

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NEUROCRINE BIOSCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 25-59-JDW
v.	)	
	)	
SPRUCE BIOSCIENCES, INC.,	)	
	)	
Defendant.	)	

**DEFENDANT SPRUCE BIOSCIENCES, INC.’S OPENING BRIEF IN SUPPORT OF
ITS MOTION TO DISMISS THE COMPLAINT**

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TABLE OF ABBREVIATIONS

'166 patent	U.S. Patent No. 12,115,166 (D.I. 1-1, Ex. D)
'201 patent	U.S. Patent No. 11,007,201 (D.I. 1-1, Ex. C)
'557 patent	U.S. Patent No. 11,344,557 (D.I. 1-1, Ex. A)
'908 patent	U.S. Patent No. 10,849,908 (D.I. 1-1, Ex. B)
CAH	congenital adrenal hyperplasia
MDD	major depressive disorder
Neurocrine	Neurocrine Biosciences, Inc.
PCOS	polycystic ovary syndrome
PTAB	Patent Trial and Appeal Board
Rosato Decl.	Declaration of Michael Rosato filed herewith
Rosato-#	Exhibits attached to the Rosato Decl.
SEC	Security and Exchange Commission
Spruce	Spruce Biosciences, Inc.

I. NATURE AND STAGE OF THE PROCEEDINGS

On January 14, 2025, Neurocrine filed a complaint against Spruce for declaratory judgment of invalidity of the '557 patent. D.I. 1 at 1. Notably absent is any evidence of even a single affirmative action by Spruce that would support declaratory judgment jurisdiction because none exists. The pleadings establish the opposite, demonstrating that any communications between the parties were solely initiated by Neurocrine—not Spruce. None of Neurocrine's allegations evidences a real and immediate injury or threat of future injury to Neurocrine caused by Spruce and no such evidence exists. Rather, Neurocrine only presents an artificially manufactured and speculative fear of harm, which is not sufficient to establish declaratory judgment jurisdiction.

On March 13, 2025, the Court set a briefing schedule for a motion to dismiss for lack of subject matter jurisdiction. D.I. 16. Because there is no actual case or controversy, Spruce now moves to dismiss Neurocrine's complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1).

II. SUMMARY OF ARGUMENT

1. Neurocrine's complaint does not allege a controversy of sufficient immediacy and reality to create a justiciable controversy because it does not "allege an affirmative act by [Spruce] relating to the enforcement of [its] patent rights" and therefore fails to "establish an injury in fact traceable to [Spruce]." *3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372, 1377 (Fed. Cir. 2012); *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008). Neurocrine cannot cure that defect because Spruce has taken no such affirmative action.

2. Neurocrine's allegation that Spruce owns patents is not sufficient to establish a justiciable controversy. *Prasco*, 537 F.3d at 1338 (it is the Federal Circuit's "long-standing rule that the existence of a patent is not sufficient to establish declaratory judgment jurisdiction").

3. Neurocrine’s challenge of Spruce patents that are not at issue in this litigation does not establish a justiciable controversy. *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1382 (Fed. Cir. 2010) (holding that, where prior litigation was not initiated by the defendant against the declaratory judgment plaintiff, this litigation did not, “in the absence of any act directed toward [plaintiff], meet the minimum standard discussed in *MedImmune [Inc. v. Genentech, Inc.]*, 549 U.S. 118 (2007)”).

4. Neurocrine’s unilateral choice not to file a post grant review petition with the PTAB regarding the ’557 patent does not establish a justiciable controversy. *Prasco*, 537 F.3d at 1341 (holding a justiciable controversy requires action by the patentee).

5. Neurocrine’s unmet demand for an unreasonably broad covenant not to sue (1) for Spruce’s entire, worldwide, current and future patent portfolio, (2) for Neurocrine and any third party of Neurocrine’s choosing now or at any time in the future, and (3) covering any product, does not establish a justiciable controversy. *Organic Seed Growers & Trade Ass’n v. Monsanto*, 851 F. Supp. 2d 544, 554 (S.D.N.Y. 2012), *aff’d*, 718 F.3d 1350 (Fed. Cir. 2013).

6. Spruce’s generic discussion of its intellectual property rights and the competitive landscape for its business in reports filed with the Security and Exchange Commission in compliance with applicable regulations does not establish a justiciable controversy. *Ontel Prods. Corp. v. Yeti Coolers, LLC*, No. 16-5712, 2017 WL 3033436, at *2 (D.N.J. June 30, 2017).

III. STATEMENT OF FACTS

A. All Contact Between Spruce and Neurocrine Was Initiated By Neurocrine, Not Spruce

Spruce has never contacted Neurocrine about Spruce’s patents, Neurocrine’s Crenessity™ product, or anything else. Any contact between the parties over the past four years

is a result of Neurocrine initiating reviews of three of Spruce’s United States patents and one of Spruce’s foreign patents.

i. Neurocrine’s Three United States Post-Grant Review Petitions

First, on May 28, 2021, without any provocation from Spruce, Neurocrine filed a petition for post-grant review with the PTAB of Spruce’s ’908 patent, which issued on December 1, 2020. D.I. 1-1, Ex. F at 2, 6. On December 10, 2021, the PTAB denied that petition, determining that Neurocrine failed to demonstrate that it is more likely than not that it would prevail in establishing the unpatentability of any claim of the ’908 patent. *Id.* at 2.

Second, on February 18, 2022, again without any provocation from Spruce, Neurocrine filed a petition for post-grant review of Spruce’s ’201 patent. D.I. 1-1, Ex. G at 2 (“On February 18, 2022, Neurocrine Biosciences, Inc. (“Petitioner”) filed a Petition for Post-Grant Review of claims 1–19 of the ’201 patent.”). Neurocrine’s complaint incorrectly alleges that this petition was filed on May 28, 2021 (D.I. 1, ¶ 43), it was not. In fact, the ’201 patent issued on May 18, 2021 (D.I. 1-1, Ex. G at 1), and petitions for post-grant review may be filed within 9 months of issuance of a patent (35 U.S.C. § 321(c))—Neurocrine waited until the day of that deadline to file its petition regarding the ’201 patent. On September 15, 2022, the PTAB denied Neurocrine’s petition, again finding that Neurocrine did not satisfy its burden to show that it is more likely than not that any claim of the ’201 patent unpatentable. D.I. 1-1, Ex. G at 2.

Following denial of its petitions regarding the ’908 and ’201 patents because Neurocrine failed to show it is more likely than not that any challenged claim was invalid, Neurocrine requested rehearing on January 10, 2022 (D.I. 1-1, Ex. F at 2) and October 13, 2022 (D.I. 1-1, Ex. G at 2). The patent office did not act on Neurocrine’s rehearing requests for 26 months, then on July 20, 2023, issued an order *sua sponte* granting director review. D.I. 1-1, Ex. F at 2; D.I. 1-1, Ex. G at 3. Through a lengthy, protracted, and highly unusual proceeding, the PTAB

reversed its denial and instituted post-grant review of both patents on December 1, 2023—two and a half years after Neurocrine filed the first petition. D.I. 1-1, Ex. F at 2-3; D.I. 1-1, Ex. G at 3. Those proceedings continued through the November 26, 2024 and November 27, 2024 Final Written Decisions that are currently subject to appeal. D.I. 1-1, Exs. F, G.

Third, on February 10, 2025 (after filing the present litigation), Neurocrine petitioned the PTAB for post grant review of Spruce’s ’166 patent which issued on October 15, 2024. That proceeding is ongoing.

Neurocrine initiated each of these proceedings without incitement, or even any contact, from Spruce. The patent at issue in the present case (the ’557 patent) issued on May 31, 2022—a year after Neurocrine filed its first post grant review petition, and three months after Neurocrine filed its second post grant review petition. D.I. 1-1, Ex. A at 1. However, for reasons that can only be known to Neurocrine, it chose not to file a post grant review petition regarding the ’557 patent by the 9-month post-issuance deadline, which passed over 2 years ago.¹

ii. Neurocrine’s Challenge of a Spruce European Patent

On December 10, 2024, again without any provocation from Spruce, Neurocrine filed a European Patent Office opposition regarding Spruce’s European Patent No. 3784233. D.I. 1-1, Ex. J at 1 (“Neurocrine has just filed a Notice of Opposition to European Patent No. 3784233.”)²

¹ During the March 12, 2025 conference with the Court regarding the present motion, counsel for Neurocrine alleged that the present case is Neurocrine’s only forum for relief; that is not true. Neurocrine could have timely challenged the ’557 patent at the PTAB in the same manner that it has challenged three other Spruce patents but chose not to.

² After filing the present suit, on January 30, 2025, also without incitement, Neurocrine filed a United Kingdom revocation action regarding the same Spruce patent.

iii. Neurocrine’s Demand for a Covenant Not To Sue for Spruce’s Entire Patent Portfolio For All Time

All correspondence regarding a covenant not to sue have been initiated, without incitement, by Neurocrine. Spruce’s only response has been requests for clarification regarding the scope of Neurocrine’s demand. Neurocrine now mischaracterizes its own outreach as Spruce somehow “attempt[ing] to extract money from Neurocrine” or threatening to enforce any of its patents against Neurocrine, for “ransom” or otherwise. D.I. 1, ¶ 57.

Without provocation from Spruce, Neurocrine initiated correspondence regarding a covenant not to sue on December 10, 2024 demanding:

[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 CRF₁ receptor antagonists, including crinecerfont.

D.I. 1-1, Ex. J at 1. The demand included an open-ended, exemplary list of the patents that Neurocrine required the covenant to encompass. *Id.* at 1-2. Given the broad, imprecise scope of the demand, on December 17, 2024, Spruce’s PGR counsel requested a clarification of whether the demand was symbolic posturing, or an attempt to initiate a business discussion. Rosato Decl., ¶ 5; D.I. 1-1, Ex. K at 1. Two days later, Neurocrine’s counsel responded by repeating the demand from the December 10, 2024 letter. Rosato Decl., ¶ 6; D.I. 1-1, Ex. K at 1. Spruce did not respond.

Again, without incitement from Spruce, Neurocrine sent a second letter on January 6, 2025, restating Neurocrine’s broad covenant demand. D.I. 1-1, Ex. Y. Neurocrine further threatened that if Spruce did not acquiesce to Neurocrine’s demand, “Neurocrine will initiate legal and administrative proceedings, both in the U.S. and elsewhere” and commanded that the covenant be provided within 2 days, by January 8, 2025. *Id.* Spruce did not respond by Neurocrine’s deadline.

On January 10, 2025, Spruce’s PGR counsel responded to Neurocrine’s second demand letter and reminded Neurocrine that all communications between Neurocrine and Spruce had at all times been initiated by Neurocrine, not Spruce. Rosato Decl., ¶ 8; Ex. Rosato-1 at 2. To resolve any potential confusion, Spruce’s PGR counsel suggested a brief phone discussion. Rosato Decl., ¶ 9; Ex. Rosato-1 at 1-2. During that call, Spruce’s PGR counsel asked if the intent was to request a covenant related to the patents at issue in the PGR proceedings and Neurocrine’s counsel stated (1) he was not authorized to discuss a scope limited to the two patents at issue in the PGR proceedings, and (2) Neurocrine’s position was rigid, and Neurocrine’s counsel was retained to conduct a worldwide campaign against Spruce until Spruce gave in to Neurocrine’s demands. Rosato Decl., ¶ 10. On January 13, 2025, Neurocrine’s counsel emailed Spruce’s PGR counsel thanking him for the discussion and reiterating Neurocrine’s demand for a broad covenant and litigation threats. *Id.*, ¶ 11; Ex. Rosato-2 at 1. The following day, January 14, 2025, Neurocrine filed the present litigation. D.I. 1.

On March 10, 2025, after the Court set a March 12 hearing regarding the present motion, Neurocrine proposed a new covenant in exchange for Neurocrine dismissing the present litigation. While styled as a covenant limited to the patent at issue here (the ’557 patent), Neurocrine presented a “license” that applies to “any past, present, or future product ... provided by or for Neurocrine or any of its Affiliates.” Spruce has not responded to Neurocrine’s March 10, 2025 demand.

B. Spruce’s Securities and Exchange Commission Filings

Spruce is a publicly traded company. As such, Spruce is required to file reports with the SEC that include, *e.g.*, a discussion of “Risk Factors” that Spruce’s business faces. 17 CFR 229.105. Those reports include the 10-Q and 8-K filings referenced in Neurocrine’s complaint, none of which contain any threat of patent enforcement action against Neurocrine.

i. Spruce's 10-Qs (Quarterly Reports)

Neurocrine's complaint references four of Spruce's 10-Q SEC submissions, dated September 30, 2020, September 30, 2022, September 30, 2023, and September 30, 2024. D.I. 1, ¶ 48 (citing Exhibits R-U).³ Each of those documents contain discussion of several risk factors that Spruce faced including, *inter alia*, potential for failure to enroll patients in clinical trials, regulatory and compliance obligations, lack of organizational experience in marketing products, changes in funding for government agencies such as FDA, healthcare legislation, and competition that Spruce faces. D.I. 1-1, Exs. R-U; *see also* Exs. R-COMPLETE, U-COMPLETE.⁴ Spruce consistently, broadly defined competition: "Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions." D.I. 1-1, Exs. R-U; Exs. R-COMPLETE at 49, U-COMPLETE at 29. There is no focus on Neurocrine in Spruce's 10-Qs or otherwise. Neurocrine is only discussed as a competitor, along with several other competitors (*e.g.*, BridgeBio Pharma, Inc. and Crinetics Pharmaceuticals, Inc.). *E.g.*, Ex. U-COMPLETE at 29.

ii. Spruce's 8-Ks (Current Reports)

Neurocrine's complaint references three of Spruce's 8-K SEC submissions, dated January 6, 2021, August 10, 2021, and August 10, 2022. D.I. 1, ¶ 49 (citing Exs. V-X). Each of these

³ Neurocrine attached excerpts of these documents to its complaint, omitting the fact that its excerpts are taken from the "Risks Related to Our Business and Industry" sections of Spruce's reports, and omitting several other risks detailed by Spruce in those reports. *E.g.*, Ex. R-COMPLETE at 30-83.

⁴ "COMPLETE" exhibits refer to complete versions of exhibits M, R & U attached to D.I. 1 and filed by Neurocrine. These "COMPLETE" exhibits are attached to the Declaration of Wendy L. Devine, filed herewith.

SEC submissions contains “corporate updates” that Spruce—a publicly traded company—provided to the public regarding progress in Spruce’s product development; they do not discuss Neurocrine. The January 6, 2021 Spruce 8-K details the beginning of Spruce’s Phase 2 studies of tildacerfont for treatment of CAH and PCOS, and notes that a new patent had issued that “extends tildacerfont patent exclusivity through 2038.” D.I. 1-1, Ex. V. The August 10, 2021 Spruce 8-K, among other things, announces submission of Spruce’s Investigational New Drug application for PCOS, publication of Spruce’s tildacerfont CAH phase 2 data, and issuance of a Spruce patent that “broadens tildacerfont’s patent exclusivity through 2038.” D.I. 1-1, Ex. W. Likewise, the August 10, 2022 Spruce 8-K, among other things, announces that an abstract regarding Spruce research would be presented at an industry meeting, Spruce had hired a new Vice President, and Spruce had received a new method of use patent. D.I. 1-1, Ex. X. There is no mention of Neurocrine in these documents.

C. Spruce’s Product Development Efforts

Spruce, which was founded in 2014, is a clinical-stage company dedicated to developing therapeutics and therapeutic protocols for patients suffering from neurological and endocrine disorders. Spruce’s focuses include disorders for which there are insufficient treatment options, including CAH, pediatric CAH, PCOS, and MDD. D.I. 1-1, Ex. M; Ex. M-COMplete at 6-8; Ex. U-COMplete at 14.

One of Spruce’s focuses has been development of tildacerfont—a CRF1 receptor antagonist that was initially developed for treatment of mental health disorders—for treatment of CAH, a rare genetic disorder that, if untreated, can be fatal. Ex. M-COMplete at 4.

Milestones related to that development include:

- **January 2017**—Tildacerfont received European Medicines Agency orphan drug designation for the treatment of CAH. *Id.* at 41.

- **July 2017**—First Phase 2 clinical trial to assess Spruce’s dosing regimen for tildacerfont in adults with CAH began. *Id.* at 16.
- **November 2017**—Tildacerfont received orphan drug designation from the U.S. Food and Drug Administration for the treatment of CAH. *Id.* at 26.
- **September 2018**—Second Phase 2 clinical trial to assess 400mg once-a-day dosing of tildacerfont in adults with CAH began. *Id.* at 19.
- **March 2019**—Spruce achieved proof of concept for therapeutic protocol in first Phase 2 study of adults suffering from CAH using tildacerfont, suggesting that Spruce’s treatment protocol could provide a first-in-class option for patients with CAH. *Id.* at 17-18.
- **September 2019**—Spruce’s second Phase 2 study achieved further positive results towards a treatment protocol that could provide a first-in-class option for patients with CAH. *Id.* at 18.
- **August 2020**—Third Phase 2 study began to assess 50mg, 100mg, and 200mg once-a-day dosing of tildacerfont for reducing adrenal hormones in adults with CAH. *Id.* at 21.
- **September 2020**—Fourth Phase 2 study began to assess 200mg once-a-day dosing of tildacerfont for glucocorticoid reduction in adults with CAH. *Id.* at 23.
- **December 2021**—Fifth Phase 2 study began to assess dose-ranging in adults and children with CAH. *Id.*
- **May 2022**—Sixth Phase 2 study of tildacerfont for the treatment of PCOS began. *Id.* at 24-25.

Spruce’s work with tildacerfont has met challenges. In December 2024, Spruce announced topline results from two further studies that provide “valuable insights that will shape the future of CAH management and research” including “data [that] suggests that a twice-daily dosing may be more effective.” D.I. 1-1, Ex. E at 1. However, because those studies did not meet their primary endpoints, Spruce is “winding down [its] investment in tildacerfont for the treatment of CAH” and is “evaluat[ing] a full range of strategic options ... in addressing diseases with serious unmet need for patients.” *Id.*

Spruce remains active in innovation, including collaborating with HMNC Brain Health GmbH (“HMNC”) to develop tildacerfont as a treatment for MDD, studying tildacerfont for treatment of PCOS, and collaborating with Kaken Pharmaceutical Co., Ltd to develop

tildacerfont as a treatment for CAH in Japan. Ex. M-COMPLETE at 24-25; Ex. U-COMPLETE at 14.

IV. LEGAL STANDARDS

A. Lack of Subject Matter Jurisdiction Under Rule 12(b)(1)

“If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.” Fed. R. Civ. P. 12(h)(3). Subject matter jurisdiction cannot be waived. *Cisco Sys. v. Sprint Commc’ns Co., L.P.*, C.A. No. 15-431-SLR, 2016 WL 690939, at *1 (D. Del. Feb. 19, 2016). Subject matter jurisdiction may be challenged through a motion to dismiss under Rule 12(b)(1) either factually or facially. *Lincoln Benefit Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). The Court may review extrinsic evidence beyond the pleadings, such as affidavits, when considering whether a factual basis for jurisdiction exists. *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). There is also no presumption of truthfulness in the complaint. *Robinson v. Dalton*, 107 F.3d 1018, 1021 (3d Cir. 1997); *Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977).

B. Lack of Subject Matter Jurisdiction in Declaratory Judgment Actions

Once jurisdiction is challenged in a declaratory judgment action, the plaintiff bears the burden to prove subject matter jurisdiction. *MedImmune*, 549 U.S. at 140. Article III of the Constitution limits the federal judicial power to actual “cases and controversies.” U.S. Const, art. III, § 2, cl. 1. “[T]here is no bright-line rule for determining whether [a declaratory judgment] action satisfies the case or controversy requirement.” *Strech, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1282 (Fed. Cir. 2012). However, the party seeking declaratory judgment must prove “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality.” *MedImmune*, 549 U.S. at 127.

“Following *MedImmune*, [the Federal Circuit] ha[s] held that to establish an injury in fact traceable to the patentee[,] a declaratory judgment plaintiff must allege an affirmative act by the patentee relating to the enforcement of his patent rights.” *3M Co.*, 673 F.3d at 1377. There must be some additional enforcement or defense effort related to the patent. *Avocent Huntsville Corp. v. Aten Int’l. Co.*, 552 F.3d 1324, 1332 (Fed. Cir. 2008). The Court has discretion whether to exercise declaratory judgment jurisdiction even where jurisdictional prerequisites are met. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286-87 (1995); *Ford Motor Co. v. United States*, 811 F.3d 1371, 1378 (Fed. Cir. 2016).

V. THE COURT LACKS SUBJECT MATTER JURISDICTION

Neurocrine did not plead any facts establishing declaratory judgment jurisdiction.

A. Spruce Has Not Taken Any Affirmative Action Against Neurocrine

Under Federal Circuit law, Neurocrine cannot establish an injury in fact traceable to Spruce because Neurocrine does not—and cannot—“allege an affirmative act by [Spruce] relating to the enforcement of [Spruce’s] patent rights.” *3M Co.*, 673 F.3d at 1377. Spruce has not taken any affirmative action to enforce its patents, or threatened to do so, against Neurocrine or otherwise. An actual, substantial controversy only exists “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.” *Prasco*, 537 F.3d at 1340 (quoting *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007)) (emphasis added); see *Edmunds Holding Co. v. Autobytel Inc.*, 598 F. Supp. 2d 606, 610-11 (D. Del. 2009) (holding prior patent enforcement and public statements of general intent to enforce patent rights insufficient to establish a case or controversy). Neurocrine does not plead that Spruce has ever taken any such action, because Spruce has not.

The only actions that Neurocrine identifies in its complaint are its own actions.

Neurocrine filed PGR petitions regarding two Spruce patents. D.I. 1, ¶¶ 41, 43. **Neurocrine challenged** Spruce’s European Patent. D.I. 1-1, Ex. J at 1. **Neurocrine demanded** a broad covenant from Spruce covering all of Spruce’s current and future, worldwide, patents related in any manner to CRF1 receptor antagonists and applicable to Neurocrine and any other entity of Neurocrine’s choosing and any product or future product. D.I. 1-1, Exs. J, Y; Ex. Rosato-1. **Neurocrine repeatedly threatened** Spruce with escalating legal action if Spruce did not acquiesce to that demand. *Id.*; Rosato Decl., ¶¶ 9-11. Spruce has never contacted Neurocrine. Neurocrine’s unilateral, unprovoked actions cannot establish a justiciable controversy, thus this case should be dismissed. *Innovative Therapies*, 599 F.3d at 1380-82 (finding that phone calls initiated by declaratory judgment plaintiff did not produce an immediate and real controversy supporting declaratory judgment jurisdiction).

B. Neurocrine’s Choice Not to File a PGR Petition For the ’557 Patent Does Not Create Declaratory Judgment Jurisdiction

Neurocrine’s complaint admits that Neurocrine’s choice to not timely file a PGR petition led to this lawsuit—not any action by Spruce:

“Because the ’557 patent, unlike the ’166 patent, is not PGR-eligible, we bring this action in this Court.”

D.I. 1, ¶ 6. Neurocrine’s deliberate, unilateral decision not to file a PGR petition regarding the ’557 patent prior to the February 28, 2023 deadline does not create declaratory judgment jurisdiction. Neurocrine had from May 31, 2022 to February 28, 2023 to file such a PGR petition. During that time, Neurocrine’s (1) request for rehearing regarding its failed ’908 patent PGR petition, and (2) PGR petition regarding the ’201 patent, were pending. Neurocrine was well aware of the procedure, rules, and deadlines for requesting PGR. Yet, Neurocrine does not even attempt to plead a reason why it chose not to timely file a PGR petition with respect to the

'557 patent. Regardless of whatever that explanation is, it is not an action by Spruce, and therefore there is no declaratory judgment jurisdiction. *Prasco*, 537 F.3d at 1340 (finding no declaratory judgment jurisdiction where the patentee had “taken no affirmative actions at all related to [plaintiff’s] current product.”).

C. Neurocrine’s Unmet Demand For a Covenant Encompassing All Spruce Patents For All Time Does Not Establish Declaratory Judgment Jurisdiction

Neurocrine’s demand for a broad covenant not to sue, and Spruce’s non-response to that demand, do not establish jurisdiction because “failure to sign a covenant not to sue ... is not sufficient to create an actual controversy—some affirmative actions by the defendant will also generally be necessary.” *Prasco*, 537 F.3d at 1341.

Courts have repeatedly found that a patentee’s choice not to acquiesce to a demand for an unreasonably broad covenant is not an affirmative action supporting declaratory judgment jurisdiction. *Organic Seed*, 851 F. Supp. 2d at 554; *Govino, LLC v. Goverre, Inc.*, No. 17-cv-01237, 2017 WL 10399451, at *5 (C.D. Cal. Dec. 11, 2017). Unreasonable breadth includes a covenant covering all claims that a patentee may ever have or a covenant that extends to products beyond those at issue in the declaratory judgment suit. *Organic Seed*, 851 F. Supp. 2d at 554 (A declaratory judgment defendant “declin[ing] to provide [a] plaintiff[] with a written covenant not to bring any claims they might ever have does not meaningfully add to [a] plaintiff[’s] case.”); *Govino*, 2017 WL 10399451, at *5 (internal quotations omitted, citations omitted) (“This is especially true... where [plaintiff’s] request for assurances extends to [products] beyond those at issue in the current suit. Certainly, where the rest of the circumstances indicate that there is no real patent dispute between the parties, [patentee’s] silence in response to such a broad request for assurances does not alone make an infringement action ... imminent.”); see *Lannett Co. v. Kv Pharm.*, C.A. No. 08-338-JJF, 2009 WL 10737496, at *5 (D. Del. Feb. 4, 2009) (granting motion

to dismiss for lack of subject matter jurisdiction where defendant did not provide assurances of non-suit in response to a letter from plaintiff). Neurocrine's demand is even broader and therefore unreasonable on its face.⁵

Spruce's non-response to Neurocrine's overbroad, rigid, unreasonable demand is not an affirmative action by Spruce that evidences any case or controversy between the parties, and thus it does not support declaratory judgment jurisdiction.

D. Spruce's Compliance With SEC Reporting Requirements Does Not Establish a Justiciable Controversy

Neurocrine's selective quoting of Spruce's 10-Q, 10-K, and 8-K SEC filings also does not establish declaratory judgment jurisdiction. Spruce's 8-K filings merely announce issuance of new Spruce patents and their expiration dates; they do not even mention, let alone threaten, Neurocrine. *Supra*, § III.B.ii. Likewise, Spruce's 10-Q and 10-K filings describe, as they must, Spruce's competitive landscape, including "major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions." D.I. 1-1, Exs. R-U. Neurocrine is merely mentioned as one of many competitors (*e.g.*, BridgeBio Pharma, Inc. and Crinetics Pharmaceuticals, Inc.). *Id.* There is no threat, explicit or veiled, in these documents regarding patent enforcement. Neurocrine's speculation otherwise is based entirely on its own subjective speculation, which is insufficient to establish declaratory judgment jurisdiction. *Prasco*, 537 F.3d at 1339 ("purely subjective or speculative fear of future harm" cannot establish a case or controversy); *Ontel Prods.*, 2017 WL 3033436, at *2.

⁵ The covenant that Neurocrine demanded after filing this suit, while narrowed to the '557 patent, remains unreasonably broad at least in that it extends to any and all past, present, or future products made, used, sold, offered for sale, leased, acquired, licensed, imported, exported, supplied or otherwise provided by or for Neurocrine or any of its present or future Affiliates.

E. Spruce's Financial Circumstances Do Not Establish a Justiciable Controversy

In an apparent attempt to distract from the lack of facts supporting declaratory judgment jurisdiction, Neurocrine's complaint paints a false picture of Spruce as a non-practicing, patent-licensing entity. This is wrong. Spruce remains dedicated to developing CRF1 receptor antagonists, including tildacerfont, for a variety of indications. *Supra* III.C; D.I. 1-1, Ex. M. The challenges that Spruce has faced in some of its development work does not change that mission or the character of Spruce's business. In reality, Spruce is working to collaborate with more likeminded companies, including HMNC for tildacerfont as a treatment for MDD and Kaken to develop tildacerfont as a treatment for CAH. *E.g.*, D.I. 1-1, Ex. N; Ex. U-COMplete at 14. Neurocrine's assumption that Spruce has thrown away over *ten years* of work for the treatment of CAH is just another example of Neurocrine's purely subjective speculation, which cannot support declaratory judgment jurisdiction.

Moreover, even if Neurocrine were correct about the state of Spruce's business (which it is not), that still would not establish declaratory judgment jurisdiction. During the March 12, 2025 conference with the Court, Neurocrine cited *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358 (Fed. Cir. 2009) as allegedly supporting the notion that Spruce's financial status creates declaratory judgment jurisdiction, it does not. In *Hewlett Packard*, the Federal Circuit found declaratory judgment jurisdiction because the patentee "took the affirmative step of twice contacting [the declaratory judgment plaintiff] directly." 587 F. 3d at 1364. The Court's finding had nothing to do with the patentee's financial status.

Neurocrine's assumptions regarding Spruce's business are wrong, but even if they were correct, they would not establish a case or controversy to support declaratory judgment jurisdiction.

VI. CONCLUSION

Neurocrine cannot establish a case or controversy to support subject matter jurisdiction. There are simply no facts supporting any action Spruce has taken against Neurocrine, because Spruce has taken no such action. Spruce respectfully requests that this Court dismiss this action.

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