IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEUROCRINE BIOSCIENCES, INC., *Plaintiff*, v. **SPRUCE BIOSCIENCES, INC.**, *Defendant*.	**Case No. 1:25-cv-00059-JDW**

MEMORANDUM

Like Mills Lane, federal courts referee real fights, not manufactured spats. Neurocrine Biosciences, Inc. fears that Spruce Biosciences, Inc. will sue it for patent infringement and seeks a declaratory judgment invalidating Spruce's patent. However, the facts alleged don't establish real case or controversy, so I will dismiss the case for lack of subject matter jurisdiction.

I. BACKGROUND

A. Facts

1. The Parties

Neurocrine is a pharmaceutical company that develops treatments for under-addressed diseases. On December 13, 2024, the U.S. Food and Drug Administration approved Neurocrine's prescription medicine for classic congenital adrenal hyperplasia ("CAH"), CRENESSITY™ (crinecerfont). Neurocrine commercially released the treatment on

December 20, 2024. CRENESSITY™ is the first and only FDA-approved CRF_1 receptor antagonist for the treatment of classic CAH.

Spruce is a clinical-stage company that develops treatments for neurological and endocrine disorders, including CAH. One of Spruce's projects was the use of tildacerfont—also a CRF_1 receptor antagonist—to treat CAH. However, in December 2024, Spruce announced that it was winding down its investment in tildacerfont to treat CAH. Spruce maintains that it "remains active in innovation" and is exploring the use of tildacerfont to treat other conditions. (D.I. 19 at 9.)

2. Related litigation

Spruce owns four patents regarding the use of CRF_1 receptor antagonists to treat CAH: U.S. Patent Nos. 10,849,908 ("'908 Patent"), 11,007,201 ("'201 Patent"), 12,115,166 ("'166 Patent"), and 11,344,557 ("'557 Patent"). According to Neurocrine, Spruce has used these patents to interfere with Neurocrine's CAH business by "improperly expand[ing] its claims to cover the *entire genus* of CRF_1 receptor antagonists to target Neurocrine's crinecerfont, without including structural limitations or sufficient written description support." (D.I. 1 at 2–3.)

Neurocrine petitioned the Patent Trial And Appeal Board ("PTAB") for post-grant review of the '908, '201, and '166 Patents. The PTAB issued Final Written Decisions as to the '908 and '201 Patents in November 2024, finding all claims invalid for lack of written description. Proceedings regarding the '166 Patent are ongoing. In December 2024,

Spruce filed for director review of the PTAB's decisions invalidating the '908 and '201 Patents. Neurocrine has also challenged Spruce's European Patent No. 3784233 before the European Patent Office.

3. Spruce's public filings

Spruce's recent Form 10-Q and 10-K submissions to the Securities and Exchange Commission identify Neurocrine as a competitor. As a representative example, Spruce's Form 10-Q for the quarter ending in September 2024 states that: "Neurocrine Biosciences, Inc. is developing a CRF_1 receptor antagonist and filed NDAs in adult and pediatric classic CAH. The FDA has accepted both NDAs with priority review designations with target action dates in December 2024." (D.I. 24-1 at 4.)

Public documents also discuss Spruce's patent holdings. Spruce's press release from January 6, 2021, shares that the company "continues to expand its patent portfolio for tildacerfont" and that its "newly issued ['908] patent covers broad claims regarding the use of a CRF1 receptor antagonist for the treatment of CAH and further extends exclusivity through 2038." (D.I. 24-2 at 3.) Similarly, its press release from August 10, 2021, discusses how its new '201 Patent "builds on existing composition of matter and method of use patents, and broadens tildacerfont's patent exclusivity through 2038." (D.I. 24-3 at 2.) Finally, its press release from August 10, 2022, states that its '557 and '177 Patents "cover broad claims regarding the use of a CRF-1 receptor antagonist" and "expand existing patent exclusivity through 2038." (D.I. 24-4 at 2.)

4. Prior correspondence

On December 10, 2024, Neurocrine contacted Spruce requesting a "covenant not to sue Neurocrine (and its licensees) on any of [Spruce's] U.S. patents and their foreign counterparts (now and in the future) with claims directed to CRF_1 receptor antagonists, including crinecerfont." (D.I. 1-1, Ex. J.) Neurocrine also asked for a written commitment that Spruce would not challenge the PTAB's decisions invalidating the '908 and '201 Patents. (*Id.*)

Spruce responded, asking for a point of contact at Neurocrine "[i]f the intent of the letter is to express interest in a business discussion rather than posturing[.]" (D.I. 1-1, Ex. K.) Neurocrine replied that it wasn't interested in business discussions and reiterated its request for a covenant not to sue. (*Id.*)

On January 6, 2025, Neurocrine contacted Spruce again with similar requests for a covenant not to sue and assurances that Spruce wouldn't challenge the PTAB's decisions. Spruce suggested a telephone call "to resolve any confusion," but Neurocrine refused and stated that unless Spruce agreed to an unconditional covenant not to sue, it would "have no choice but to begin legal and administrative proceedings." (D.I. 1-1, Ex. Z.)

On March 10, 2025, Neurocrine proposed a new, narrower covenant in exchange for dismissal of this suit. Specifically, Neurocrine requested a "license" applying to "any past, present, or future product … provided by or for Neurocrine or any of its Affiliates." (D.I. 19 at 6.) Spruce has not responded to this most recent demand.

B. Procedural History

Neurocrine filed a complaint against Spruce for declaratory judgment of invalidity of the '557 Patent on January 14, 2025. On March 19, 2025, Spruce filed a Motion To Dismiss for lack of subject matter jurisdiction. (*See* D.I. 18.) The Motion is ripe.

II. LEGAL STANDARD

A challenge to subject matter jurisdiction under Rule 12(b)(1) may be facial or factual. *See Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). A facial attack raises a pleading deficiency without disputing the facts alleged in the complaint, and it requires the court to accept the allegations of the complaint as true. *See Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016) (citation omitted). A factual attack raises a factual dispute, "either through the filing of an answer or otherwise present[ing] competing facts." *Id.* (quotation omitted). Unlike a facial attack, no presumption of truthfulness attaches to the allegations in the complaint. *Id.* Instead, the court may weigh evidence outside of the pleadings and "satisfy itself as to the existence of its power to hear the case." *Id.* (citation omitted). Regardless of whether the challenge is facial or factual, the plaintiff bears the burden of proving that the court has subject matter jurisdiction. *Id.* at 349 (citation omitted). If the court concludes that it lacks subject matter jurisdiction, it must dismiss the case. *See* FED. R. CIV. P. 12(h)(3).

The Declaratory Judgment Act requires "a case of actual controversy" to exist between the parties for a federal court to exercise jurisdiction. 28 U.S.C. § 2201(a). The

phrase "case of actual controversy" refers to the type of cases and controversies that are justiciable under Article III of the Constitution. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted). To satisfy this requirement, "the facts alleged, under all the circumstances, [must] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (citation omitted).

In a patent case, declaratory judgment jurisdiction arises "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license[.]" *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007) (citation omitted). Jurisdiction "generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *Id.* The party seeking a declaratory judgment bears the burden of establishing the existence of an actual case or controversy. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95 (1993).

III. ANALYSIS

Spruce didn't file an answer or present competing facts, so I treat its motion to dismiss as a facial attack and consider only the allegations of the complaint and the documents referenced in that pleading, all in the light most favorable to Neurocrine. *See Davis*, 824 F.3d at 346; *Gould Elecs. Inc. v. U.S.*, 220 F.3d 169, 176 (3d Cir. 2000).

To establish declaratory judgment jurisdiction, Neurocrine must show that Spruce has committed "some affirmative act" to assert its patent rights. *SanDisk*, 480 F.3d at 1381. But the alleged facts don't support that narrative, nor does Neurocrine explain why this case should be an exception to that "general[]" rule. *Id.* Instead, this is a story in which Neurocrine, not Spruce, is the protagonist. Neurocrine sought to invalidate Spruce's patents, and Spruce resisted. When Neurocrine contacted Spruce, attempting to extract a covenant not to sue, Spruce responded. Though Neurocrine succeeded in eliciting these reactions from Spruce, it can't cobble them together to manufacture declaratory judgment jurisdiction. Its arguments don't persuade me otherwise.

First, Neurocrine points to the Parties' ongoing litigation over the validity of Spruce patents that articulate similar claims as the disputed '557 Patent. However, unlike cases where related litigation led courts to conclude that the parties are "plainly ... at war," the litigation here consists solely of Neurocrine's attempts to invalidate Spruce's patents, and Spruce's defense of its patents. *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1331 (Fed. Cir. 2014). So, if this is a war, only Neurocrine is waging it. Finding declaratory judgment jurisdiction on this basis would flout the requirement of some "affirmative" action by the defendant. *SanDisk Corp.*, 480 F.3d at 1381. And it would empower plaintiffs to single-handedly create declaratory judgment jurisdiction. That's inconsistent with the case-or-controversy requirement, which limits jurisdiction to "substantial" disputes "of sufficient immediacy and reality." *MedImmune*, 549 U.S. at 127.

Second, Neurocrine points to Spruce's public filings and press releases, which discuss its patent holdings and identify Neurocrine as a competitor. Based on these statements, Neurocrine concludes that "[t]he most reasonable inference" is that Spruce intends to sue Neurocrine for infringement. (D.I. 23 at 8–9.) But none of these statements indicates that Spruce believes that CRENESSITY™ infringes its patents, much less that it plans to sue. Neurocrine's inference stretches the evidence too far. All that Neurocrine has shown is that Spruce issued statements "identifying its patent and [Neurocrine's] product line," which isn't enough to establish "adverse legal interests between the parties, let alone the existence of a 'definite and concrete' dispute." *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1362 (Fed. Cir. 2009).

Neurocrine's reliance on *Birchwood* misses the mark. *See Birchwood Lab'ys, Inc. v. Battenfeld Techs., Inc.*, No. 09-cv-3555, 2010 WL 1687789 (D. Minn. Apr. 26, 2010). In that case, the defendant alleged that there was an infringing device on the market and the unnamed plaintiff was necessarily the maker of that device. *See id.* at *4. In this case, only the latter is true; Neurocrine has the only approved CRF_1 receptor antagonist to treat CAH. However, Spruce has never alleged that an infringing product exists. Thus, *Birchwood* doesn't change my analysis of the facts, and the other cases that Neurocrine cites are similarly distinguishable. (D.I. 25 at 7.)

Third, Neurocrine characterizes Spruce as "a non-practicing, patent-licensing entity" in financial distress, with a strong incentive to extract royalties from Neurocrine.

(D.I. 23 at 14–15.) Even if this characterization of Spruce's business is correct, it doesn't weigh in favor of exercising declaratory judgment jurisdiction. At best, these are factors that could make a company more likely to assert its intellectual property rights. But some actual assertion—an affirmative act—is still necessary for declaratory judgment jurisdiction, and Neurocrine can't point to one.

Nor does *Hewlett-Packard* suggest that jurisdiction is appropriate here. In that case, the Federal Circuit observed that the defendant was "solely a licensing entity" and that "without enforcement it receives no benefits from its patents." *Hewlett-Packard Co.*, 587 F.3d at 1364. The court concluded that this "adds significance to the fact that [the defendant] refused [the plaintiff's] request for a mutual standstill—and such a limited standstill is distinguishable from a covenant not to sue[.]" *Id.* This case doesn't involve a request for a mutual, limited standstill or affirmative outreach from the patentee to the declaratory judgment plaintiff, as *Hewlett-Packard* did. *See id.*

Finally, Neurocrine argues that Spruce's refusal to agree to a covenant not to sue, together with Spruce's other actions, "objectively demonstrate a justiciable controversy[.]" (D.I. 23 at 18.) But a failure to sign a covenant not to sue, on its own, "is not sufficient to create an actual controversy," and Spruce's other alleged actions don't help Neurocrine cross that threshold. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1341 (Fed. Cir. 2008) (citation omitted). None of them constitutes affirmative action by Spruce, and they don't collectively amount to such action—a string of zeros sums to zero.

Spruce's responses to Neurocrine's outreach don't change that conclusion. Neurocrine construes Spruce's offer to engage in "business discussions" as nefarious, but nothing suggests that this was anything beyond a response to Neurocrine's own outreach. And Neurocrine's "subjective or speculative fear" doesn't create an actual controversy. *Id.* at 1339. Nor did Spruce have a responsibility to counter Neurocrine's proposed covenant with one of its own, for "[a] patentee has no obligation ... to make a definitive determination, at the time and place of the competitor['s] choosing, that it will never bring an infringement suit." *Id.* at 1341.

IV. CONCLUSION

Neurocrine's allegations demonstrate that it sees Spruce's patents as a potential threat, but it hasn't shown that Spruce has done anything to assert its patent rights against Neurocrine. Instead, the most it has pled is that Spruce refused to concede when Neurocrine asked it to do so. Therefore, there is no Article III case or controversy, and I must dismiss this case for lack of subject matter jurisdiction. An appropriate Order follows.

BY THE COURT:

/s/ Joshua D. Wolson
JOSHUA D. WOLSON, J.

June 9, 2025

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEUROCRINE BIOSCIENCES, INC., *Plaintiff*, v. **SPRUCE BIOSCIENCES, INC.**, *Defendant*.	**Case No. 1:25-cv-00059-JDW**

ORDER

AND NOW, this 9th day of June, 2025, upon consideration of Spruce Biosciences, Inc.'s Motion To Dismiss (ECF No. 18), it is **ORDERED** that the Motion is **GRANTED** and the above-captioned matter is **DISMISSED WITHOUT PREJUDICE** for lack of subject matter jurisdiction. The Clerk of Court shall mark this case closed for statistical purposes.

BY THE COURT:

/s/ Joshua D. Wolson
JOSHUA D. WOLSON, J.