed Moody that “[o]n costs other than salary costs we are pushing to keep all selling costs flat except for specific investments. Any other investment will need to be self funding.”<sup>69</sup> Moody forwarded the email to Higham and commented, “I’m working hard to keep the team together, but this is very discouraging.”<sup>70</sup>

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<sup>65</sup> *Id.*

<sup>66</sup> JX 611.

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

<sup>68</sup> JX 594.

<sup>69</sup> JX 620 at 2.

<sup>70</sup> *Id.* at 1.

On November 25, 2015, the Pharmaceuticals Division submitted a formal white paper to Higham which asked for authority to hire an inside sales force of three telephone representatives to supplement the work of the field sales representatives. The white paper noted that the current seven-member sales force left “~60% of the market opportunity and oncology centers uncovered,” and that “[e]ven if direct team expanded to 16 [people], ~30% of the market [is] still left completely uncovered.”<sup>71</sup>

On December 10, 2015, the Pharmaceuticals Division submitted a second white paper to Higham that proposed immediately hiring nine additional representatives. The white paper again emphasized the importance of additional representatives to Vistogard’s success. “Vistogard will require promotional efforts to raise disease awareness; early investment will be critical to achieve potential of product . . . . Various case studies suggest that inadequate investment at launch significantly impacts peak revenue potential of the product. Early underinvestment would likely decrease peak sales.”<sup>72</sup> The white paper noted that Vistogard and Voraxaze warranted at least twenty-two sales representatives. The Pharmaceuticals Division nonetheless “trimmed the proposal down to 16” because a higher number of representatives “would likely be dilutive to earnings in FY17.”<sup>73</sup>

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<sup>71</sup> JX 625 at 2.

<sup>72</sup> JX 645 at 2.

<sup>73</sup> *Id.*

In accordance with the instruction that Higham had given to phase in the representatives over time, the white paper included an alternative which had BTG phase in the additional sales representatives over six months. This proposal contemplated BTG immediately hiring four representatives, then hiring five more in mid-2016 if the four initial sales representatives were effective.<sup>74</sup> The evidence as a whole demonstrates that the Pharmaceuticals Division only included this alternative because Higham insisted on it. The Pharmaceuticals Division similarly only proposed sixteen sales representatives because of the directives from senior management.

**G. The Makin-Approved Plan**

On December 9, 2015, Nadine Wohlstadter, Wellstat’s CEO, asked Higham to provide the Vistogard “sales force design study indicating the number and geographic spread” as well as the “[s]ales forecast or sales projections for launch and years thereafter.”<sup>75</sup> Higham forwarded the email to Dan Schneider, BTG’s Senior Vice President for United States Commercial Operations. Schneider was concerned that Wellstat was “setting [up a] base case for breach.”<sup>76</sup> Schneider told Moody that BTG did not “need or have to give all info to her.”<sup>77</sup> This unwarranted reaction evidenced a guilty conscience.

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<sup>74</sup> *Id.* at 4.

<sup>75</sup> JX 641 at 1-2.

<sup>76</sup> *Id.* at 1.

<sup>77</sup> *Id.*

Had BTG been doing what it was contractually obligated to do, Schneider would not have jumped to the conclusion that Wellstat was preparing to sue.

On December 10, 2015, the FDA approved Vistogard for commercial launch. On December 15, Wohlstadter followed up on her December 9 request. Higham again declined to give her the information.<sup>78</sup>

Even after the white papers and Wellstat's inquiries, Higham believed that Makin would not support immediately hiring nine additional sales representatives, so his staff did not present that plan.<sup>79</sup> On December 16, 2015, the Pharmaceuticals Division presented only the proposal that called for BTG to phase in the nine additional representatives over six months. The division again emphasized that Vistogard was "promotionally sensitive," and thus "aggressive investment in Vistogard, *now* will pay dividends to achievement of peak sales potential."<sup>80</sup>

Makin approved the request and authorized the Pharmaceuticals Division to immediately hire four additional sales representatives.<sup>81</sup> This number was later increased to five representatives. These new representatives, once hired, would increase BTG's oncology sales team to a total of twelve representatives. But BTG did not actually hire any of the new representatives for another three months.

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<sup>78</sup> JX 661.

<sup>79</sup> JX 662 at 14.

<sup>80</sup> *Id.*

<sup>81</sup> *See* JX 663.

## H. The Relationship Deteriorates.

At BTG, key employees in the Pharmaceuticals Division believed that the oncology sales force was too small to provide adequate support for Vistogard’s impending launch. On January 7, 2016, Christine Coyne, a marketing executive, asked Higham and Schneider to move up the hiring schedule and bring on four additional sales representatives in February.<sup>82</sup> Schneider was sympathetic, but felt there was nothing he could do. He told Coyne, “I know this is painful at times . . . but it is the reality we currently live in.”<sup>83</sup> Shortly after sending this email, Schneider received data indicating that the existing twelve-person sales team only covered 61% of Vistogard’s market and that a sixteen-person sales team would only cover 73% of the market. Schneider candidly and correctly responded that this was “[p]ainfully low coverage.”<sup>84</sup>

Moody also understood that the oncology sales force was too small, and he continued to advocate for more support for Vistogard. In January 2016, BTG fired him. When he ran into some Wellstat executives, Moody confided that he had been fired for “pushing too hard for Vistogard internally.”<sup>85</sup> He also told them that “BTG’s focus had

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<sup>82</sup> JX 698.

<sup>83</sup> *Id.* at 1.

<sup>84</sup> JX 697.

<sup>85</sup> Tr. (Bamat) 908:13-909:7; *see also* JX 704 (Higham to Makin: “[T]he sooner we can get [Moody] out of the business the better!!”).

shifted to interventional medicine, and away from specialty pharma.”<sup>86</sup> The evidence at trial demonstrated that Moody’s assessments were accurate.

Moody’s termination caused Wellstat to become more suspicious about BTG’s efforts. Wellstat pressed BTG for its internal sales forecasts and its plan for Vistogard’s sales team. BTG continued to resist providing Wellstat with this information. Both sides began preparing for litigation.<sup>87</sup>

On February 17, 2016, the Committee met for the first time since September 2015. The meeting was contentious, and the exact nature of the discussions is disputed. In the weeks following the meeting, BTG and Wellstat exchanged differing versions of the minutes.<sup>88</sup> They ultimately could not agree on a set of minutes.<sup>89</sup> Having reviewed the evidence and considered the testimony and demeanor of the witnesses, I regard Wellstat’s account as more accurate and reliable.

Regardless, both sides agree that, during the meeting, BTG described its plan for the oncology sales team. The plan contemplated five new sales representatives by the end of March, which would bring the total number of sales representatives to twelve. BTG also said that it would consider hiring four additional sales representatives “[p]ending

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<sup>86</sup> Tr. (Bamat) 909:9-15.

<sup>87</sup> *See, e.g.*, JX 754.

<sup>88</sup> *See* JX 826; JX 869.

<sup>89</sup> JX 888.

evaluation of initial launch performance.”<sup>90</sup> Wellstat argued strongly that these staffing levels were not sufficient and asked to see the ZS Associates report analyzing staffing levels.<sup>91</sup> BTG knew that the ZS Associates report supported Wellstat’s position, so BTG refused to provide it.

During the Committee meeting, BTG also provided Wellstat with a sales forecast for Vistogard that contemplated \$9.8 million in sales during the first year and \$28 million in the third year.<sup>92</sup> Wellstat thought that these numbers were too low and demanded to see the underlying model. BTG promised to provide the information to Wellstat.<sup>93</sup>

#### **I. BTG Manipulates Its Model.**

On February 23, 2016, BTG sent Wellstat a presentation which purported to show how BTG calculated its estimate of \$9.8 million in sales for Vistogard during the first year. BTG did not provide any estimates beyond the first year, stating only that that the model assumed “a smooth [month-over-month] growth rate, which diminishes through year 3 and

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<sup>90</sup> JX 759 at 84.

<sup>91</sup> *See* JX 823; 869.

<sup>92</sup> JX 759 at 90; *see also* JX 779 at 7 (noting a price per packet of \$3,750).

<sup>93</sup> JX 760 at 14.

flattens at 1% thereafter,” and that “[y]ears 2-7 do not assume any additional resources . . . .”<sup>94</sup> Wellstat insisted on seeing a full seven-year forecast.<sup>95</sup>

When BTG’s personnel tried to prepare the full seven-year forecast for Wellstat, they discovered that BTG’s model did not support the sales figures that BTG had provided.<sup>96</sup> The model showed that a sales force of sixteen representatives would generate only \$24 million in gross sales in the third year. This was less than the \$28 million figure that BTG had given Wellstat and significantly lower than the \$39.8 million figure BTG had used in its long-term budget. And that was only the beginning of the problems. Because BTG’s model assumed a regular month-over-month growth rate, the revenue forecasts for all subsequent periods fell short of BTG’s projections. The model supported peak annual sales of \$39 million,<sup>97</sup> well below BTG’s earlier projections of \$50-55 million.<sup>98</sup>

To solve this problem, BTG falsified the data. Between February 25 and March 2, 2016, someone at BTG hard-coded the data in the spreadsheet so that the model purportedly generated an output of \$39.8 million for the third year. To accomplish this, BTG replaced

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<sup>94</sup> JX 779 at 9.

<sup>95</sup> JX 805.

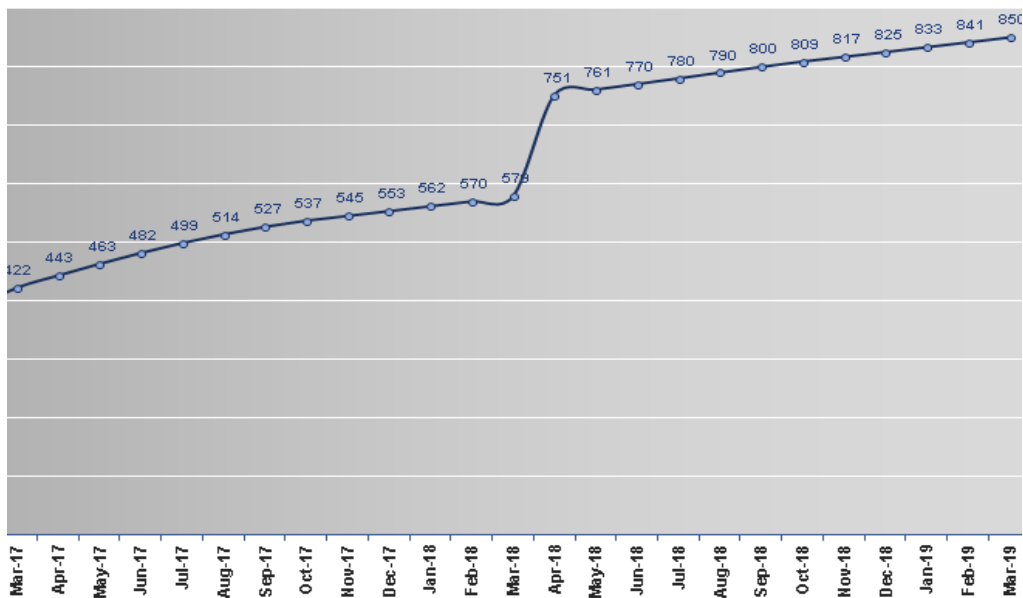
<sup>96</sup> JX 788 (noting “a fairly significant disconnect”).

<sup>97</sup> Tr. (Lewis) 402:3-13; *see also* JX 295 at 3.

<sup>98</sup> JX 823 at 35.



the 1.5% month-over-month growth rate used in the model with an artificial 30% increase between March and April 2018. The result is depicted graphically as follows:<sup>99</sup>



At trial, none of BTG’s witnesses could recall how the change came about.<sup>100</sup> Nor could BTG’s witnesses offer any benign explanation for why the model was hard-coded in this manner. In its post-trial brief, BTG suggested that the change might have resulted from “curve smoothing when annual projections are converted into monthly ones” and that the

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<sup>99</sup> JX 829.

<sup>100</sup> See, e.g., Tr. (Lewis) 400:12-21. The evidence indicates that high-level executives in the Pharmaceuticals Division were involved in the decision to alter the model. See, e.g., JX 809 (invitation for March 1, 2016 meeting among executives in Pharmaceuticals Division with subject: “Vistogard 3 year forecast discussion”); JX 824 (BTG executive: “Can you send me the model (ugly as it may be) that populated the graph to [W]ellstat?”).

modification was just a “blip.”<sup>101</sup> The graphic reveals otherwise. I find that BTG falsified its model to conceal that its sixteen-person sales force could not provide adequate support for Vistogard.

On March 2, 2016, BTG sent Wellstat a seven-year sales forecast. To hide its manipulation of the data, BTG did not send the underlying spreadsheets. BTG only disclosed the annual revenue numbers. BTG claimed that its model forecasted \$39.8 million in revenue in the third year and \$56 million in revenue in the seventh year.<sup>102</sup> These statements were knowingly and intentionally false.

**J. Vistogard Launches With Three Full-Time-Equivalent Sales Representatives.**

On March 2, 2016, BTG began selling Vistogard commercially. Although Makin had authorized the Pharmaceuticals Division to hire five additional oncology sales representatives three months earlier, BTG had not yet hired any of them. On top of that, one of BTG’s existing sales representatives had left before Vistogard’s launch. Consequently, BTG launched Vistogard with a sales force of six oncology representatives who split their time equally between Vistogard and Voraxaze. That translated into three full-time equivalent sales representatives.

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<sup>101</sup> Dkt. 266 at 57.

<sup>102</sup> JX 823 at 35.

BTG scrambled to hire more sales representatives.<sup>103</sup> By April 5, 2016, BTG had filled the vacant position and added five more representatives.<sup>104</sup> This brought BTG's sales team up to the twelve representatives that BTG had planned to have ready when Vistogard launched. BTG knew from the TGaS report, the ZS Associates report, and its own internal analyses that having twelve representatives was inadequate for a full launch. Moreover, an analysis by ZS Associates concluded that the new sales representatives would not be fully effective for six or seven months.<sup>105</sup>

**K. BTG Disregards The Commercial Plan.**

In April 2016, BTG developed a budget for Vistogard for the coming fiscal year.<sup>106</sup> The budget disregarded the numbers in the Commercial Plan that BTG had presented to the Committee in September 2015.

Overall, BTG budgeted approximately 10% less for Vistogard than it had in the Commercial Plan, a shortfall of \$4.31 million. These reductions included a cut of \$1.24 million from advertising and promotions, which slashed that category by approximately 50%. Within that category, BTG gutted the line item for "Commercial Operations," which

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<sup>103</sup> See JX 835 (Schneider: "We have tremendous pressure to get people in the field now. Honestly should have hired by Mid February.").

<sup>104</sup> See JX 921.

<sup>105</sup> JX 462 at 16; *see also* Tr. (Lewis) 395:24-396:11.

<sup>106</sup> JX 928.

included training for sales representatives. BTG budgeted only \$35,000 for this line item, approximately 90% less than what BTG committed to spend in the Commercial Plan.<sup>107</sup>

When the senior executives in the Pharmaceuticals Division realized that the budget differed from what BTG had presented in the Commercial Plan, they instructed their staff that the numbers “approved in the FY17 budget will be the reference point for development of any numbers going forward.”<sup>108</sup> No one disclosed the changes to Wellstat.<sup>109</sup>

**L. BTG Tries To Make Its Efforts Look Better.**

Fearing litigation and recognizing that its sales efforts were inadequate, BTG tried to make its sales efforts look better. On May 24, 2016, Schneider asked the Pharmaceuticals Division to prepare a white paper that would propose expanding the oncology sales team from twelve to sixteen representatives.<sup>110</sup> Schneider and Higham were scheduled to meet with Wellstat in July, and Schneider told his staff that “it is in our best interests to have the +4 on board [and] in training” before the meeting.<sup>111</sup> On June 2, Higham forwarded the completed white paper to Makin. He noted that “early indication[s] . . . highlight traction

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<sup>107</sup> JX 942 at 5.

<sup>108</sup> *Id.* at 1.

<sup>109</sup> Tr. (Lewis) 385:8-386:1.

<sup>110</sup> JX 985 at 2.

<sup>111</sup> *Id.*

(~80% of all sales) in the covered territories” and that all of the additional sales representatives would be “self-funding.”<sup>112</sup> Makin approved the request.<sup>113</sup>

BTG rushed the new representatives into service without adequate training or support. On July 5, 2016, a BTG employee reported that “the existing reps are already very frustrated at their lack of training on Vistogard, and the new ones never had any formal training on Voraxaze. I don’t understand why [BTG management is] unwilling to train the new reps appropriately.”<sup>114</sup> The answer is that BTG had not supported Vistogard adequately and was trying to cover up its failure to meet its obligations.

#### **M. This Litigation**

On July 7, 2016, the Wellstat and BTG teams met. Wellstat demanded BTG return the distribution rights to Vistogard and compensate Wellstat to fund a “re-launch” of Vistogard. Wellstat gave BTG ten days to respond.<sup>115</sup>

Instead of responding, BTG filed this action. In a complaint filed on July 15, 2016, BTG sought (i) a declaratory judgment that it did not breach the Distribution Agreement, (ii) specific performance by Wellstat of its obligations under the Distribution Agreement, (iii) a preliminary injunction enjoining Wellstat from declaring BTG in breach, and (iv) in

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<sup>112</sup> JX 996 at 1.

<sup>113</sup> JX 997.

<sup>114</sup> JX 1029 at 1.

<sup>115</sup> JX 1041; Tr. (Higham) 645:4-646:11.

the alternative, damages for breach of contract. In the course of this litigation, BTG largely abandoned its affirmative claims against Wellstat.

On July 18, 2016, Wellstat gave BTG written notice that BTG had breached the Distribution Agreement. On August 11, Wellstat answered the complaint and filed counterclaims against BTG for breach of contract.

## II. LEGAL ANALYSIS

Each side claims that the other breached the Distribution Agreement. Under Delaware law, the elements of a breach of contract claim are “first, the existence of the contract, whether express or implied; second, the breach of an obligation imposed by that contract; and third, the resultant damage to the plaintiff.”<sup>116</sup> The existence of the contract, namely the Distribution Agreement, is undisputed.

The central issue in this case is whether BTG breached the Distribution Agreement. BTG originally sought a declaratory judgment that it did not breach the Distribution Agreement. Wellstat filed a counterclaim asserting that BTG did breach the Distribution Agreement. BTG’s claim that Wellstat breached the Distribution Agreement is advanced principally as a defense to Wellstat’s assertion of breach.

This decision holds that BTG breached the Distribution Agreement and that Wellstat is entitled to damages of approximately \$55.8 million. This decision rejects the defensive contention by BTG that Wellstat breached the Distribution Agreement.

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<sup>116</sup> *VLIW Tech., LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 612 (Del. 2003).

## **A. BTG's Breach Of The Distribution Agreement**

Wellstat contends that BTG breached the Distribution Agreement in two ways. First, Wellstat claims that BTG failed to use Diligent Efforts to promote and market Vistogard. Second, Wellstat claims that BTG failed to develop a Commercial Plan in good faith and then failed to comply with the minimum commitments it set forth in the Commercial Plan. Wellstat proved at trial that BTG breached the Distribution Agreement in both respects.

### **1. The Failure To Use Diligent Efforts**

To exercise Diligent Efforts, BTG had to devote “efforts and resources, *including reasonably necessary personnel and financial resources*, that specialty pharmaceutical companies typically devote to their own internally discovered compounds or products . . . .”<sup>117</sup> Led by Makin, BTG’s senior management deployed a strategy of “[o]ptimising cash contribution from [the Pharmaceuticals Division] and investing proceeds in high-growth areas of Interventional Medicine.”<sup>118</sup> Because of this strategy, Makin and her senior management team did not permit the Pharmaceuticals Division to invest the resources in Vistogard, including reasonably necessary personnel and financial resources, that specialty pharmaceutical companies typically devote to their own internally discovered compounds or products.

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<sup>117</sup> JX 152 § 2.11 (emphasis added).

<sup>118</sup> JX 543 at 4.

Consistent with Makin’s strategy, the Pharmaceuticals Division sought to launch Vistogard as cheaply as possible. Makin emphasized to senior management that Vistogard was a “[l]ow priority for additional investment” and that the goal was to ensure that Vistogard’s launch would be “delivered cost neutrally.”<sup>119</sup> Higham carried out Makin’s directive ardently by implementing a cost-cutting initiative and telling the division’s staff that “all established products are prioritized ahead of [Vistogard] . . . .”<sup>120</sup>

The result of BTG’s cost-cutting was a sales force that was inadequate to launch Vistogard. Until April 2016, BTG had, at most, seven oncology sales representatives who split their time equally between Vistogard and Voraxaze.<sup>121</sup> There is overwhelming contemporaneous evidence that this was far fewer personnel than specialty pharmaceutical companies would have devoted to Vistogard had it been one of “their own internally discovered compounds or products . . . .”<sup>122</sup>

Outside consultants advised BTG that it needed to hire more sales representatives for Vistogard. TGaS told the Pharmaceuticals Division that it needed to “at a minimum . . . double your sales organization” of nineteen representatives in advance of Vistogard’s

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<sup>119</sup> JX 361 at 3.

<sup>120</sup> JX 424.

<sup>121</sup> JX 523 at 56; JX 828.

<sup>122</sup> JX 152 § 2.11.



launch.<sup>123</sup> Because Makin’s strategy and the resulting budget constraints foreclosed this path, the Pharmaceuticals Division engaged a new consulting firm, ZS Associates, and instructed them to assume as an “immutable factor” in their analysis that the Pharmaceuticals Division would not expand its sales force.<sup>124</sup> Notwithstanding this limitation, ZS Associates saw the matter much as TGaS had. In July 2015, ZS Associates told BTG it would need “**19-20 Oncology focused [full-time equivalents]**,” or more than twice BTG’s existing oncology sales force, to reach Vistogard’s sales targets.<sup>125</sup> ZS Associates also concluded that “up to 22 Oncology [full-time equivalents],” or more than three times Vistogard’s existing oncology sales force, would still provide BTG with returns that exceeded the industry average.<sup>126</sup> Four months later, ZS Associates reported that using thirty representatives, or more than four times BTG’s existing oncology sales force, would still be profitable for BTG, even after deducting the royalty payments to Wellstat (in violation of the Distribution Agreement).<sup>127</sup>

The Pharmaceuticals Division also recognized that Vistogard’s sales force was too small and repeatedly made this clear to BTG’s senior management. In October 2015, the

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<sup>123</sup> JX 382.

<sup>124</sup> JX 387; JX 388.

<sup>125</sup> JX 462 at 6.

<sup>126</sup> *Id.*

<sup>127</sup> JX 588.

Pharmaceuticals Division sought authority to hire nine additional oncology sales representatives immediately and emphasized that the additional representatives were “crucial to achiev[ing] optimal top line revenues.”<sup>128</sup> Consistent with the ZS Associates analysis, the managers in the Pharmaceuticals Division believed that BTG should have twenty-two sales representatives servicing Vistogard and Voraxaze, but they proposed sixteen because of the limitations that Makin had placed on the division.<sup>129</sup> When Higham sensed Makin’s disapproval and pushed for phasing in nine sales representatives over time, the managers in the Pharmaceuticals Division immediately asked to accelerate the hiring because they knew the sales team had “[p]ainfully low coverage.”<sup>130</sup>

Faced with overwhelming contemporaneous evidence, BTG’s witnesses offered several after-the-fact justifications for the inadequate sales force. None were credible.

First, BTG’s witnesses claimed that sales representatives were not expected to be the “main promotional driver” for Vistogard and so a smaller sales force was appropriate.<sup>131</sup> The contemporaneous documents contradict this carefully prepared testimony. Documents authored by ZS Associates and the Pharmaceuticals Division repeatedly touted the

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<sup>128</sup> JX 594 at 1.

<sup>129</sup> *See* JX 996.

<sup>130</sup> JX 697; *see also* JX 698.

<sup>131</sup> *See, e.g.*, Tr. (Schneider) 57:20-58:6; Tr. (Lewis) 289:5-14.

importance of sales representatives for achieving Vistogard's potential.<sup>132</sup> Just as tellingly, the number of sales representatives was the key driver in BTG's sales model,<sup>133</sup> so much so that BTG falsified other inputs to conceal that its planned sales force would be unable to achieve BTG's own projections.<sup>134</sup> Sales representatives in fact proved critical once Vistogard launched.<sup>135</sup> BTG did not use a small sales force because it believed that sales representatives were unimportant to Vistogard's success. BTG used a small sales force because senior management did not want to invest the necessary resources in Vistogard.

Second, BTG's witnesses claimed that their executives made a reasonable judgment that phasing in additional sales representatives over time was the better approach.<sup>136</sup> BTG asserts that this decision "was made by those who knew the market best – the team responsible for the-day-to-day work on Vistogard."<sup>137</sup> There is considerable irony in this

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<sup>132</sup> *See, e.g.*, JX 462 at 6 (ZS Associates opining that Vistogard was "promotionally sensitive"); JX 594 at 1 (Moody telling Soderstrom that more sales representatives "will strongly bolster the launch of Vistogard and will be crucial to achieve optimal top line revenues"); JX 607 at 18 (highlighting importance of sales representatives); JX 645 at 2 (white paper justifying increased sales representatives on grounds that "Vistogard will require promotional efforts to raise disease awareness").

<sup>133</sup> *See* JX 823 at 31; Tr. (Schneider) 212:19-213:20.

<sup>134</sup> *See* JX 829.

<sup>135</sup> *See* JX 996 at 1 (noting that approximately 80% of all sales had occurred in territories with sales representatives).

<sup>136</sup> *See, e.g.*, Tr. (Schneider) 93:24-95:2.

<sup>137</sup> Dkt. 266 at 34-35.

litigation-driven, counter-factual contention. The managers in the Pharmaceuticals Division, who knew the market best and were responsible for the day-to-day work on Vistogard, repeatedly argued for expanding the sales force immediately. They thought that Vistogard's "[l]ong-term performance [would] be set in first 6 months."<sup>138</sup> Moody told Soderstrom explicitly that the managers in the Pharmaceuticals Division "don't recommend" phasing in sales representatives.<sup>139</sup>

Higham overruled the team that knew the market best. Importantly, Higham did not overrule the team because he thought hiring additional sales representatives over time was the best way to increase Vistogard's revenue. He overruled the team because he understood Makin's corporate strategy, including not investing in the Pharmaceuticals Division, and believed that Makin would not approve the team's plan.<sup>140</sup>

Third, BTG's witnesses claimed that they were caught flatfooted when the FDA approved Vistogard earlier than expected and that BTG responded by hiring additional sales representatives as quickly as it could.<sup>141</sup> The litigators invented that story as well. When Wellstat filed the New Drug Application in July 2015, BTG believed that FDA approval could come as soon as January 2016, and BTG also recognized the "need to plan

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<sup>138</sup> JX 607 at 18.

<sup>139</sup> JX 594.

<sup>140</sup> *See, e.g.*, JX 424.

<sup>141</sup> *See, e.g.*, Tr. (Schneider) 72:2-74:3, 205:8-206:7.

(and be ready) for earlier approval . . . .”<sup>142</sup> FDA approval came just one month earlier than anticipated, in December 2015. BTG then waited nearly four months to hire any additional sales representatives.<sup>143</sup> BTG did not fail to hire enough sales representatives because the FDA approved Vistogard early. BTG failed to hire enough sales representatives because it did not want to incur the expense.

Fourth, BTG points to the number of sales representatives that it used when launching Voraxaze as proof that Vistogard’s sales force was large enough. If anything, the comparison proves that BTG should have used a larger sales force for Vistogard than it did for Voraxaze. It is true that the two drugs are comparable in that both treat toxicity from chemotherapy drugs, but the chemotherapy drug Voraxaze treats is used far less frequently than 5-FU. Consequently, the market for Voraxaze is much smaller than it is for Vistogard. For Voraxaze, BTG projected peak sales of \$15 million.<sup>144</sup> For Vistogard, BTG projected peak sales of \$56 million.<sup>145</sup> BTG therefore should have deployed more sales representatives for Vistogard.

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<sup>142</sup> JX 478.

<sup>143</sup> JX 921.

<sup>144</sup> JX 1304 at 10.

<sup>145</sup> JX 823 at 35; Tr. (Suvvari) 824:18-825:10.

Perhaps more importantly, BTG viewed the launch of Voraxaze as unsuccessful, in large part because BTG failed to deploy an adequate sales force.<sup>146</sup> In fact, when developing their internal analysis in preparation for the launch of Vistogard, the Pharmaceuticals Division included a slide titled “Lessons Learned from Voraxaze.”<sup>147</sup> The lessons included that “[o]ncology products are promotionally sensitive,” that “[i]t is important to identify and call on all stakeholders within an account,” and that “[i]n-depth training . . . is necessary to ensure that [sales representatives] are confident selling to oncologists . . . .”<sup>148</sup> Yet, because of Makin’s corporate strategy and Higham’s zealous implementation of it, BTG ignored all of these “lessons learned.” It cut the promotional budget for Vistogard, did not pursue the necessary promotional efforts, failed to hire enough sales representatives, and then failed to provide them with adequate training or support.

BTG finally argues that, even if it failed to provide “reasonably necessary personnel” as required by the Distribution Agreement, BTG’s other marketing activities constituted Diligent Efforts. To make this argument, BTG overstated the extent of its other marketing activities. For example, BTG emphasized its medical education efforts, but BTG

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<sup>146</sup> See JX 472 at 3 (“Voraxaze has been short of annual goals”); JX 535 at 43 (BTG noting that Voraxaze was “underperform[ing]”).

<sup>147</sup> JX 600 at 20.

<sup>148</sup> *Id.*

also conceded that pre-launch disease awareness was a critical component of these efforts.<sup>149</sup> BTG had to adjust its sales forecast downward in February 2016 because it had engaged in “[m]inimal pre-launch disease education effort[s].”<sup>150</sup> Similarly, BTG emphasized its digital marketing strategy, but BTG budgeted minimal amounts for digital marketing,<sup>151</sup> and Vistogard’s full website was not operational until June 2016, three months after launch.<sup>152</sup>

Even assuming that BTG’s other promotional activities were as significant as BTG claims, they would not show that BTG met its obligation to exercise Diligent Efforts. The Distribution Agreement defines Diligent Efforts as what “specialty pharmaceutical companies typically devote to their own internally discovered compounds or products . . . .”<sup>153</sup> BTG’s outside consultants and its own employees emphasized the critical role of sales representatives for Vistogard’s success, and they told BTG to hire more sales representatives. BTG’s own model treated the number of sales representatives as the key

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<sup>149</sup> *See, e.g.*, JX 463 at 3 (“Increasing clinical understanding of severe 5-FU toxicity . . . will be a cornerstone to initial and sustained product usage.”); JX 936 at 2; *accord* JX 1083 at 67 (“Conducting pre-market diseases state education 4-6 months prior to [FDA] approval is better practice in industry.”).

<sup>150</sup> JX 759 at 63 (emphasis omitted); *see also* JX 824 (showing “Impact of truncated Dis. Awareness”).

<sup>151</sup> *See* JX 1132 (showing \$135,000 budget for “Digital” for the entire Pharmaceuticals Division).

<sup>152</sup> JX 998; JX 1046 at 12.

<sup>153</sup> JX 152 § 2.11.

input and showed that BTG could not achieve its projections for Vistogard using the number of sales representatives that BTG deployed. Other specialty pharmaceutical companies would not have ignored this data. They would not have deployed a sales force—both before and after Vistogard’s launch—that was far smaller than what the most knowledgeable people recommended, what the model contemplated, and what would generate greater-than-industry-standard profits.

Despite warnings from Wellstat, BTG’s outside consultants, and its own employees, BTG deployed a sales force that was far too small to achieve Vistogard’s revenue potential. BTG breached the Distribution Agreement by failing to exercise Diligent Efforts when sizing and deploying its sales force for Vistogard.

## **2. The Failure To Develop And Implement A Commercial Plan**

To comply with its obligations under the Distribution Agreement, BTG had to “prepare in good faith [an] initial commercial plan and budget” for Vistogard that “include[d] minimum commitments of resources, personnel and financing . . . .”<sup>154</sup> BTG breached this obligation by failing to prepare a Commercial Plan in good faith. BTG then breached the Distribution Agreement again by failing to deliver on the inadequate commitments contemplated by the hastily prepared Commercial Plan.

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<sup>154</sup> JX 152 § 8.1.



BTG's initial Commercial Plan was a PowerPoint presentation that BTG assembled in one week.<sup>155</sup> The Distribution Agreement required that the Commercial Plan identify a minimum commitment of personnel. The presentation did not contain a commitment; BTG said only that "there may be" additional sales representatives beyond its existing seven, "[d]epending on strength of indication and initial uptake."<sup>156</sup> BTG also misleadingly implied that it could assign up to forty representatives from another business unit to Vistogard when BTG already had rejected this idea internally.<sup>157</sup> Contrary to what the Distribution Agreement required, BTG had not thought through how many sales representatives it would use after the launch of Vistogard and told the Committee that its plans for this phase were "[u]nder development."<sup>158</sup>

The Distribution Agreement also required that the Commercial Plan identify minimum commitments for expenditures. BTG's Commercial Plan did not contain these commitments. BTG specified the amount of money that it had budgeted in different high-level categories, but refused to commit to those numbers.<sup>159</sup> More importantly, the numbers that BTG included in its Commercial Plan were not reliable budget numbers developed

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<sup>155</sup> See JX 514; JX 519.

<sup>156</sup> JX 523 at 61.

<sup>157</sup> *Id.*; see also JX 472 at 5.

<sup>158</sup> JX 527 at 3.

<sup>159</sup> See JX 523 at 60 ("Revisions may occur throughout the course of the business planning cycle.").

after meaningful analysis. BTG generated the numbers simply by taking the percentage allocated to that category in the Pharmaceuticals Division's budget from the prior fiscal year and multiplying that number by the amount that BTG intended to spend on Vistogard.<sup>160</sup> The numbers in the Commercial Plan were therefore not "minimum commitments of resources" prepared in good faith. They were artificial numbers that BTG included to give the appearance that BTG had prepared a real plan, when in fact BTG had not done the necessary work.

BTG subsequently changed the expenditure figures that it had presented in the Commercial Plan. This fact demonstrates that BTG never took those numbers seriously. In April 2016, BTG set its budget for Vistogard without regard for the numbers that BTG had presented. BTG cut spending on advertising and promotion by almost 50%. BTG cut spending on Commercial Operations, which included training for sales representatives, by almost 90%.<sup>161</sup> BTG's disregard for the Commercial Plan during its internal budgeting process shows that BTG did not prepare the Commercial Plan in good faith. Equally important, BTG's cavalier disregard for the numbers it provided to Wellstat resulted in BTG separately breaching its obligation to "promote and distribute [Vistogard] . . . in material compliance" with the Commercial Plan.<sup>162</sup> Even though BTG failed to develop

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<sup>160</sup> JX 942.

<sup>161</sup> JX 928.

<sup>162</sup> JX 152 § 8.1.

meaningful figures for the Commercial Plan, once it showed those numbers to Wellstat, BTG had to stick to those numbers. BTG could not cut them unilaterally and without disclosing the cuts to Wellstat, yet that is precisely what BTG did.

BTG did not prepare a Commercial Plan in good faith. It prepared a disingenuous and misleading plan that BTG never took seriously. BTG then failed to market Vistogard in accordance with its Commercial Plan. These acts constituted further breaches of the Distribution Agreement.

## **B. The Defense Of An Alleged Breach By Wellstat**

Before turning to damages, this decision addresses BTG's claim that Wellstat breached the Distribution Agreement. BTG advances this claim in an effort to excuse its own material breaches of the Distribution Agreement on the theory that Wellstat breached first and compromised BTG's efforts to fulfill its own contractual obligations. BTG's arguments are meritless.

BTG first claims that Wellstat failed to use Diligent Efforts to obtain FDA approval for Vistogard because Wellstat filed the New Drug Application approximately eighteen months later than Wellstat initially had planned. The evidence at trial showed that the delay did not result from Wellstat's failure to exercise Diligent Efforts. It instead occurred due to events outside of Wellstat's control.<sup>163</sup> In any event, Wellstat's delay in filing the New

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<sup>163</sup> These events included (i) Wellstat's third-party manufacturer suffering equipment failures that contaminated one of Vistogard's first batches, (ii) unexpected FDA

Drug Application did not prejudice BTG’s ability to market Vistogard, nor did it cause BTG any damage.<sup>164</sup> If anything, the delay gave BTG more time to plan and prepare.

BTG also claims that Wellstat refused to provide BTG with clinical data that BTG needed for commercial activities. Dr. Michael Bamat, a Wellstat scientist, candidly acknowledged that, for several months at the beginning of 2015, Wellstat did not share data from its clinical studies with Vistogard, even though Bamat believed that Wellstat should have.<sup>165</sup> In May 2015, BTG and Wellstat met to address the issue, and afterwards BTG sent Wellstat a list of the data that they wanted.<sup>166</sup> In the weeks following the meeting, Bamat gave BTG the information that he had.<sup>167</sup> Thereafter, Wellstat regularly provided BTG with clinical information as it became available.<sup>168</sup> Assuming, for the sake of argument, that Wellstat did not provide the information in as timely a fashion as it should have, Wellstat cured the problem long before it created any issues for BTG with the launch of Vistogard.

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decisions on several matters, and (iii) poor performance by Wellstat’s third-party database vendor. *See* Tr. (Bamat) 882:6-887:21.

<sup>164</sup> BTG in fact argued that it would have benefited from even more time. *See, e.g.*, Tr. (Schneider) 203:8-24 (asserting BTG was forced to “accelerate[] our spend in preparation for this faster-than-expected launch”).

<sup>165</sup> Tr. (Bamat) 892:10-893:10.

<sup>166</sup> *See* JX 418; JX 420.

<sup>167</sup> *See, e.g.*, JX 419; JX 421; JX 422; JX 426.

<sup>168</sup> *See* Tr. (Bamat) 896:22-900:16.

Viewing the evidence as a whole, Wellstat acted in good faith and fulfilled its contractual commitments. The same cannot be said for BTG. Wellstat's actions do not excuse BTG's breaches of the Distribution Agreement.

### **C. Damages**

“[T]he standard remedy for breach of contract is based upon the reasonable expectations of the parties . . . .”<sup>169</sup> “It is a basic principle of contract law that remedy for a breach should seek to give the nonbreaching [] party the benefit of its bargain by putting that party in the position it would have been but for the breach.”<sup>170</sup> “Expectation damages thus require the breaching promisor to compensate the promisee for the promisee's reasonable expectation of the value of the breached contract, and, hence, what the promisee lost.”<sup>171</sup> Expectation damages should “be measured as of the time of the breach.”<sup>172</sup>

Expectation damages “should not act as a windfall.”<sup>173</sup> But “the injured party need not establish the amount of damages with precise certainty where the wrong has been

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<sup>169</sup> *Duncan v. Theratx, Inc.*, 775 A.2d 1019, 1022 (Del. 2001).

<sup>170</sup> *Genecor Int'l, Inc. v. Novo Nordisk A/S*, 766 A.2d 8, 11 (Del. 2000).

<sup>171</sup> *Duncan*, 775 A.2d at 1022.

<sup>172</sup> *Comrie v. Enterasys Networks, Inc.*, 837 A.2d 1, 17 (Del. Ch. 2003).

<sup>173</sup> *Paul v. Deloitte & Touche, LLP*, 974 A.2d 140, 146 (Del. 2009).

proven and injury established.”<sup>174</sup> “[D]oubts about the extent of damages are generally resolved against the breaching party.”<sup>175</sup>

Wellstat claims expectation damages equal to the net present value of the difference between (i) the revenue Wellstat would have earned if BTG had used Diligent Efforts and (ii) the revenue that Wellstat will earn under the status quo, given BTG’s actual efforts. Both sides retained multiple experts to grapple with the calculation. Wellstat claims that its damages exceed \$112 million. BTG claims that Wellstat suffered no damages at all.

The amount of Wellstat’s damages turns primarily on three hotly disputed issues. The first is the size of Vistogard’s patient population. The second is the rate at which an appropriately sized sales team could gain access to physicians and educate them on Vistogard’s benefits. The third is which set of BTG’s projections to use when determining what Wellstat will earn under the status quo.

### **1. Vistogard’s Patient Population**

The first major damages-related dispute is the size of Vistogard’s patient population. Neel Patel, one of Wellstat’s expert witnesses, estimated the size of Vistogard’s patient population using a sixty-eight question survey that he distributed to forty-two

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<sup>174</sup> *Siga Techs., Inc. v. PharmAthene, Inc.*, 132 A.3d 1108, 1131 (Del. 2015) (internal quotation marks omitted).

<sup>175</sup> *Id.*; accord *Beard Research, Inc. v. Kates*, 8 A.3d 573, 613 (Del. Ch. 2010) (“Public policy has led Delaware courts to show a general willingness to make a wrongdoer bear the risk of uncertainty of a damages calculation where the calculation cannot be mathematically proven.” (internal quotation marks omitted) (collecting cases)).

physicians.<sup>176</sup> Patel's opinion regarding Vistogard's patient population largely turns on two data points: (i) the number of patients who suffer early-onset 5-FU toxicity and (ii) the percentage of physicians who would treat those patients with Vistogard.

Patel's survey distinguished among patients suffering from mild, moderate, and severe toxicity. Patel included all three categories of patients in Vistogard's patient population. BTG claims that Patel's model should have excluded patients that his survey classifies as suffering from "mild" or "moderate" toxicity, because the FDA only approved Vistogard for "early-onset, severe or life-threatening toxicity."<sup>177</sup> Excluding both categories would reduce Wellstat's damages to no more than \$19.2 million.

Physicians often assess the severity of toxicity using grades. One widely used industry standard, the Common Terminology Criteria for Adverse Events (the "Common Terminology"), defines mild toxicity as Grade 1, moderate toxicity as Grade 2, severe toxicity as Grade 3, and life-threatening toxicity as Grade 4. Patel used a four-grade metric in his survey, but he did not precisely align his metric with the Common Terminology. Patel's survey defined mild toxicity as Grades 1-2, moderate toxicity as Grade 3, and severe toxicity as Grade 4.<sup>178</sup> Thus, Patel's survey described Grade 3 patients as "moderate," while

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<sup>176</sup> Tr. (Patel) 1210:22-1211:8.

<sup>177</sup> JX 1077 at 27.

<sup>178</sup> JX 674 at 6.

the Common Terminology would classify them as “severe.” BTG accordingly argues that the Grade 3 patients should be excluded when calculating damages.<sup>179</sup>

The problem with BTG’s position is that Patel’s classifications worked in BTG’s favor. The drug profile presented in the survey accurately described Vistogard as indicated for patients “exhibiting early-onset, severe or life-threatening toxicity.”<sup>180</sup> Because the survey described Grade 3 as “moderate,” rather than “severe,” some of the physicians who responded that they would not treat Grade 3 patients with Vistogard likely did so because the drug’s indication did not support using Vistogard to treat moderate toxicity. Had Patel classified Grade 3 toxicity as “severe,” as called for by the Common Terminology, it is likely that more doctors would have said that they would prescribe Vistogard. This conclusion is supported by Patel’s survey, which found that physicians were almost twice

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<sup>179</sup> More aggressively, BTG argued that deviating from the Common Terminology warranted disregarding Patel’s survey entirely. BTG relied on two trademark cases in which the court rejected surveys that used classifications that did not accord with statutory definitions. *See Icon Enters. Int’l, Inc. v. Am. Prods. Co.*, 2004 WL 5644805, at \*28 (C.D. Cal. Oct. 7, 2004); *J & J Snack Foods, Corp. v. Earthgrains Co.*, 220 F. Supp. 2d 358, 369 (D.N.J. 2002). Those cases are obviously distinguishable. Toxicity grades are not fixed by statute and, as noted, lack a precise industry standard. Moreover, the surveys in those cases skewed the classifications far beyond recognition. *See Icon*, 2004 WL 5644805, at \*27-28 (noting the definition “omits a crucial and indeed distinguishing characteristic of suggestive marks” and that omission was “no mere technical flaw”); *J & J*, 220 F. Supp. 2d at 370-71 (noting that the flaws in the definition were “substantial” and “permeated the entire survey to make its finding completely untrustworthy and unreliable”). Patel’s work shifted the grades slightly in a manner that favored BTG. A wholesale rejection of Patel’s analysis is not warranted.

<sup>180</sup> JX 1077 at 27.



as likely to prescribe Vistogard to treat “severe” toxicity (i.e. Grade 4 in the survey) as they were to treat “moderate” toxicity (Grade 3 in the survey).<sup>181</sup> By classifying Grade 3 as moderate toxicity, rather than severe toxicity, Patel depressed the size of Vistogard’s patient pool and favored BTG.

The empirical literature supports this finding. Patel’s survey indicated that only 5% of all 5-FU patients experience *either* Grade 3 or Grade 4 toxicity (as defined in the survey), yet numerous scientific studies have found a 15-20% rate of Grade 3 or Grade 4 toxicity (as defined in the Common Terminology).<sup>182</sup> Similarly, Patel’s survey found that 39% of physicians would prescribe Vistogard for Grade 3 toxicity (as defined in the survey), yet a January 2016 pricing study by BTG found that 53% of physicians would prescribe Vistogard for Grade 3 toxicity (as defined by the Common Terminology).<sup>183</sup>

Because Patel’s classification of Grade 3 toxicity favored BTG by reducing the size of the patient pool, there is no reason to exclude the “moderate” patients from Patel’s estimate. The treatment of patients suffering from mild toxicity (Grades 1-2) warrants a different conclusion. Because Grades 1-2 patients did not fall within the indicated use of

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<sup>181</sup> JX 1077 at 57 (73% of physicians reported that they would treat severe toxicity with Vistogard, compared to 39% for moderate toxicity).

<sup>182</sup> *See, e.g.*, JX 68 at 20 (BTG presentation citing two scientific studies finding 16% of patients suffer early-onset severe toxicities); JX 1081 at 31 (noting that literature generally reports “15-20% incidence of severe early-onset toxicity” and collecting authorities).

<sup>183</sup> JX 681 at 19, 22.

Vistogard, BTG could not market Vistogard for use by these patients.<sup>184</sup> Even though physicians are permitted to prescribe Vistogard for off-label use and to purchase Vistogard for that purpose, the evidence indicates that sales for mild toxicity are likely to be minimal, because there are cheap and widely available alternative therapeutic treatments.<sup>185</sup> Moreover, pharmaceutical companies generally do not include off-label prescriptions in their sales forecasts.<sup>186</sup> Patients receiving Vistogard for mild toxicity are therefore excluded from Patel's sales forecast.

## **2. Access Rate**

The second major damages-related dispute concerns the access rate, which is the rate at which sales representatives can gain access to oncologists to discuss Vistogard. The rate is expressed as a percentage of oncologists. Wellstat's expert, Howard Brock, estimated access rates ranging from 50% to 90%, depending on how frequently the

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<sup>184</sup> See 21 U.S.C. § 355(a); 82 Fed. Reg. 2193 (Jan. 9, 2017) (to be codified at 21 C.F.R. §§ 201, 801, 1100) (amending definition of “intended uses” to read “if the totality of the evidence establishes that a manufacturer objectively intends that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it has been approved, cleared, granted marketing authorization, or is exempt from premarket notification requirements (if any), he is required . . . to provide for such device adequate labeling that accords with such other intended uses.”).

<sup>185</sup> See Tr. (Patel) 1222:22-1223:12 (noting that other oncology products involving off-label use do not have “many viable substitutes”).

<sup>186</sup> Tr. (Boghigian) 1006:4-9.

oncologists prescribe 5-FU.<sup>187</sup> BTG's expert, William Suvari, estimated an average access rate of 30% across all oncologists.<sup>188</sup>

Neither expert offered compelling evidence to support their access rate. Brock justified his range based on his industry experience. He testified that "doctors have a tendency to be very interested" in specialty oncology pharmaceuticals.<sup>189</sup> He opined that a higher access rate was appropriate for Vistogard because "the low disease state awareness" for early-onset 5-FU toxicity would lead doctors to be "more interested to learn about the product."<sup>190</sup> Brock's opinion makes intuitive sense, but it would be more powerful if backed by empirical data.

Suvari attempted to ground his conclusion in empirical data, but did so unpersuasively. Suvari pointed to an executive summary of a ZS Associates study that found that 27% of oncologists were "accessible" to sales representatives. Suvari chose not to obtain or review the full study, nor did he examine the underlying data.<sup>191</sup> He also does not appear to have interpreted the 27% figure accurately, because the ZS Associates study defines an "accessible" oncologist as one that is reached by sales representatives more than

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<sup>187</sup> Tr. (Brock) 1249:6-24.

<sup>188</sup> JX 806 at 3; Tr. (Suvari) 857:14-860:15.

<sup>189</sup> Tr. (Brock) 1250:1-20.

<sup>190</sup> Tr. (Brock) 1252:11-21.

<sup>191</sup> Tr. (Suvari) 860:20-861:18.

70% of the time.<sup>192</sup> The ZS Associates study observed that sales representatives still reached doctors outside of the “accessible” category, albeit with less frequency. The ZS Associates study, therefore, did not provide meaningful support for Suvvari’s access rate.

The competing expert testimony results in some doubt about the appropriate access rate, but “doubts about the extent of damages are generally resolved against the breaching party.”<sup>193</sup> That principle applies here. Brock’s arguments for the higher access rate were logical and his testimony was credible. This decision adopts Brock’s access rate.

### **3. Projections Of Vistogard’s Sales Under The Status Quo**

The final major damages-related issue is what sales forecast to use to determine the amounts Wellstat would earn under the status quo in light of BTG’s actual efforts to market Vistogard. Wellstat points to Vistogard’s statements to investors in early 2016 that Vistogard would generate peak sales of \$35 million, but BTG did not create an internal sales forecast supporting peak sales of \$35 million. Instead, one of Wellstat’s experts, Christopher Gerardi, constructed a forecast by applying a curve that implied peak sales of \$35 million after ten years.<sup>194</sup> Gerardi’s top-down forecast is too speculative to be a reliable measure of what Wellstat would have earned under the status quo.

The better approach is to use BTG’s actual sales forecast, albeit after removing the false, hard-coded increase that BTG inserted to mislead Wellstat. Once that deviation is

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<sup>192</sup> *Id.*

<sup>193</sup> *Siga Techs.*, 132 A.3d at 1131.

<sup>194</sup> JX 1082 at 25.

removed, the model provides the best evidence of the sales that BTG would achieve based on its actual efforts. The remainder of the model was prepared in the ordinary course of business and its assumptions accurately reflect BTG's actual marketing efforts, including BTG's decision to deploy a sixteen-person sales team, with nine of the representatives phased in over time. This decision adopts BTG's corrected sales forecast for purposes of calculating Wellstat's damages.<sup>195</sup>

#### **4. Other Damages Arguments**

In addition to the three major damages-related issues discussed above, BTG threw a grocery bag of other arguments against the wall. Wellstat added an argument of its own. Nothing stuck.

##### **a. The Cost Of Vistogard**

BTG criticized Patel's survey for omitting information about Vistogard's price. BTG argued that physicians would be less likely to prescribe Vistogard if they knew that each treatment costs \$75,000. This argument is not persuasive. Patel testified credibly that oncologists are not particularly price-sensitive for specialty products like Vistogard because they only prescribe them when it is clearly warranted.<sup>196</sup> BTG's January 2015

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<sup>195</sup> Another Wellstat expert, Harry Boghigian, opined in a rebuttal report that BTG's sales forecast had other flaws in addition to the hard-coded bump such that a higher figure should be used. Wellstat did not elicit testimony on this topic during trial. *See* Tr. (Boghigian) 988:6-995:22. Wellstat also did not meaningfully address these issues in post-trial briefing. Wellstat's other challenges to BTG's model are therefore waived. *See Emerald P'rs v. Berlin*, 726 A.2d 1215, 1224 (Del. 1999).

<sup>196</sup> Tr. (Patel) 1220:12-1222:4.

pricing study for Vistogard supports Patel’s testimony. That study found the greatest price elasticity for Grade 1 or Grade 2 toxicity, which this decision excluded from Patel’s model.<sup>197</sup> That study also found that more physicians would prescribe Vistogard at the much higher price of \$120,000 than Patel found in his survey.<sup>198</sup> Patel’s failure to include Vistogard’s price in his survey does not undermine the validity of his data. His opinion regarding the size of the Vistogard market remains conservative.

**b. The Early Termination Right**

BTG claims that Wellstat’s damages should be limited by the fact that BTG has the right to terminate the Distribution Agreement “for convenience” five years after FDA approval of Vistogard.<sup>199</sup> Contract damages are determined by the “expectations of the parties before or at the time of the breach.”<sup>200</sup>

When BTG breached the Distribution Agreement, BTG did not intend to exercise its early termination right. In March 2016, Schneider characterized the Distribution Agreement as an “evergreen contract for 10 years.”<sup>201</sup> In June 2016, BTG analyzed the financial impact of *Wellstat* exercising its early termination right, precisely because BTG

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<sup>197</sup> JX 681 at 22.

<sup>198</sup> *Id.*; see also Schneider Dep. at 322:18-23 (acknowledging that BTG chose a price for Vistogard that “for the most part avoided physicians making an economic choice”).

<sup>199</sup> JX 152 §12.2.

<sup>200</sup> *Siga Techs.*, 132 A.3d at 1133.

<sup>201</sup> JX 870.

did not want to terminate the Distribution Agreement and was concerned that Wellstat might. BTG's analysis showed that BTG would lose at least \$79 million if Wellstat terminated the Distribution Agreement after five years.<sup>202</sup>

It would have been economically irrational for BTG to terminate the Distribution Agreement at a point when Vistogard was approaching its peak sales potential, after BTG had invested in generating those sales, and when Vistogard needed relatively little additional investment from BTG. Tellingly, BTG's damages expert did not model the possibility of BTG's early termination and BTG did not advance the argument until trial.<sup>203</sup> BTG's early termination right does not reduce Wellstat's damages.

**c. Mitigation**

The Distribution Agreement provides that Wellstat is entitled to the return of Vistogard's distribution rights if BTG has materially breached the agreement.<sup>204</sup> BTG argues that Wellstat's damages should be reduced to account for any potentially greater sales of Vistogard that Wellstat could achieve after it recovers the distribution rights and pursues a new promotional plan.

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<sup>202</sup> JX 1002 at 27. The actual number would be higher if BTG terminated, because BTG's analysis assumes that Wellstat would pay BTG 30% of net sales for three years after Wellstat's exercise of the early termination right. *See* JX 152 § 12.2.

<sup>203</sup> *See* JX 1084 at 4.

<sup>204</sup> JX 152 § 12.11(a)(i).

“Failure to mitigate damages is an affirmative defense, and the burden of proving the failure falls upon the defendant.”<sup>205</sup> BTG failed to introduce any evidence or expert testimony that would quantify how much Wellstat’s damages might be mitigated through future sales of Vistogard.<sup>206</sup> BTG accordingly failed to meet its burden of proof that Wellstat’s damages should be mitigated by future sales of Vistogard.

**d. Renewal**

The initial term of the Distribution Agreement was ten years, beginning on the date the FDA approved Vistogard. The Distribution Agreement provides that it “shall automatically renew for successive two (2) year periods unless either Party provides notice three (3) months in advance of the expiration of the then-current Term.”<sup>207</sup> To increase the size of its damages recovery, Wellstat argues that it should receive damages for lost Vistogard sales during the first two-year renewal period.

Courts will award damages for a renewal term when a plaintiff can prove that the contract would have been renewed with reasonable certainty.<sup>208</sup> In this case, whether the Distribution Agreement would have been renewed is highly speculative. The Distribution

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<sup>205</sup> *Tanner v. Exxon Corp.*, 1981 WL 191389, at \*4 (Del. Super. July 23, 1981).

<sup>206</sup> At trial, the court rejected BTG’s attempt to introduce previously undisclosed expert testimony about Wellstat’s failure to mitigate. Tr. (Court) 1319:10-20.

<sup>207</sup> JX 152 § 12.1.

<sup>208</sup> See *M & G Polymers USA, LLC v. Carestream Health, Inc.*, 2009 WL 3535466, at \*9 (Del. Super. Aug. 9, 2009); see also *Supervalu, Inc. v. Assoc. Grocers, Inc.*, 2007 WL 624342, at \*3 (D. Minn. Jan. 3, 2007).



Agreement's initial term does not expire until December 2025. Predicting how BTG and Wellstat would approach the renewal right eight years in the future would be, at best, an educated guess. This fact countenances against awarding Wellstat lost profits for the renewal period.<sup>209</sup>

At the same time, much of the difficulty inherent in assessing whether the Distribution Agreement would be renewed results from BTG's breach. The major factor that BTG and Wellstat would consider when deciding whether to renew is how successful Vistogard had been and would continue to be. BTG botched Vistogard's launch, making it impossible to evaluate Vistogard's success. Because Delaware law resolves doubts regarding the amount of damages against the breaching party, a sound argument exists that Wellstat should receive damages for the renewal term.

Nonetheless, on the facts of this case, awarding damages for the renewal period would be too speculative. The damages analysis is already assumption-laden and covers a ten-year period that extends eight years into the future. Adding damages for a renewal period is not something that this court can attempt with any degree of confidence.

## **5. The Damages Award**

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<sup>209</sup> Cf. *Bradshaw v Trover*, 1999 WL 463847, at \*3 (Del. Super. Apr. 30, 1999) (disallowing personal injury plaintiff's evidence on lost profits from the non-renewal of a contract as a result of her injury; finding that "[a]lthough the contract had previously been renewed, whether [the contract] would have been renewed further is unknown and speculative").

BTG's expert, Christopher Barry, calculated what Wellstat's damages would be under various scenarios depending on how the court resolved the three major damages issues in this case. Barry helpfully provided a decision tree that illustrated the different outcomes. Barry's chart arrives at damages of \$55.8 million in a scenario that (i) excludes mild toxicity patients from Patel's forecast, (ii) uses Brock's access rate of 50-90%, and (iii) uses the corrected BTG model. Wellstat has not objected to Barry's calculations.

Barry did not provide a more precise figure than \$55.8 million. Barry will provide Wellstat with his specific figure in dollars and cents, and that figure will be used as the damages award.

#### **D. Interest**

Prejudgment interest in Delaware cases is awarded as a matter of right.<sup>210</sup> Subject to the court's discretion, a party is also entitled to post-judgment interest until the date of payment on an amount that includes both the amount of the judgment and the amount of prejudgment interest.<sup>211</sup> Unless the parties have specified another rate by contract or the

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<sup>210</sup> *Brandywine Smyrna, Inc. v. Millenium Builders, LLC*, 34 A.3d 482, 486 (Del. 2011).

<sup>211</sup> *Beard Research, Inc. v. Kates*, 8 A.3d 573, 620-21 (Del. Ch. 2010).

court determines that a different rate is warranted by the equities, the statutory rate of interest governs.<sup>212</sup> In a breach of contract case, interest runs from the date of breach.<sup>213</sup>

In this case, Section 4.8 of the Distribution Agreement specifies a rate of 1% per month for “payments that are not paid on or before the date such payments are due under this Agreement.”<sup>214</sup> Similar language has been held to be sufficient to specify an interest rate for purposes of pre- and post-judgment interest.<sup>215</sup>

Pre- and post-judgment interest therefore will accrue at a rate of 1% per month, compounded monthly. Interest shall run from September 15, 2015, when BTG first breached the Distribution Agreement by failing to provide the Commercial Plan.

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<sup>212</sup> See 6 Del. C. § 2301(a) (establishing legal rate); *Summa Corp. v. Trans World Airlines, Inc.*, 540 A.2d 403, 409 (Del. 1988) (“While the legal rate of interest has historically been the benchmark for pre-judgment interest, a court of equity has broad discretion, subject to principles of fairness, in fixing the rate to be applied.” (citations omitted)); *Brandin v. Gottlieb*, 2000 WL 1005954, at \*29 (Del. Ch. July 13, 2000) (“In the Court of Chancery the legal rate is a mere guide, not the inflexible rule.” (internal quotation marks omitted)).

<sup>213</sup> *Citadel Hldg. Corp. v. Roven*, 603 A.2d 818, 826 (Del. 1992); *Wilson v. Pepper*, 1995 WL 562235, at \*6 (Del. Super. Aug. 21, 1995).

<sup>214</sup> JX 152 § 4.8.

<sup>215</sup> See *Miller v. Silverside*, 2016 WL 4502012, at \*9 (Del. Super. Aug. 26, 2016); see also *Bride One, LLC v. Regency Ctrs., L.P.*, 2017 WL 3189230, at \*5 (Del. Super. July 20, 2017); *Millcreek Shopping Ctr. LLC v. Jenner Enters., Inc.*, 2017 WL 1282068, at \*2 (Del. Super. Mar. 31, 2017).

## E. Attorneys' Fees

Wellstat sought attorneys' fees under the bad faith exception to the American Rule. "The bad faith exception to the American Rule applies in cases where the court finds litigation to have been brought in bad faith or finds that a party conducted the litigation process itself in bad faith, thereby unjustifiably increasing the costs of litigation."<sup>216</sup>

Wellstat correctly points out that BTG acted aggressively and took disingenuous positions during the litigation. In discovery, BTG refused to produce documents relating to BTG's strategic shift away from specialty pharmaceuticals or provide a witness pursuant to Court of Chancery Rule 30(b)(6) on the topic, claiming that the subject was not relevant. BTG also objected to Makin being identified as a custodian for documents, claiming that she did not possess relevant information. These positions could not have been asserted in good faith, yet BTG forced Wellstat to prevail on a motion to compel before BTG complied with its discovery obligations.<sup>217</sup> Equally concerning, at trial BTG presented a misleading demonstrative regarding the calculation of Wellstat's damages.<sup>218</sup>

Although these instances of misconduct were problematic, it would be disproportionate to shift attorneys' fees broadly in favor of Wellstat. A more tailored remedy would address these problems. The parties shall confer regarding an award of

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<sup>216</sup> *Beck v. Atl. Coast PLC*, 868 A.2d 840, 850-51 (Del. Ch. 2005) (Strine, V.C.).

<sup>217</sup> See Dkt. 140 (granting Wellstat's first and second motions to compel); Dkt. 219 (granting Wellstat's third motion to compel).

<sup>218</sup> See Tr. (Gerardi & Court) 1299:14-1302:4; Tr. (Court) 1319:10-1320:1-2.

attorneys' fees that will remedy the harm that Wellstat suffered. If the parties cannot agree, then Wellstat may make a targeted application.

### **III. CONCLUSION**

Judgment is entered in favor of Wellstat on its claim for breach of contract. BTG is liable for damages of \$55.8 million plus compound interest at a rate of 1% per month from September 15, 2015, until the date of payment. Wellstat is awarded its costs as a prevailing party. BTG and Wellstat shall confer regarding the limited award of attorneys' fees contemplated by this decision. If there are other outstanding issues that the court needs to address before a final order can be entered, then the parties shall submit a joint letter within thirty days that identifies the issues and proposes a path that will enable the court to bring this case to a conclusion. Otherwise, the parties shall confer regarding a final order to implement these rulings.