UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDA PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

FOOD & DRUG ADMINISTRATION, et al.,

Defendants.

Civil Action No. 19-301 (JDB)

MEMORANDUM OPINION

The underlying dispute in this case involved plaintiff Vanda Pharmaceuticals, Inc.'s ("Vanda") challenge under the Administrative Procedure Act ("APA") to the Food and Drug Administration's ("FDA") partial clinical hold on Vanda's human testing of the as-yet unapproved digestive drug tradipitant. In that litigation, as is required in any action brought under the APA, the FDA filed an index to the administrative record, and the parties filed a joint appendix containing copies of the record documents they cited to or relied upon in their briefing. One volume of the joint appendix was filed under seal with this Court's permission. The underlying litigation between Vanda and FDA concluded when this Court granted FDA's cross-motion for summary judgment over a year ago, but now non-party law firm Robbins Geller Rudman & Dowd LLP ("RGRD") has moved to intervene for the limited purpose of unsealing much of the administrative record. Both Vanda and FDA oppose unsealing the records, and Vanda also opposes intervention. For the following reasons, the Court will permit RGRD to intervene and will partially grant its motion to unseal, while also allowing Vanda to redact or withhold its proprietary information to avoid any competitive harm from disclosure.

Background

The factual background underlying the dispute between Vanda and FDA is laid out in full in this Court's January 2020 decision granting FDA's cross-motion for summary judgment, see Vanda Pharms., Inc. v. FDA, 436 F. Supp. 3d 256, 262–63 (D.D.C. 2020), but some recapitulation is appropriate to provide relevant context here. In September 2016, Vanda submitted an Investigational New Drug Application ("IND") to FDA to begin clinical trials on tradipitant—an experimental drug that has not yet been approved by FDA—for the treatment of the digestive disorder gastroparesis. Id. at 262. After conducting a six-month animal toxicity study of the drug on rats and a three-month study on dogs, Vanda filed an IND to conduct a four-week clinical trial on human subjects, which FDA granted. Id. In 2018, Vanda proposed extending its four-week trial by twelve months, but FDA denied that request because the drug had not undergone the requisite nine-month nonrodent toxicity study to prove to FDA that the drug was safe for long-term human experimentation. Id. Vanda continued pressing for approval to extend its human trial, but FDA refused to authorize any human testing in excess of three months and ultimately placed a partial clinical hold on Vanda's proposed twelve-month trial. Id. at 263.

Vanda filed suit under the APA in February 2019, alleging that FDA's decision to halt Vanda's trial lacked "an adequate scientific basis" and impermissibly applied "non-binding . . . guidance as a binding regulation." Id. Pursuant to Local Civil Rule 7(n), which governs the submission of the administrative record in APA cases filed in this District, FDA filed an index listing all of "the contents of the administrative record" it relied upon in reaching its partial clinical hold decision. See Local Civ. R. 7(n); Admin. R. Certified Index [ECF No. 38]. After summary judgment briefing concluded, and again in compliance with Local Civil Rule 7(n), the parties jointly filed a two-volume appendix "containing copies of those portions of the administrative

record that [they] cited or otherwise relied upon" in their briefs. See Local Civ. R. 7(n). Vanda submitted a motion to file Volume One of the appendix—"contain[ing] extremely sensitive proprietary information about tradipitant's development and therapeutic characteristics"—under seal, see Pls.' Sealed Mot. for Leave to File Vol. 1 of the Admin. R. App. Under Seal [ECF No. 42], which the Court granted, see Min. Order (Oct. 16, 2019). Volume Two was filed on the public docket. See Admin. R. App. [ECF No. 43]. The Court held a hearing on the parties' cross-motions for summary judgment and ruled in favor of FDA in January 2020. See Vanda, 436 F. Supp. 3d at 262–64. Vanda did not timely appeal, and the case was closed.

Meanwhile, RGRD represents a putative class of Vanda shareholders in a securities-fraud action in the Eastern District of New York. See Gordon v. Vanda Pharms. Inc., Case No. 1:19-cv-01108-FB-LB, 2021 WL 911755 (E.D.N.Y. Mar. 10, 2021). Vanda's motion to dismiss that case was recently denied in relevant part, advancing the litigation to discovery. See id. at *4. As part of its representation in that case, RGRD filed a Freedom of Information Act ("FOIA") request with FDA in July 2019 for fifteen documents that formed part of the sealed Volume One of the joint appendix in this case. See Mem. of Law in Supp. of Mot. for Leave to Intervene & Unseal Jud. Records ("RGRD's Mot.") [ECF No. 51-1] at 5. Some sixteen months later, FDA issued a response refusing to release any of the requested documents, stating it "lacks authority to consider the releasability" of any records sealed under this Court's Order. Id. Ex. 4, RGRD's Mot. [ECF No. 51-6] at 2.[1]

[1] FDA's stated interpretation of its FOIA obligations is incorrect. An agency may only withhold sealed documents from a FOIA requester if it meets its burden to prove that "the seal, like an injunction, prohibits the agency from disclosing the records." Judicial Watch, Inc. v. Dep't of Just., 813 F.3d 380, 383 (D.C. Cir. 2016) (quoting Morgan v. U.S. Dep't of Just., 923 F.2d 195, 197 (D.C. Cir. 1991)). If it is unclear from the court's sealing order whether it intended to prohibit the agency from disclosing the sealed documents outside of the litigation, the agency may be required to obtain clarification from the issuing court to meet its burden. Id. at 384 (citing Morgan, 923 F.2d at 198).

RGRD then filed the present motion to intervene in this case to unseal fifty-nine documents from the administrative record "for the benefit of the public interest." RGRD's Mot. at 1. The set of "Challenged Documents" in dispute has since evolved over the course of briefing on the motion. First, FDA and Vanda pointed out that twenty-seven of the fifty-nine documents RGRD initially sought to unseal were "listed on the corrected certified index of the administrative record but not contained in the joint appendix submitted to the Court," and are therefore not "judicial records" subject to unsealing. See Defs.' Opp'n to RGRD's Mot. to Unseal Jud. Records ("Defs.' Opp'n") [ECF No. 57] at 5 & n.2, 7–8; Vanda's Opp'n to RGRD's Mot. for Leave to Intervene & Unseal Docs. ("Vanda's Opp'n") [ECF No. 58] at 11–12.[2] Upon becoming aware of that fact, in its reply brief RGRD withdrew its motion as to any document "not included in the joint appendix." Reply Mem. of Law in Further Supp. of Mot. for Leave to Intervene & Unseal Jud. Records ("Reply") [ECF No. 60] at 15.

In the same reply brief, RGRD also sought to add one more document to the thirty-two remaining Challenged Documents—namely, the FDA's "Remand Response," which appears in the sealed volume of the joint appendix as Item 82. Id. at 24. Even though FDA and Vanda did not have an opportunity specifically to oppose unsealing the Remand Response, they conceded that the thirty-three Challenged Documents listed in RGRD's initial motion that are included in the joint appendix are judicial records, and the same logic applies to the Remand Response. See Defs.' Opp'n at 7; Vanda's Opp'n at 12. The Court will thus consider the Remand Response

[2] The documents identified in RGRD's motion that do not appear in the joint appendix are items 3–12, 14–16, 21, 23–25, 28–31, 33, 34, 43, 64, 73, and 78.

among the Challenged Documents in dispute—bringing the total number to thirty-three—for the sake of judicial efficiency in avoiding further litigation over this single document.[3]

Both Vanda and FDA oppose RGRD's motion. Vanda asks this Court to reject RGRD's request at the gate and deny the motion to intervene as untimely. Vanda's Opp'n at 1. FDA, for its part, "take[s] no position on RGRD's motion to intervene." Defs.' Opp'n at 1. But both FDA and Vanda assert that the balance of interests weighs against unsealing and, in the alternative, that the Court should permit Vanda to review and redact any documents the Court decides to unseal. See Vanda's Opp'n at 23; Defs.' Opp'n at 12. RGRD agrees that Vanda should have the opportunity to redact confidential information prior to unsealing. See Reply at 16. RGRD's motion has now been fully briefed and is ripe for decision. For the following reasons, the Court will grant RGRD's motion to intervene and will grant its motion to unseal with respect to certain documents. Given Vanda's commercial interest in the Challenged Documents, however, and with the apparent consent of RGRD, the Court will permit Vanda to review and redact all documents prior to their unsealing.

RGRD's Motion to Intervene

Before proceeding to the merits of RGRD's motion to unseal, the Court will address the dispute over whether RGRD should be permitted to intervene in this matter. Federal Rule of Civil Procedure 24(b) provides that a district "court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). However, the D.C. Circuit has "eschewed strict readings of the phrase 'claim or defense'" and embraced "a flexible reading of Rule 24(b)" when the proposed third-party

[3] The documents that appear in the joint appendix are items 1, 2, 13, 17–20, 22, 26, 27, 32, 35–42, 65–72, 74–77, 79, and 82. For the purposes of this Memorandum Opinion, these thirty-three documents will be collectively referred to as the "Challenged Documents."

intervention does not fit the mold of a non-litigant seeking to stake a claim in an ongoing civil action. See EEOC v. Nat'l Children's Ctr., Inc., 146 F.3d 1042, 1046 (D.C. Cir. 1998) (citing Nuesse v. Camp, 385 F.2d 694, 704 (D.C. Cir. 1967)). Specifically, "third parties may be allowed to permissively intervene under Rule 24(b) for the limited purpose of seeking access to materials that have been shielded from public view . . . by seal." Id. The only statutory requirement for the court's exercise of discretion over a motion to permissively intervene is that "the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3).

Where intervention is sought only for a collateral purpose like unsealing documents, the ordinary requirements for permissive intervention are relaxed. For one, "[a]n independent jurisdictional basis is . . . unnecessary when the movant seeks to intervene only for the limited purpose of obtaining access to documents covered by seal, . . . because the third party does not ask the court to rule on the merits of a claim or defense." EEOC, 146 F.3d at 1047. Moreover, "Rule 24(b)'s timeliness requirement," the purpose of which "is to prevent prejudice in the adjudication of the rights of the existing parties," need not apply "when the existing parties have settled their dispute and intervention is for a collateral purpose." Id. (quoting United Nuclear Corp. v. Cranford Ins. Co., 905 F.2d 1424, 1427 (10th Cir. 1990)). Accordingly, there is "consensus among the courts of appeals that intervention to challenge confidentiality orders may take place long after a case has been terminated." Id. (quoting Pansy v. Borough of Stroudsburg, 23 F.3d 772, 779 (3rd Cir. 1994)). And finally, unlike in an ordinary motion for permissive intervention, "no particularly strong nexus of fact or law need exist between" the underlying litigation and the case for which the intervenor is seeking to access the sealed documents. Id. at 1048.

Vanda advances two arguments against RGRD's motion to intervene. First, Vanda asserts that "RGRD's intervention motion—filed fourteen months after the documents in question were sealed and ten months after this case was closed . . . —fails the 'threshold question of timeliness.'" Vanda's Opp'n at 5 (quoting United States v. British Am. Tobacco Australia Servs., Ltd., 437 F.3d 1235, 1239 (D.C. Cir. 2006)). But as noted above, that "threshold" is low—to the extent it exists at all—when a third party only seeks to intervene for the narrow purpose of unsealing judicial records. See, e.g., EEOC, 146 F.3d at 1047. Not one of the litany of cases Vanda cites in support of its timeliness argument against intervention arose in the same context as RGRD's motion. Indeed, Vanda plainly states that the "key factor" in evaluating the timeliness of a motion to intervene "is 'whether any delay in seeking intervention unfairly disadvantage[s] the original parties.'" Vanda's Opp'n at 5 (quoting Roane v. Leonhart, 741 F.3d 147, 151 (D.C. Cir. 2014)). Where, as here, the original parties' dispute has already been resolved "and intervention is for a collateral purpose," that "concern [is] not present." EEOC, 146 F.3d at 1047 (quoting United Nuclear Corp., 905 F.2d at 1427).

Next, Vanda urges the Court to exercise its discretion to reject RGRD's proposed intervention "because it is an attempt to shift a discovery dispute in Gordon to this Court." Vanda's Opp'n at 8. Part of Vanda's argument on this score relies on the automatic stay of discovery in Gordon pursuant to the Private Securities Litigation Reform Act, which was in effect at the time RGRD filed its motion. See id. at 9 (citing 15 U.S.C. § 78u-4(b)(3)(B)). That stay was subsequently lifted when the Gordon court denied in relevant part Vanda's motion to dismiss on March 10, 2021, allowing RGRD's client's claims to proceed to discovery. See Non-Party RGRD's Notice of Supp. Auth. ("Notice of Supp. Auth.") [ECF No. 62] at 1 & n.2. Accordingly, the now-lifted stay has no bearing on this Court's consideration of RGRD's motion.

Still, Vanda insists that "RGRD is attempting an end-run around the Gordon court" and should not be permitted to intervene "to seek records here that it has alternative avenues to obtain" there. Pls.' Resp. to Non-Party Law Firm RGRD's Notice of Supp. Auth. ("Resp. to Notice") [ECF No. 63] at 3. But the docket in Gordon does not indicate any ongoing discovery dispute or restrictions in that case, so permitting intervention here would not be "evad[ing] restrictions on discovery in" Gordon as Vanda suggests. See Vanda's Opp'n at 9. Conversely, the cases Vanda cites against permissive intervention to evade discovery restrictions all involve some material roadblocks to discovery in parallel lawsuits which are simply not present in this case now that the stay has been lifted. See, e.g., AT&T Corp. v. Sprint Corp., 407 F.3d 560, 562 (2d Cir. 2005) (intervention "to circumvent the close of discovery" in a parallel action was improper); United Nuclear Corp., 905 F.2d at 1428 ("[A] collateral litigant has no right to obtain discovery materials that are privileged or otherwise immune from eventual involuntary discovery in the collateral litigation." (quoting Wilk v. Am. Med. Ass'n, 635 F.2d 1295, 1298 (7th Cir. 1980))). Finally, as discussed at length below, the meritorious grounds for unsealing cited in RGRD's motion do not arise out of its client's particularized interest in accessing the Challenged Documents for use in Gordon at all. Even if RGRD is ultimately seeking the Challenged Documents to advance the interests of the Gordon plaintiffs, its motion asserts the public's "common law right of access to judicial records," which exists independent of RGRD's representation in Gordon. RGRD's Mot. at 10 (citing Nixon v. Warner Commc'ns, 435 U.S. 589, 597–98 (1978)). Hence, the Court will exercise its discretion to permit intervention in order to reach the merits of whether that public right favors unsealing.

RGRD's Motion to Unseal the Challenged Documents

In the federal courts of the United States, "there is a 'strong presumption in favor of public access to judicial proceedings" and the records thereof in order to "ensur[e] the integrity of judicial proceedings in particular and of the law enforcement process more generally." Metlife, Inc. v. Fin. Stability Oversight Council, 865 F.3d 661, 665 (D.C. Cir. 2017) (quoting United States v. Hubbard, 650 F.2d 293, 315, 317 (D.C. Cir. 1980)). However, "the right of public access . . . is not absolute." Id. at 663. In United States v. Hubbard, the D.C. Circuit developed a "six-factor test to balance" the litigants' interests in sealing documents against the presumption of public access:

> [W]hen a court is presented with a motion to seal or unseal, it should weigh: "(1) the need for public access to the documents at issue; (2) the extent of previous public access to the documents; (3) the fact that someone has objected to disclosure, and the identity of that person; (4) the strength of any property and privacy interests asserted; (5) the possibility of prejudice to those opposing disclosure; and (6) the purposes for which the documents were introduced during the judicial proceedings."

Id. at 665 (quoting EEOC, 98 F.3d at 1409); see also Hubbard, 650 F.2d at 317–22. After considering these six "Hubbard factors," a court may only place or keep judicial records under seal if it "concludes that justice so requires." Metlife, 865 F.3d at 666 (quoting In re Nat'l Broad. Co., 653 F.2d 609, 613 (D.C. Cir. 1981)).

I. Need for Public Access

RGRD advances a number of reasons why the Challenged Documents should be publicly accessible. Only one of those reasons—the inherent public interest in access to judicial records—is persuasive, and it weighs substantially in favor of unsealing.

At bottom, "[p]ublic access to judicial records is 'fundamental to a democratic state' and 'serves the important function[] of ensuring the integrity of judicial proceedings.'" Guttenberg v.

Emery, 26 F. Supp. 3d 88, 92 (D.D.C. 2014) (quoting Hubbard, 650 F.2d at 315 & n.79). Indeed, the "strong public interest in the openness of judicial proceedings . . . exists irrespective of whether the proceedings at issue relate to disputes among private litigants." In re McCormick & Co., No. MC 15-1825 (ESH), 2017 WL 2560911, at *1 (D.D.C. June 13, 2017) (quoting Upshaw v. United States, 754 F. Supp. 2d 24, 28 (D.D.C. 2010)). Accordingly, "[i]t is not the [party seeking unsealing's] burden to proffer a need for public access; the burden is instead the respondent's to demonstrate the absence of a need for public access because the law presumes that the public is entitled to access the contents of judicial proceedings." United States v. ISS Marine Servs., Inc., 905 F. Supp. 2d 121, 140–41 (D.D.C. 2012) (citing Hubbard, 650 F.2d at 314–15). The public has an especially strong interest in reviewing documents "specifically referred to in the trial judge's public decision," Guttenberg, 26 F. Supp. 3d at 94 (quoting Hubbard, 650 F.2d at 318), to further the public interest in open access "as a check on the judiciary" that bolsters litigants' "confiden[ce] that they will be treated fairly and justly," id. at 92. Reviewing the materials underlying a judge's decision enables the public to "understand[] what needs to be pleaded to satisfy the pleading standard," or in this case, what evidence needs to be put forward to satisfy the summary judgment standard. See id. at 93. And in a democracy like ours, it is a "well-established principle that 'in cases where the government is a party . . . [t]he appropriateness of making court files accessible' is enhanced" even further. United States v. Thomas, 840 F. Supp. 2d 1, 4 (D.D.C. 2011) (quoting Friedman v. Sebelius, 672 F. Supp. 2d 54, 58 (D.D.C. 2009)).

As RGRD points out, several "of the Challenged Documents were affirmatively relied upon by this Court, even though they remain sealed." RGRD's Mot. at 13 (citing Vanda, 436 F. Supp. 3d at 263–75).[4] Indeed, even though it opposes unsealing the Challenged Documents, "FDA

[4] The nine Challenged Documents identified as having been cited by the Court are items 19, 20, 39, 66, 68, 70–72, and 82. See RGRD's Mot. at 4–5; Defs.' Opp'n at 9, 12 n.4; Reply at 24.

acknowledges . . . D.C. Circuit precedent recogniz[ing] a particular need for public access" to sealed documents cited in a judicial opinion. See Defs.' Opp'n at 9 (citing EEOC, 98 F.3d at 1409). At least with respect to the cited documents, then, this factor plainly favors unsealing.

Although less strongly, the first Hubbard factor also favors unsealing the other Challenged Documents submitted for the Court's review in the joint appendix. Those documents also contain "information with which the parties hope[d] to influence the court." See Metlife, 865 F.3d at 667. And the public also has a transparency interest in knowing what record evidence the Court saw fit to exclude from its explanation of the reasons underlying its ultimate decision. See id. at 668 ("Without access to the sealed materials, it is impossible to know which parts of those materials persuaded the court and which failed to do so (and why).").

The other arguments RGRD advances under the first Hubbard factor are too attenuated from the public interest in "ensur[ing] the integrity of judicial proceedings" or "the law enforcement process" to carry any additional persuasive weight, but nor do the private interests RGRD asserts turn the first Hubbard factor against unsealing as Vanda would have it. See Metlife, 865 F.3d at 665. For one, the interest asserted by RGRD for "Vanda's investors . . . to understand how, why, and when Vanda decided not to conduct the required safety study" falls outside of the public interest in open judicial proceedings. See RGRD's Mot. at 14. As Vanda points out, there is "an entire doctrinal framework of private corporate law" governing shareholders' rights to inspect a corporation's books and records. See Vanda's Opp'n at 14 (citing 8 Del. Code § 220(b)). Moreover, now that Gordon will advance to discovery, Vanda's investors that make up the putative class of plaintiffs there have a separate path to assert their private interest in any documents in Vanda's custody and control, including the Challenged Documents. See Vanda's Opp'n at 15–16. And as a publicly traded company, Vanda is also required by the federal securities laws to

accurately disclose relevant information to the public in order to inform current shareholders, prospective investors, and other market actors of its business conduct. See 15 U.S.C. § 78m.[5]

At the same time, Vanda misinterprets the contours of the first Hubbard factor when it asserts that "RGRD's unsealing request here is completely divorced from any of" the interests underlying the common-law right of public access. See Vanda's Opp'n at 14; ISS Marine Servs., 905 F. Supp. 2d at 140 (party seeking to maintain seal "misunderstands the meaning of the first factor in arguing" that party seeking unsealing "has proffered no public need for access apart from a generalized need for inspection" given strong presumption favoring public access). Indeed, Vanda completely overlooks the fact that this Court cited and discussed at length several of the Challenged Documents in its summary judgment ruling. Even if RGRD merely "seeks unsealing for the express purpose of bolstering its client's claims in private litigation against Vanda," Vanda's Opp'n at 16, that does not undercut the public's independent interest in accessing documents relied upon in a published judicial opinion. See, e.g., Upshaw, 754 F. Supp. 2d at 28 (argument that there is no need for public to access court documents "because the case relates solely to private matters, . . . quite simply[] misconstrues the relevant inquiry and completely ignores the strong public interest in the openness of judicial proceedings, which exists irrespective of whether the proceedings at issue relate to disputes among private litigants").

Separately, RGRD states "that any person or entity that is contemplating conducting human clinical trials" would benefit from a review of the sealed correspondence between Vanda and FDA in order to understand FDA's prerequisite requirement for long-term nonrodent studies. RGRD's Mot. at 14. FDA retorts that "the parties' unredacted filings and the Court's opinion describe the

[5] The Court recognizes the possibility that documents sealed or redacted under this Court's sealing order may not be discoverable without further order from this Court, but it is not this Court's intention to curtail the authority of the Eastern District of New York to manage discovery in Gordon.

scientific dispute at length" already, and that any presumptive drug-maker "may directly solicit FDA's views through normal regulatory channels. Defs.' Opp'n at 9. The Court agrees with FDA. The particularized interests of sophisticated pharmaceutical companies that may seek FDA approval for human clinical trials is significantly narrower than the common-law public right to access judicial records given the robust regulatory framework in place governing the IND process and the prohibitions on disclosing data on experimental drugs submitted to FDA prior to approval. See 21 C.F.R. § 314.430(d)(1). Importantly, though, the presence of FDA regulations prohibiting public disclosure of IND information "does not displace the common-law right of public access to judicial records, or the Hubbard test" absent any specific statutory or regulatory language indicating an intent to do so. See Metlife, 865 F.3d at 674 (rejecting argument that similar statutory confidentiality provision precludes unsealing of covered documents).

On the whole, then, the first Hubbard factor strongly favors unsealing the nine Challenged Documents cited in the Court's opinion and, to a somewhat lesser extent, favors unsealing the rest as well.

II. Extent of Previous Public Access

The second Hubbard factor looks to "whether, when and under what conditions the public has already had access to court records." Hubbard, 650 F.2d at 318. If members of the public already have had access to the Challenged Documents, there would presumably be less justification to keep them under seal. See id. at 318 n.97. However, "the second Hubbard factor is neutral where there has been no previous access." Grynberg v. BP P.L.C., 205 F. Supp. 3d 1, 3 (D.D.C. 2016) (quoting Am. Prof'l Agency v. NASW Assurance Servs., 121 F. Supp. 3d 21, 24 (D.D.C. 2013)).

Claiming this factor in its favor, RGRD asserts that "the sum and substance of the Challenged Documents has been in the public domain for some time." RGRD's Mot. at 14. To put it mildly, this is an overstatement. The only evidence RGRD cites in support of its factually unmoored averment is a one-page press release from Vanda's CEO broadly outlining Vanda's lawsuit against FDA and the limited references to the Challenged Documents in this Court's summary judgment ruling. See id. "A district court weighing the second factor should consider the public's previous access to the sealed information, not its previous access to the information available in the overall lawsuit." Cable News Network, Inc. v. FBI, 984 F.3d 114, 119 (D.C. Cir. 2021) (emphasis added). RGRD does not allege that any of the Challenged Documents—beyond the already publicly available portions quoted in the Court's published opinion—have ever been accessible to or accessed by the public. Hence, this factor is neutral.

III. Objections to Disclosure

Both FDA and Vanda oppose unsealing the Challenged Documents. For its part, "RGRD acknowledges that the parties' opposition means that the third Hubbard factor does not favor unsealing." RGRD's Mot. at 14. Although this factor weighs somewhat against unsealing, it is not by itself dispositive. See, e.g., EEOC, 98 F.3d at 1410 (reversing district court's decision to seal consent decree when objection to unsealing was only factor weighing in favor of maintaining seal). And FDA does not assert any special governmental interest that should give its objection added weight, as would exist, for example, when law enforcement agencies object to unsealing documents with national security implications. See Cable News Network, 984 F.3d at 119–20.

IV. Strength of Property and Privacy Interests in Sealing

The fourth Hubbard factor corresponds to the exception to public access that "protect[s] trade secrets" and "business information that might harm a litigant's competitive standing."

Hubbard, 650 F.2d at 315 (quoting Nixon, 435 U.S. at 598). Importantly, this factor does not serve as a blanket excuse to keep the public from accessing entire judicial records—rather, it may justify only "keep[ing] under seal those documents or portions of documents which would result in an unwarranted invasion of privacy" or business confidentiality. Id. at 324 (emphasis added).

Vanda stakes its strongest claim against unsealing the Challenged Documents under this factor based on its purportedly "very strong property and privacy interests" in the "extremely sensitive documents containing proprietary information about tradipitant's development and therapeutic characteristics." See Vanda's Opp'n at 3, 18. For its part, "FDA does not assert any confidentiality interest . . . independent of Vanda's," but acknowledges that "[a] sponsor like Vanda generally possesses strong privacy interests in IND information." Defs.' Opp'n at 11.

According to Vanda, the Challenged Documents "are comprised of: (1) Vanda's IND submissions, attached documents, and related correspondence (Item Nos. 1-35); (2) FDA's return correspondence discussing Vanda's INDs (Item Nos. 36-43); and (3) FDA's internal scientific evaluations of the information contained in Vanda's INDs (Item Nos. 64-81)." Vanda's Opp'n at 19. All of these categories of documents relate directly to Vanda's IND submission. As both Vanda and FDA note, see id. at 20; Defs.' Opp'n at 3–4, 11, the statutory and regulatory framework governing the IND process generally prohibits the public disclosure of "data or information contained in the application . . . before the agency sends an approval letter," see 21 C.F.R. § 314.430(d)(1); see also 21 U.S.C. § 331(j) (prohibiting public disclosure of information from, inter alia, an IND application "concerning any method or process which as a trade secret is entitled to protection"). Likewise, in conducting similar (though not identical) inquiries into withholding IND materials under FOIA Exemption 4—protecting confidential commercial or financial information from disclosure, see 5 U.S.C. § 552(b)(4)—the D.C. Circuit has recognized a property

interest where "other companies 'could make use of the information in the INDs in order to eliminate much of the time and effort that would otherwise be required to bring to market a product competitive with the product for which' the submitting company filed the IND." Judicial Watch, Inc. v. FDA, 449 F.3d 141, 148–49 (D.C. Cir. 2006) (quoting Pub. Citizen Health Research Grp. v. FDA, 185 F.3d 898, 905 (D.C. Cir. 1999)). However, "all information in INDs" cannot be "categorically exempt" from public disclosure absent a particularized interest in keeping protected information under seal. See id. at 149.

To be sure, RGRD overstates its case for unsealing when it asserts that "the Challenged Documents cannot possibly contain confidential business information that could negatively impact Vanda by . . . disclosing sensitive information to its competitors." RGRD's Mot. at 15. But RGRD's hyperbolic framing does not relieve "the party seeking to avoid disclosure" from its burden to "identify specific privacy interests in the documents at issue." Guttenberg, 26 F. Supp. 3d at 94 (emphasis added). It is insufficient for Vanda to simply "mak[e] broad reference to 'confidential and sensitive information'" even if the Challenged Documents comprise voluminous materials. See Friedman, 672 F. Supp. 2d at 60.

Here, Vanda has provided two examples of documents it claims would "put Vanda at an unfair competitive disadvantage were [they] made public to pharmaceutical companies developing their own gastroparesis drugs." Vanda's Opp'n at 20. It states that "Item No. 13 . . . consists of the reports from ten separate toxicology studies of tradipitant in various animals for various durations, amounting to thousands of pages." Id. RGRD appears to concede, see Reply at 23, and the Court agrees, that such reports constitute precisely the type of sensitive business information a competitor "could make use of." Moreover, the public interest in Item 13 is somewhat diminished because it was not affirmatively relied on in the Court's ruling. But Vanda's other example, Item

68, was cited by the Court and contains non-proprietary information about Vanda's arguments against conducting long-term nonrodent studies alongside "FDA's internal evaluation and analysis of tradipitant's safety and efficacy results and other underlying data" that could presumably be redacted to shield trade secrets. See Vanda's Opp'n at 20; Item 68 [ECF No. 42-5] at 141.

As for the rest of the Challenged Documents, the descriptions in the Table of Contents to the sealed volume of the administrative record appendix provide some limited insight into whether, and to what extent, they consist fully or partially of confidential business information that could cause Vanda competitive harm. See Admin. R. App. Vol. 1 – Table of Contents [ECF No. 42-1]. For example, documents consisting entirely of clinical studies, protocols, and results are likely to comprise confidential proprietary data necessitating continued protection under seal. On the other hand, materials regarding the dispute over Vanda's human trial proposal, including large portions of the Remand Response, appear less susceptible to unfair or improper use by competitors.

This Court "declines to sift through the record to attempt to divine" which documents ought to be fully or partially redacted, see Friedman, 672 F. Supp. 2d at 60, but it hopes the above discussion will guide Vanda in making sound and reasonably narrow determinations over which documents to redact or keep under seal. The Court is cognizant of the administrative burden of reviewing the thousands of pages of records at issue here, but the D.C. Circuit has expressly held that "the burden of producing judicial records may not permanently foreclose their unsealing." See In re Leopold to Unseal Certain Elec. Surveillance Applications & Orders, 964 F.3d 1121, 1134 (D.C. Cir. 2020). Moreover, removing Item 13 from the equation in its entirety reduces the page count of the Challenged Documents by more than 4,000.

In sum, the fourth Hubbard factor weighs strongly in favor of keeping confidential trade secrets and proprietary information under seal, but more work is required of Vanda to specifically

identify which documents or portions thereof among the Challenged Documents—other than Item 13—must be withheld or redacted to protect it from competitive harm. As Vanda appears to acknowledge, its risk of competitive harm would be mitigated by giving Vanda the "opportunity to either challenge disclosure" of entire documents "or provide document-by-document redactions to protect its confidential business information." Vanda's Opp'n at 23. And RGRD has agreed that Vanda should be permitted to redact confidential information prior to unsealing. See Reply at 16.

V. Prejudice

The fifth Hubbard factor looks to "whether disclosure of the documents will lead to prejudice in future litigation to the party seeking the seal." Friedman, 672 F. Supp. 2d at 60. FDA concedes that "it cannot identify any specific prejudice in future litigation that would result from unsealing." Defs.' Opp'n at 11. Vanda insists that "[t]he D.C. Circuit recently clarified that prejudice in this context encompasses real-world 'consequences' from the publication of information, not just prejudice that may occur within the litigation itself." Vanda's Opp'n at 21 n.11 (citing Cable News Network, 984 F.3d at 120). But the D.C. Circuit's discussion of the fifth factor in Cable News Network consists of a single sentence advising district courts simply to "consider the dire consequences that may occur if an agency discloses its intelligence sources and methods." 984 F.3d at 120. That direction is in the uniquely sensitive context of national security litigation. But even if that sentence were meant to expand the meaning of "prejudice" for the purposes of the fifth Hubbard factor more generally, Vanda has not identified any prejudice it would suffer from disclosure apart from the competitive harm discussed at length under factor four. Importantly, Vanda does not allege that unsealing would prejudice its position in the Gordon

litigation. Therefore, the fifth Hubbard factor does not move the needle in favor of maintaining the seal.

VI. Purpose of Challenged Documents During Judicial Proceedings

The sixth Hubbard factor favors disclosure where "the parties explicitly intended the Court to rely on [the sealed] materials in adjudicating their dispute." Berliner Corcoran & Rowe LLP v. Orian, 662 F. Supp. 2d 130, 135 (D.D.C. 2009). The interest in disclosure is especially strong for documents relevant "to the central claims of the litigation." Guttenberg, 26 F. Supp. 3d at 96. And "[w]hen a sealed document is considered as part of judicial decisionmaking, the sixth factor will oftentimes carry great weight." Cable News Network, 984 F.3d at 120. At the same time, "when the sixth factor highlights the fact that a sealed document didn't affect a judicial decision, it can be the 'most important' element cutting against disclosure." Id.

Not surprisingly, given the number and volume of Challenged Documents at issue here, their significance in the underlying litigation is varied and so, therefore, is the weight of support for unsealing provided by the sixth Hubbard factor. Obviously, this factor most strongly favors unsealing the documents the Court cited in its Memorandum Opinion. See RGRD's Mot. at 24. Even FDA acknowledges as much, conceding that those documents, including the Remand Response, are "the most relevant." Defs.' Opp'n at 12 & n.4. Vanda does not confront this conclusion head-on, but rather asserts that the lengthy record documents included in the joint appendix "were tangential at best" to the litigation. Vanda's Opp'n at 22. FDA similarly argues against disclosing "the thousands of pages in the other 24 Appendix Documents" not cited by the Court, which it maintains were "unnecessary for the disposition of the case." Defs.' Opp'n at 12. Even though, as RGRD notes, the non-cited documents were cited to or relied on in the parties' summary judgment briefing, the Court is sympathetic to Vanda's and FDA's position, and this

APA case involving review of a massive administrative record is distinguishable from the cases cited by RGRD involving unsealing a more discrete set of substantive exhibits. See, e.g., Berliner, 662 F. Supp. 2d at 132. So while the Court finds that the sixth factor strongly favors disclosing the documents cited in the Court's ruling, it only marginally supports unsealing the rest.

VII. Balancing the Hubbard Factors

On balance, the Hubbard factors favor lifting the seal from the Challenged Documents inasmuch as doing so will not expose Vanda to competitive harm. Most important to the equation is the "fundamental" common-law right of "[p]ublic access to judicial records," weighing strongly in favor of unsealing pursuant to factor one. See Guttenberg, 26 F. Supp. 3d at 92 (quoting Hubbard, 650 F.2d at 315 & n.79). The fact that the parties submitted the Challenged Documents into the record "hop[ing] to influence the court" strengthens the public interest in accessing them to better analyze and understand the Court's ultimate decision. See Metlife, 865 F.3d at 667. This public interest is strongest as to those nine documents cited in this Court's summary judgment ruling. See EEOC, 98 F.3d at 1409; Upshaw, 754 F. Supp. 2d at 30. Given the Court's reliance on those documents, factor six also weighs strongly in favor of unsealing them. See Cable News Network, 984 F.3d at 120.

Conversely, factors three and four weigh against lifting the seal. The parties' objections to unsealing carry limited weight under factor three and fall well short of outweighing the public interest in access under factor one. See EEOC, 98 F.3d at 1410. But the stronger consideration against unsealing stems from Vanda's interest in shielding its proprietary information from disclosure to avoid suffering competitive harm. However, that interest—while compelling—can be served by granting Vanda the opportunity to review and redact the Challenged Documents before unsealing. Hence, Vanda will be permitted to review and redact these documents prior to

their unsealing, with the benefit of this Court's expressed position on the confidentiality of clinical trials and related sensitive information regarding still-unapproved tradipitant.

The Court is not persuaded that RGRD's ability to obtain some or all of the Challenged Documents through discovery in Gordon diminishes or undermines the public interest in open access. See In re McCormick & Co., 2017 WL 2560911, at *1. If anything, the necessity of Vanda's document-by-document review of the Challenged Documents pursuant to its discovery obligations in Gordon reduce the administrative burden of effectuating this Court's order to unseal here. Presumably the Gordon plaintiffs will seek all of the Challenged Documents in discovery anyway, so Vanda's review for confidential information here need not result in duplicative efforts.

Conclusion

For the foregoing reasons, the Court will grant RGRD's motion to intervene, and will grant its motion to unseal in part. It will deny RGRD's motion to unseal as to Item 13 and permit Vanda to review and redact the remaining Challenged Documents prior to their unsealing. A separate order will issue on this date.

/s/
JOHN D. BATES
United States District Judge

Dated: May 6, 2021