

**SUPERIOR COURT
OF THE
STATE OF DELAWARE**

VIVIAN L. MEDINILLA
JUDGE

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Decided: March 25, 2024
Issued: April 11, 2024*

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**Re: Nivagen Pharm., Inc. v. Hikma Pharm. USA Inc.
C.A. No. N23C-09-062 VLM CCLD**

Dear Counsel:

This is the Court’s decision on Defendant Hikma Pharmaceuticals PLC’s Motion to Dismiss under Superior Court Civil Rule 12(b)(6). For the reasons stated herein, Defendant’s Motion is **GRANTED**.

Relevant Facts & Procedural History¹

Plaintiff Nivagen Pharmaceuticals, Inc. (“Nivagen”) and Defendants Hikma Pharmaceuticals USA, Inc. (“Hikma USA”) and Hikma Pharmaceuticals PLC (“Hikma PLC”) are, as their names portend, pharmaceutical companies. Nivagen and Hikma USA are both Delaware corporations.² Hikma PLC is a United Kingdom entity and Hikma USA’s parent.³

In December 2019, Nivagen filed an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”), seeking

* This decision is issued after approval of the parties’ request for redactions to the originally issued order.

¹ The following facts are derived from Plaintiff’s Complaint, D.I. 1 (hereinafter, “Compl.”) and are presumed to be true solely for purposes of this motion.

² Compl. ¶¶ 2-3.

³ *Id.* ¶¶ 1, 3.

approval to market a generic cysteine hydrochloride injection in 72.5 mg/mL single-dose vials (the “Product”).⁴ In January 2023, representatives from Defendants proposed a deal to Nivagen in which Hikma USA would purchase the ANDA and market the Product.⁵ Following due diligence, Hikma USA and Nivagen entered into an “Exclusive Licensing and Commercialization Agreement” on April 14, 2023 (the “Agreement”).⁶

The Agreement required Nivagen to transfer ownership of the ANDA to Hikma USA.⁷ In return, Hikma USA was obligated to make a “one-time upfront payment” [REDACTED] to Nivagen.⁸ The Agreement further provided that Nivagen and Hikma USA “would share equally in the net profits generated by the sales of the Product.”⁹ To ensure that the Product would generate profits, Hikma USA was “responsible for maintaining the ANDA” and obligated to “use best efforts to Commercialize the Product.”¹⁰

The parties’ plans to commercialize the Product were disrupted less than two weeks after they executed the Agreement. Specifically, on April 25, 2023, the FDA sent Hikma USA a letter [REDACTED]”¹¹ The FDA [REDACTED] which had been the topic of disclosures during due diligence.¹² The next day, April 26, 2023, [REDACTED] the ANDA.¹³ The ANDA was [REDACTED].¹⁴ This development changed Hikma USA’s views on the Agreement.

On April 27, 2023—one day before the [REDACTED] upfront payment was due—Hikma USA sent Nivagen a letter seeking to modify the Agreement.¹⁵ Hikma USA took the position that [REDACTED]

⁴ *Id.* ¶ 7.

⁵ Compl. ¶¶ 10, 14.

⁶ *Id.* ¶¶ 14, 35.

⁷ *Id.* ¶ 36.

⁸ *Id.* ¶ 40.

⁹ *Id.* ¶ 42.

¹⁰ *Id.* ¶¶ 37, 43.

¹¹ *Id.* ¶ 62.

¹² *Id.* ¶¶ 17-21, 28-34.

¹³ *Id.* ¶ 64.

¹⁴ *Id.* ¶¶ 63-64.

¹⁵ *Id.* ¶ 66.

██████████¹⁶ Hikma USA ██████████
██████████.¹⁷ Nivagen refused and requested assurances that Hikma USA would pay the full ██████████¹⁸ Hikma USA did not do so and has not paid Nivagen to date.¹⁹ In addition to failing to make the upfront payment, Hikma USA allegedly chose to discontinue the ANDA without Nivagen’s consent, apparently giving up on commercializing the Product.²⁰

Hikma PLC’s role in these events is less clear. The Complaint alleges that Hikma PLC was actively involved in the negotiation of the Agreement and the related due diligence.²¹ But after the Agreement was executed, Nivagen only alleges that “[u]pon information and belief, Hikma [USA]’s [alleged breaches of the Agreement were] made at the direction of, and with the connivance of, [Hikma PLC].”²² Nivagen’s Complaint also asserts, without explanation, that Hikma PLC’s alleged actions were unjustified and malicious.²³

Following Hikma USA’s alleged breaches of the Agreement, Nivagen initiated this action by filing a three-Count Complaint against Defendants in September 2023. Counts I and III are against Hikma USA and plead breach of contract and unjust enrichment, respectively.²⁴ Count II is against Hikma PLC and pleads tortious interference with contract.²⁵

On December 18, 2023, Hikma USA answered the Complaint,²⁶ but Hikma PLC moved to dismiss Count II of the Complaint under Superior Court Civil Rule

¹⁶ *Id.*

¹⁷ *Id.* ¶ 67.

¹⁸ Compl. ¶ 67

¹⁹ *Id.* ¶ 72.

²⁰ *Id.* ¶¶ 79, 84. Hikma PLC asserts that ██████████

██████████ See Hikma PLC’s Reply Brief in Support of its Motion to Dismiss, D.I. 38 (hereinafter, “Def.’s Reply”) at 4 n.1. Nevertheless, for present purposes, only the allegations in the Complaint are relevant. See *US Dominion, Inc. v. Fox News Network, LLC*, 2021 WL 5984265, at *21 (Del. Super. Dec. 16, 2021) (“The complaint generally defines the universe of facts that the trial court may consider in ruling on a Rule 12(b)(6) motion to dismiss” (quoting *In re Gen. Motors (Hughes) S’holder Litig.*, 897 A.2d 162, 168 (Del. 2006))).

²¹ Compl. ¶¶ 9-11, 15.

²² *Id.* ¶¶ 74, 83, 87.

²³ *Id.* ¶¶ 114-16.

²⁴ *Id.* ¶¶ 98-107, 118-24.

²⁵ *Id.* ¶¶ 108-117.

²⁶ Hikma USA’s Answer, D.I. 25.

12(b)(6).²⁷ Nivagen opposed Hikma PLC’s Motion on January 30, 2024.²⁸ Hikma PLC replied on February 22, 2024.²⁹ The Court heard argument on February 29, 2024.

Parties’ Contentions

Hikma PLC’s Motion is based on a single theory. It relies on the so-called “affiliate privilege,” which elevates the standard for tortious interference with contract when the interferer is affiliated with the breaching party.³⁰ Under that rule, a plaintiff must allege that the interferer engaged in conduct that diverged from the legitimate pursuit of its affiliate’s economic interests.³¹ According to Hikma PLC, Nivagen fails to plead any facts that support an inference of such bad faith conduct.³²

Nivagen takes the opposite view. Although Nivagen accepts that the affiliate privilege applies, it claims it has met its burden.³³ Nivagen contends that breaching the Agreement was not in Hikma USA’s economic interest.³⁴ And that since Hikma PLC was involved in the inception of the Agreement, it is reasonable to infer that Hikma PLC was also involved in the contravention of that Agreement.³⁵ Nivagen concludes that its allegations are enough to clear the low bar applicable at the pleading stage.³⁶

Standard of Review

On a motion to dismiss for failure to state a claim under Rule 12(b)(6), all well-pleaded allegations in the complaint must be accepted as true.³⁷ Even vague allegations are considered well pled if they give the opposing party notice of a claim.³⁸ The Court must draw all reasonable inferences in favor of the non-moving party.³⁹ However, the Court will not “accept conclusory allegations unsupported

²⁷ Hikma PLC’s Motion to Dismiss, D.I. 24 (hereinafter, “Def.’s Mot.”).

²⁸ Nivagen’s Answering Brief in Opposition to Hikma PLC’s Motion to Dismiss, D.I. 35 (hereinafter “Pl.’s Opp’n”).

²⁹ Def.’s Reply.

³⁰ See Def.’s Mot. at 4.

³¹ *Id.* at 5 (citing *Shearin v. E.F. Hutton Grp., Inc.*, 652 A.2d 578, 589 (Del. Ch. 1994)).

³² *Id.* at 6-9.

³³ Pl.’s Opp’n at 7.

³⁴ *Id.* at 8-10.

³⁵ *Id.* at 10.

³⁶ *Id.*

³⁷ *Spence v. Funk*, 396 A.2d 967, 968 (Del. 1978).

³⁸ *In re Gen. Motors*, 897 A.2d at 168 (quoting *Savor, Inc. v. F.M.R. Corp.*, 812 A.2d 894, 896-97 (Del. 2002)).

³⁹ *Id.*

by specific facts,” nor “draw unreasonable inferences in favor of the non-moving party.”⁴⁰ The Court will grant the motion to dismiss “only if it appears with reasonable certainty that the plaintiff could not prove any set of facts that would entitle [the plaintiff] to relief.”⁴¹

Discussion

A tortious interference with contract claim must satisfy five elements: “(1) a contract, (2) about which defendant knew, and (3) an intentional act that is a significant factor in causing the breach of such contract, (4) without justification, (5) which causes injury.”⁴² The scope of this tort is “narrowly circumscribe[d]” in Delaware to avoid penalizing legitimate competition in the marketplace.⁴³ The affiliate privilege emanates from similar principles.

Respect for corporate separateness is a pillar of Delaware jurisprudence.⁴⁴ In light of that tenet, Delaware courts have chosen to make it difficult to implicate a parent entity in a claim for its subsidiary’s breach of contract.⁴⁵ Were it otherwise, “every-day consultation or direction between parent corporations and subsidiaries about contractual implementation would lead parents to be always brought into breach of contract cases.”⁴⁶ So, Delaware courts will presume that a parent entity’s alleged interference was justified by legitimate profit-seeking activities, and plaintiffs must allege specific facts to rebut that presumption.⁴⁷ In other words, the plaintiff “must adequately plead that the defendant ‘was motivated by some malicious or other bad faith purpose.’”⁴⁸

⁴⁰ *Price v. E.I. DuPont de Nemours & Co.*, 26 A.3d 162, 166 (Del. 2011) (citation omitted).

⁴¹ *Sliney v. New Castle Cty.*, 2019 WL 7163356, at *1 (Del. Super. Dec. 23, 2019).

⁴² *Surf’s Up Legacy Partners, LLC v. Virgin Fest, LLC*, 2021 WL 117036, at *6 (Del. Super. Jan. 13, 2021) (quoting *Bhole, Inc. v. Shore Invs., Inc.*, 67 A.3d 444, 453 (Del. 2013)).

⁴³ *Id.* (quoting *Shearin*, 652 A.2d at 589).

⁴⁴ *See Barbey v. Cerego, Inc.*, 2023 WL 6366055, at *9 (Del. Ch. Sept. 29, 2023) (“[O]ur corporation law is largely built on the idea that the separate legal existence of corporate entities should be respected” (alteration in original) (quoting *Allied Cap. Corp. v. GC-Sun Hldgs., L.P.*, 910 A.2d 1020, 1038 (Del. Ch. 2006))).

⁴⁵ *Surf’s Up*, 2021 WL 117036, at *7; *see also New Enter. Assocs. 14, L.P. v. Rich*, 292 A.3d 112, 143 (Del. Ch. 2023) (discussing the conceptual underpinnings of the affiliate privilege).

⁴⁶ *Renco Grp., Inc. v. MacAndrews AMG Hldgs. LLC*, 2015 WL 394011, at *9 (Del. Ch. Jan. 29, 2015) (quoting *Allied Cap.*, 910 A.2d at 1039)).

⁴⁷ *Surf’s Up*, 2021 WL 117036, at *7 (citations omitted); *Shearin*, 652 A.2d at 591.

⁴⁸ *James Cable, LLC v. Millennium Digit. Media Sys., L.L.C.*, 2009 WL 1638634, at *4 (Del. Ch. June 11, 2009) (quoting *Shearin*, 652 A.2d at 591).

Although a plaintiff’s burden at the pleading stage is light here, Nivagen fails to carry its burden to save its tortious interference claim. Nivagen’s allegations against Hikma PLC are conclusory and lack any specific assertions that raise a reasonable inference of bad faith conduct. Since bad faith is required in this context, Nivagen’s Complaint fails as to Hikma PLC.

Not one fact in the Complaint relates to a reason why Hikma PLC would be motivated to injure Nivagen or otherwise act against Hikma USA’s pecuniary interest. Nivagen’s brief states that “Nivagen specifically averred that Hikma PLC’s actions were taken without justification and not in good faith, to injure Nivagen.”⁴⁹ But, while the Complaint uses that language, it is entirely conclusory.⁵⁰ Instead of “alleg[ing] facts”⁵¹ to show Hikma PLC’s malice, Nivagen simply parrots the language of the standard in the guise of a factual allegation. That is not enough.⁵²

Nivagen’s contention that Hikma PLC must have been acting in bad faith because Hikma USA’s breach was financially inefficient is unpersuasive. An efficient breach occurs where adhering to a contract is more burdensome than compensating the other party for a breach; and it is a classic example of a justified breach.⁵³ In claiming Hikma USA’s alleged breaches were inefficient, Nivagen only addresses the costs Hikma USA might be obliged to pay as a result.⁵⁴ Nivagen takes no account of the countervailing expenses that Hikma USA potentially avoided.

Even assuming Hikma PLC was involved in the decision to breach the Agreement, and further assuming that the breach was inefficient, that alone only suggests Hikma PLC made a poor business choice. It takes an inferential leap to conclude that Hikma PLC harbored an improper motive when the Complaint offers no hint of what that motive might have been. Even at the pleading stage, the Court will not preserve unsupported claims by crediting speculation.⁵⁵

⁴⁹ Pl.’s Opp’n at 10.

⁵⁰ Compl. ¶¶ 115-16.

⁵¹ *Renco Grp.*, 2015 WL 394011, at *9 (emphasis in original).

⁵² *See Yu v. GSM Nation, LLC*, 2018 WL 2272708, at *19 (Del. Super. Apr. 24, 2018) (“[I]t is not enough to make conclusory allegations mirroring the elements . . .”).

⁵³ *James Cable*, at *4 (Del. Ch. June 11, 2009) (quoting *Allied Cap.*, 910 A.2d at 1039).

⁵⁴ Pl.’s Opp’n at 8-10.

⁵⁵ *See In re Paramount Gold & Silver Corp. Stockholder Litig.*, 2017 WL 1372659, at *12 n.65 (Del. Ch. Apr. 13, 2017) (explaining an inference cannot “be based on surmise, speculation, conjecture, or guess, or on imagination or supposition” (quoting *In re Asbestos Litig.*, 2017 WL 510463, at *1 n.2 (Del. 2017) (TABLE))).

Nivagen’s principal authority in defense of its Complaint—*PPL Corp. v. Riverstone Holdings LLC*⁵⁶—does not militate for a different result. In that case, the Court of Chancery permitted a tortious interference claim to go forward against the parent of a breaching party.⁵⁷ But, critically, the Court found “it is well-pled here that [the parent] ‘use[d] its control of a subsidiary, not to enrich the subsidiary, but to divert value from the subsidiary to itself in a bad faith manner’”⁵⁸ Indeed, the complaint in *PPL* detailed an alleged scheme in which a parent entity drained its subsidiary of resources and then caused the subsidiary to breach an indemnity agreement by filing suit against PPL.⁵⁹ The alleged purpose of that scheme was for the parent to “profit from a subsequent lawsuit against the PPL parties.”⁶⁰ Nivagen offers no comparable explanation of what unjustified benefit Hikma PLC sought to obtain from Hikma USA’s alleged breaches, let alone an explanation supported by facts. Because the focus is on Hikma PLC’s motivation, that explanation is necessary.

Nivagen’s other chief authority—*New Enterprise Associates 14 L.P. v. Rich*⁶¹—is distinguishable on the same grounds. The plaintiffs in *New Enterprise* were able to overcome the affiliate privilege at the pleading stage.⁶² Like in *PPL*, the *New Enterprise* plaintiffs did so by pleading specific facts about how the parent entities benefitted themselves at the expense of the subsidiary.⁶³ In *New Enterprise*, the defendant parents bought additional stock in their subsidiary “at what was inferably an undervalued price.”⁶⁴ That displeased other investors in the subsidiary whose right of first offer was dishonored in the process.⁶⁵ The Court of Chancery reasoned that by paying a bargain price for the stock, the defendants ostensibly benefitted themselves at the expense of the subsidiary.⁶⁶ The Court concluded, “[b]ased on these pled facts, it is reasonably conceivable that the [defendants] acted without justification.”⁶⁷ So, like *PPL*, *New Enterprise*’s result was based on

⁵⁶ 2019 WL 5423306 (Del. Ch. Oct. 23, 2019).

⁵⁷ *Id.* at *13.

⁵⁸ *Id.* (second alteration and omission in original) (quoting *Allied Cap.*, 910 A.2d at 1042).

⁵⁹ *Id.* at *2-5.

⁶⁰ *Id.* at 13.

⁶¹ 292 A.3d at 140-43.

⁶² *Id.* at 143.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at 126-27, 143.

⁶⁶ *Id.* at 143.

⁶⁷ *Id.* (emphasis added).

specific factual allegations about the defendants' motivation. Analogous allegations do not appear anywhere in Nivagen's Complaint.

In sum, Nivagen has not pled facts that raise a reasonable inference of an improper motive by Hikma PLC. Its failure to do so is fatal to its tortious interference claim. To the extent Nivagen is entitled to recovery, its remedy is against Hikma USA, not Hikma PLC. Thus, Hikma PLC's Motion to Dismiss Count II of the Complaint is **GRANTED**.

Sincerely,
/s/ Vivian L. Medinilla
Vivian L. Medinilla
Judge