

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

JUBILANT DRAXIMAGE INC.,

Plaintiff,

v.

UNITED STATES INTERNATIONAL
TRADE COMMISSION,

Defendant.

Civil Action No. 19-1494 (RDM)

MEMORANDUM OPINION AND ORDER

Plaintiff Jubilant DraxImage Inc. (“JDI”) manufactures a Rubidium Elution System (“RUBY”), one of only two medical devices used for Cardiac Positron Emission Tomography, a non-invasive imaging procedure designed to evaluate patients for coronary artery disease. JDI’s principal—indeed only—competitor in this specialized field is Bracco Diagnostics Inc. (“Bracco”), a company manufacturing a similar device. JDI is currently in proceedings before the United States International Trade Commission (“the Commission”) addressing whether JDI’s RUBY technology infringes on a series of Bracco’s patents. In the course of those proceedings, the Commission ordered JDI publicly to disclose portions of its briefs, all of which were filed under seal. JDI objects to making public those portions of its briefs that cite or reference Bracco’s patent claims. The reason? Revealing the specific Bracco claim elements at issue would, according to JDI, allow Bracco to modify or remove the very claim elements that make JDI’s products non-infringing. In other words, Bracco could use JDI’s references to particular portions of Bracco’s lengthy patent claims, which are public, to infer the manner in which JDI has attempted to engineer around Bracco’s patents, which is not public. JDI seeks a preliminary

injunction to prohibit the Commission from enforcing its disclosure order. As explained below, JDI has demonstrated that it is entitled to preliminary relief. The Court will therefore **GRANT** the motion for a preliminary injunction.

I. BACKGROUND

JDI is a radiopharmaceutical company based in Kirkland, Canada. Dkt. 1 at 3 (Compl. ¶ 7). Among other things, JDI markets a medical device named RUBY, an elution system that generates Rubidium-82 Chloride, a chemical used for Cardiac Positron Emission Tomography, a non-invasive imaging procedure used to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease. *Id.* at 4 (Compl. ¶ 11). The Food and Drug Administration (“FDA”) first approved RUBY in 2016. *Id.* (Compl. ¶ 12). As soon as the FDA approved JDI’s device, Bracco submitted a FOIA request to the FDA and obtained a RUBY product manual from the agency. *Id.* (Compl. ¶ 13). Bracco was able to claim priority to earlier-filed patent applications and, between September and November 2017, Bracco used information in the product manual to seek and to obtain three continuation patents crafted to claim the technology found in the RUBY product. *Id.* at 4–5 (Compl. ¶ 13). As soon as those patents issued, Bracco filed a complaint with the Commission, alleging violations of Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337. *Id.* at 5 (Compl. ¶ 14). The Commission instituted the current investigation in May 2018. *Id.*

In response to Bracco’s complaint with the Commission, JDI created two new versions of RUBY “specifically designed to avoid infringement of Bracco’s three patents”—Versions 3.1 and 4. *Id.* (Compl. ¶ 17). In proceedings before the Commission, JDI attempted to show that these new versions did not infringe Bracco’s existing patents. JDI filed a motion for summary determination (“MSD”)—the equivalent of a summary judgment motion—which compared the

technology behind Versions 3.1 and 4 against Bracco’s patent claims. *Id.* at 6 (Compl. ¶ 21); *see also* Dkt. 4-5 at 15–56 (Ex. 1 to Confidential Ex. E). To show that the new versions did not infringe Bracco’s patents, JDI quoted specific portions of—and highlighted key terms in—Bracco’s lengthy patent claims. Dkt. 4-5 at 24–27. “Because the emphasized claim limitations identifi[ed] the specific features of the RUBY product that were redesigned,” JDI feared that, if made aware of the precise claim elements that JDI had designed around, Bracco would file yet another set of continuation patents in an effort to exclude the new designs utilized in Versions 3.1 and 4. Dkt. 1 at 6–7 (Compl. ¶¶ 23–24). JDI, accordingly, treated all references to Bracco’s claim elements as “confidential business information” pursuant to Commission regulations and “redacted the portions of its [briefs] discussing, quoting, and emphasizing these limitations of Bracco’s patent claims in the public version of its brief.” Dkt. 1 at 6 (Compl. ¶ 23). JDI did this in four portions of its brief: the background sections for Versions 3.1 and 4, which list the particular claim elements at issue, and in the merits sections for Versions 3.1 and 4, which argue that the new designs do not infringe the identified claim elements.

Commission staff attorneys objected to a number of JDI’s redactions and filed a motion to declassify portions of JDI’s brief. *See* Dkt. 4-1 (Confidential Ex. A). Specifically, the Commission staff argued that “passages quoting from [Bracco’s] patents or descriptions of the scope of patents and claims do not fall within the Commission’s definition of confidential business information” and that, “unless the sentence explicitly describes the specific aspects of the RUBY Version 3.1 and Version 4 systems, any quotation from or discussion of the asserted [Bracco] patents should not be redacted.” *Id.* at 4–5. JDI opposed the motion, arguing that “[a]ny patent attorney reading a brief seeking a determination of noninfringement that provides a background overview of specific claim limitations would readily recognize that those claim

limitations form the basis for why the confidential products do not infringe” and that, “for example,” one of Bracco’s limitations “concerns a binary design option.” Dkt. 4-2 at 11 (Confidential Ex. B). Reviewing a proposed, redacted brief provided by Commission staff, moreover, JDI compared redactions approved by the Commission staff to those rejected and argued that “there is no real difference between the redacted passages reproduced below that the Staff seeks to reclassify. . . and those it has approved.” *Id.* at 12–13.

On March 21, 2019, a Commission Administrative Law Judge (“ALJ”) issued Order No. 31, “Initial Determination Granting-in-Part Commission Investigative Staff’s Motion to Declassify Portions of Respondents’ Motion for Summary Determination.” Dkt. 4-3 (Confidential Ex. C). The Order explained that “confidentiality determinations . . . are governed by the definition given in 19 C.F.R. § 201.6(a).” *Id.* at 4. That definition, according to the ALJ, mandates a “two-part test.” *Id.* First, the ALJ “asks whether the contested information ‘concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value.’” *Id.* at 3 (citation omitted) (quoting 19 C.F.R. § 201.6(a)). Second, the ALJ determines whether “the disclosure of such information [would] be likely to have the effect of either (1) ‘impairing the Commission’s ability to obtain such information as is necessary to perform its statutory functions,’ or (2) ‘causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained.’” *Id.* at 3–4 (alteration in original) (citation omitted) (quoting 19 C.F.R. § 201.6(a)).

The ALJ acknowledged JDI's argument that, "by identifying specific claim limitations that are not practiced by [JDI's] revised products, a reader may deduce the operation of those products." *Id.* at 4. With respect to Version 3.1, for example, the ALJ noted JDI's argument that the relevant claim element concerned "a binary design decision" and "that language in its brief stating that it does not practice the [specific] limitation necessarily reveals . . . the [RUBY] elements in question . . . and that is competitive information not available to the public." *Id.* at 4–5. Applying the two-part test, the ALJ "agree[d] that declassification of those redactions [i.e., those that revealed a "binary design decision"] from the public version of the [JDI] MSD would reveal a confidential design feature of [JDI's] product," and, accordingly, rejected the Commission staff's motion with respect to those redactions. *Id.* at 5. Turning to the Version 4 patents, however, the ALJ determined that "it is not true, as a factual matter, that a reader can deduce the configuration of [JDI's] product from [those specific Bracco claim] statements" because "[m]ultiple possibilities exist . . . that avoid[] the limitation in question." *Id.* at 5–6. The ALJ, accordingly, concluded that specific references to Bracco's patents related to RUBY Version 4 "do not constitute [JDI's] confidential business information" and ordered JDI "to file a replacement public version of its motion for summary determination with the improper redactions removed." *Id.* at 6.

JDI appealed to the Commission. Dkt. 4-4 (Confidential Ex. D). Arguing that the ALJ's focus on whether the specific design choices "involve[d] a binary, either-one-or-the-other choice . . . misses the point," JDI stressed that "early identification of the emphasized claim limitations will reveal to Bracco the specific limitations that [JDI's] Version 4 products omit, which would allow Bracco to file new applications containing claims that simply omit the designed-around limitations." *Id.* at 15. On May 6, 2019, the Commission issued a Notice of

Commission Decision to Review in Part an Initial Determination Granting-in-Part a Motion to Declassify (“Notice”). Dkt. 1-1 (Compl. Ex. A). In a single sentence, the Commission affirmed the ALJ’s Order No. 31.¹ *Id.* at 3. The Commission also attached a version of JDI’s brief, edited by Commission staff, showing which redactions the Commission approved and which redactions JDI would have to forgo. *See id.* at 2; *see also* Dkt. 4-5 at 11–56 (Ex. 1 to Confidential Ex. E). The Commission stayed its order for 21 days to allow JDI to seek judicial review of its disclosure order. Dkt. 1-1 at 3 (Compl. Ex. A). The Commission later extended that stay until July 12, 2019. June 21, 2019 Hrg. Tr. (Rough at 20:17–19).

JDI filed the instant suit on May 22, 2019, seeking relief under the Administrative Procedure Act (“APA”), 5 U.S.C. § 701 *et seq.* and a writ of mandamus, 28 U.S.C. § 1361. Among other things, JDI alleges that the Notice is “arbitrary, capricious, and contrary to law,” Dkt. 1 at 11 (Compl. ¶ 44), and that the Commission “owes a non-discretionary duty not to disclose information properly designated as confidential under Commission rules,” *id.* at 12 (Compl. ¶ 56). JDI filed a motion for a preliminary injunction that same day, Dkt. 3, as well as a motion to seal portions of the administrative record, Dkt. 4.² After setting a schedule with the

¹ The Commission also ordered that JDI make one additional redaction. Dkt. 1-1 at 3 (Compl. Ex. A). That redaction is not at issue here. *See* Dkt. 1 at 8 (Compl. ¶ 33).

² The Commission opposes the motion to seal portions of the administrative record to the extent that sealing goes beyond “information considered [confidential business information (“CBI”)] by the Commission and not in dispute in this case.” *See* Dkt. 12 at 12. The dispute regarding the motion to seal, accordingly, “simply parallels the merits” of the parties’ disclosure/non-disclosure arguments. *See* June 21, 2019 Hrg. Tr. (Rough at 31:17–18). Because the Court grants the preliminary injunction on APA grounds without deciding whether the underlying information can be properly withheld, the Court will preliminarily **GRANT** the motion to seal for the period that the preliminary injunction remains in place in order to preserve the status quo. Should the Court subsequently dissolve the injunction, the Commission is welcome to renew its request that JDI file unredacted versions of the sealed exhibits on the public docket.

parties' consent, the Court held oral argument on June 21, 2019, and those motions are now ripe for decision.

II. ANALYSIS

“A preliminary injunction is an extraordinary remedy never awarded as of right,” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008), but “only when the party seeking the relief, by a clear showing, carries the burden of persuasion,” *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004). To secure a preliminary injunction, a plaintiff “must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.” *Winter*, 555 U.S. at 20. “The last two factors ‘merge when the Government is the opposing party.’” *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 10 (D.C. Cir. 2019) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

Before the Supreme Court’s decision in *Winter*, courts in this circuit applied a “sliding-scale” approach to the preliminary injunction analysis under which “a strong showing on one factor could make up for a weaker showing on another.” *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011). Since *Winter*, the D.C. Circuit has hinted on several occasions that “a likelihood of success is an independent, free-standing requirement for a preliminary injunction,” *id.* at 393 (quoting *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh, J., concurring)), but it has repeatedly declined to decide that issue, *see Am. Meat Inst. v. U.S. Dep’t of Agric.*, 746 F.3d 1065, 1074 (D.C. Cir. 2014), *reinstated in relevant part by* 760 F.3d 18 (D.C. Cir. 2014) (en banc); *see also League of Women Voters of United States v. Newby*, 838 F.3d 1, 7 (D.C. Cir. 2016); *Sherley*, 644 F.3d at 393 (reading “*Winter* at least to suggest if not to hold ‘that a likelihood of success is an independent, free-standing requirement

for a preliminary injunction,” but declining to decide the issue (quoting *Davis*, 571 F.3d at 1296)).

Here, because all four factors weigh in favor of granting a preliminary injunction, JDI is entitled to preliminary relief regardless of whether the sliding-scale approach applies.

A. Likelihood of Success on the Merits

The APA directs courts to “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). JDI contends that it is likely to succeed on the merits of its APA challenge because the Commission’s order was both “contrary to law and arbitrary and capricious.” Dkt. 3-1 at 14. In support, JDI raises a host of APA challenges to the Commission’s choice to redact claim elements relating to the “binary” design choices of Version 3.1 but not elements concerning the “non-binary” possibilities of Version 4.

JDI first argues that the Commission’s “binary/non-binary” distinction is contrary to law because it does not appear in the Commission’s regulations. June 21, 2019 Hrg. Tr. (Rough at 24:10–15). Second, JDI contends that even if the binary/non-binary distinction was proper, the Commission misapplied that distinction. JDI suggests, for example, that claim elements emphasized for Version 4 should themselves be considered “binary” because “they are either in the claims or they are not.” Dkt. 3-1 at 15. JDI also argues that the Commission erroneously concluded that several design features were non-binary when, in fact, JDI had only “essentially binary” design options. June 21, 2019 Hrg. Tr. (Rough at 28:13–17); *see also* Dkt. 13 at 11 n.7 (“[T]he available design choices related to Version 4 are ‘virtually’ binary.” (quoting Dkt. 4-4 at 12–13) (Confidential Ex. D)). Third, and most forcefully, JDI contends that the Commission erred when it failed to recognize that, “if the redacted limitations are disclosed, Bracco can draft

new patent claims to cover JDI’s trade-secret designs simply by eliminating the language JDI has identified from its existing claims.” Dkt. 3-1 at 15. This, according to JDI, was doubly-wrong under the APA: the Commission both misconstrued its own regulations when defining “substantial harm to [JDI’s] competitive position,” *id.* at 14–15 (citing 19 C.F.R. § 201.6(a)), and “[f]ail[ed] to properly consider” JDI’s “principal argument,” an independent and distinct ground for finding the order arbitrary and capricious, *id.* at 15.

Ultimately, JDI may prevail on none, or one, or several of these claims. The Court, however, need not evaluate each and every one of JDI’s theories for present purposes. Mindful that the Court must not “substitute its judgment for that of the agency,” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983), it is sufficient at this early stage of the litigation to conclude that JDI is likely to succeed on another, more straightforward APA theory: that the proposed redactions themselves lack a coherent basis. As JDI contends, the Commission treated identical language as confidential business information in some parts of JDI’s brief, while ordering disclosure of that same language elsewhere in the same brief. *See* Dkt. 13 at 7; *see also* June 21, 2019 Hrg. Tr. (Rough at 18:17–19:1).

It is axiomatic that the APA requires “reasoned decisionmaking.” *State Farm*, 463 U.S. at 52. That principle requires the Court to assess whether the agency considered “the relevant factors and whether there was a clear error in judgment.” *Id.* at 31; *see also Judulang v. Holder*, 565 U.S. 42, 53 (2011). To be sure, “[t]he scope of review under the ‘arbitrary and capricious’ standard is narrow.” *State Farm*, 463 U.S. at 43. But “the process by which [an agency] reaches [its] result must be logical and rational.” *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998). In other words, although a “court is not to substitute its judgment for that of the agency, neither may a court sanction agency action when the agency . . . fails to justify seeming

inconsistencies in its approach,” *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 884 (D.C. Cir. 2004) (internal quotations omitted) (quoting *Prof'l Pilots Fed'n v. FAA*, 118 F.3d 758, 771 (D.C. Cir. 1997)).

Looking at the proposed redactions in detail, the Court concludes that the Commission fails this deferential standard. In a version of JDI’s brief reflecting the Commission’s decisions, the Commission highlighted approved redactions in yellow and rejected redactions in red. But on multiple occasions, the Commission reached inconsistent results as to identical or equivalent language. On page 30 of JDI’s motion for summary determination, for example, JDI included a table identifying specific claim elements that JDI designed around in Version 4. *See* Dkt. 4-5 at 49 (Confidential Ex. E). The Commission ordered JDI to disclose every claim element on this page. *Id.* at 48–49 (highlighting elements in red). Yet, on the very next page, JDI begins a section entitled “no literal infringement” with the sentence: “The Version 4 design has no . . .” and proceeds to quote one of the claim elements from the preceding page. *Id.* at 50. Notably, the Commission concluded that that language was properly redacted. *Id.* (highlighting elements in yellow). This appears to be more than a simple oversight. On page 32 of JDI’s brief, the Commission approved redacting the sentence: “[T]he Version 4 design does not possess [a specific Bracco claim element].” *Id.* at 51 (highlighting in yellow). Appended to that sentence is a footnote, which reads: “[A different Bracco claim element] recites this same subject matter using alternate language. It states that . . .” and then quotes from the separate claim element. *Id.* The claim element “recit[ing] this same subject matter using alternate language” is then marked as unredacted. *Id.* (highlighting in red). Other, similar inconsistencies appear elsewhere. *Compare, e.g.*, Dkt. 4-5 at 51 (Confidential Ex. E) (“Version 4 . . . does not possess [claim language A].”) (highlighted in yellow), *with id.* at 52 (“[Claim A] recites . . . [claim language

A] . . . Version 4 is the antithesis of the Assert Patent.”) (highlighted in red). In other words, there are both inconsistencies between treatment of identical language in the background and the analysis sections, and also inconsistent treatment of language *within* the analysis section.

Neither the Commission’s final order nor the ALJ’s decision explains the reason for these discrepancies. At oral argument, counsel for the Commission argued that these examples are not really inconsistencies at all because the ALJ redacted information where “the subject of [the] sentence is the Version 4 design product,” but not where the brief merely “recites” a patent claim—because “that’s clearly claim language that is public information.” June 21, 2019 Hrg. Tr. (Rough at 48:10–20). There are several problems with that argument. As an initial matter, neither the Court nor counsel may “supply a reasoned basis for [an] agency’s action that the agency itself has not given,” *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285–86 (1974) (citing *SEC v. Chenery Corp.* (“*Chenery II*”), 332 U.S. 194, 196 (1947)), and a distinction based on the “subject of [the] sentence,” June 21, 2019 Hrg. Tr. (Rough at 48:11–12), does not appear anywhere in the ALJ’s decision or the Commission’s order.

Nor, moreover, is that logic compatible with the ALJ’s actual reasoning. According to the ALJ’s decision, which the Commission affirmed, the Bracco claim elements “do not constitute [JDI’s] confidential business information” because “it is not true, as a factual matter, that a reader can deduce the configuration of [JDI’s] product from [those specific Bracco claim] statements;” rather, “[m]ultiple possibilities exist . . . that avoid[] the limitation in question.” Dkt. 4-3 at 5–6 (Confidential Ex. C). In other words, revealing a non-binary Bracco claim element does no competitive harm to JDI because Version 4 could be configured in any number of other ways. But if that were true, it would make little sense for the ALJ to redact Bracco’s claim elements even when “the subject of [the] sentence is the Version 4 design product.” Put

differently, if the ALJ was correct that there are multiple design possibilities, it would make no difference whether the corresponding claim element was revealed in a background description of the relevant portions of Bracco’s patent or in the portion of the brief explaining that those elements are not present in JDI’s products.

Counsel’s argument also runs headlong into another, more fundamental problem: if the ALJ sought to disclose portions of the brief that merely “recite[]” a patent claim on the grounds that the Bracco claim elements are “public information,” he would have ordered the claim elements associated with Version 3.1 disclosed as well. But, as discussed, the ALJ and the Commission agreed that *those* claim elements should remain redacted. In sum, no matter which way the Commission tries to cut it, the proposed redactions are inconsistent. And because the redactions are “internally inconsistent,” they are “arbitrary and capricious.” *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1028 (D.C. Cir. 2018).

Counsel for the Commission, though, offered a further response at oral argument. According to the Commission, JDI forfeited an argument based on inconsistency because it “didn’t argue it before the Commission” and, instead, raised it “for the first time in their reply brief” before this Court. June 21, 2019 Hrg. Tr. (Rough at 37:1–7). The Court is unpersuaded. To be sure, “[i]t is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review.” *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) (citing *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952)). Here, however, the Court concludes that JDI raised the dispositive issue below and, accordingly, did not forfeit the argument.

Several pages of JDI’s brief seeking confidential treatment highlighted, in large boxes, inconsistencies in the Commission’s approach. Pointing to these portions, JDI argued that “there

is no real difference between the redacted passages reproduced below that the [s]taff seeks to reclassify. . . and those it has approved.” Dkt. 4-2 at 12 (Confidential Ex. B). JDI identified specific inconsistencies similar to those raised here. *Id.* at 12–13. The fact that JDI did not couch this argument in the register of “arbitrary and capricious” agency action, moreover, is hardly surprising: JDI was urging the Commission to expand its view of what should be redacted, not arguing that the agency action must be set aside. In any event, even if JDI did not raise the argument as clearly as it could have, the Commission was on reasonable notice that its proposed redactions needed to clear the bar of internal consistency. In short, this was hardly a case in which the aggrieved party “with[held] legal arguments for tactical reasons,” *USAir, Inc. v. Dep’t of Transp.*, 969 F.2d 1256, 1260 (D.C. Cir. 1992), or subjected the Commission to “[u]nfair surprise,” *Okl. Dep’t of Envtl. Quality v. EPA*, 740 F.3d 185, 192 (D.C. Cir. 2014).

Counsel for the Commission raised one final, fallback argument at oral argument: that even if the Court found the redactions inconsistent or incoherent, those discrepancies constituted “harmless error.” June 21, 2019 Hrg. Tr. (Rough at 35:18–36:2). According to counsel for the Commission, any inconsistencies are simply the result of the Commission having been overly cautious in its earlier redactions, and, if the Court remands to the Commission, staff will simply recommend disclosing any portion of JDI’s brief that does not comport with the ALJ’s reasoning. As an initial matter, the Court is—at this preliminary stage—merely evaluating whether to preserve the status quo, and any substantive discussion of remand or vacatur is premature. But, in any event, neither counsel nor the Court knows what the Commission will do on remand. It is far from clear, for example, that the Commission will not simply expand—rather than roll back—its existing redactions. The Court is mindful of its limited role and must not “substitute its judgment for that of the agency.” *State Farm*, 463 U.S. at 43. In the event that

the Court ultimately sets aside the Notice, it would be for the Commission to correct the Notice in the first instance.

The bottom line is this: because the specific redactions proposed by the Commission are internally inconsistent and run counter to the reasons given by the agency, JDI appears likely to succeed on the merits of at least one of its APA claims. At this stage of the litigation, nothing more is required to tip the first factor in JDI's favor.

B. Irreparable Harm

Next, the Court must consider whether JDI “is likely to suffer irreparable harm in the absence of preliminary relief.” *Winter*, 555 U.S. at 20. “[A] showing that irreparable injury is ‘likely’ is the *sine qua non* for obtaining a preliminary injunction—it is what justifies the extraordinary remedy of granting relief before the parties have had the opportunity fully to develop the evidence and fully to present their respective cases.” *Achagzai v. Broad. Bd. of Governors*, No. 14-cv-768, 2016 WL 471274, at *3 (D.D.C. Feb. 8, 2016); *see also Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (“A movant’s failure to show any irreparable harm is therefore grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief.”); *Tex. Children’s Hosp. v. Burwell*, 76 F. Supp. 3d 224, 241–42 (D.D.C. 2014); *Trudeau v. FTC*, 384 F. Supp. 2d 281, 296 (D.D.C. 2005), *aff’d*, 456 F.3d 178 (D.C. Cir. 2006). As a result, if JDI fails to demonstrate that it is likely to suffer an irreparable injury, the Court must deny the motion.

JDI contends that this factor “present[s] an easy question” and that it will suffer irreparable harm “in two distinct senses.” Dkt. 3-1 at 17. First, if JDI’s confidential business information is disclosed, “[t]here is no way that this Court or any other could compensate JDI for the potentially enormous competitive harm in disclosure of trade-secret information,” as *Bracco*

could likely use the information to prepare patent claims that would exclude JDI from the market altogether. *Id.* Second, JDI argues that disclosure would “defeat[] JDI’s ability to obtain [judicial] review and keep trade secrets, secret,” because, “[o]nce the ‘cat is out of the bag,’ the right against disclosure cannot later be vindicated.” *Id.* at 18 (quoting *SEC v. Rajaratnam*, 622 F.3d 159, 170 (2d Cir. 2010)). The Commission, on the other hand, contends that JDI will suffer no injury at all, arguing that “[t]here is simply no cognizable harm from the disclosure of public patent claim language and public infringement contentions in this case or any other.” Dkt. 12 at 25. That is so, it argues, because “the harm that JDI identifies—that Bracco *could* use the redacted information to amend its patent applications to include JDI’s designs—is not only speculative, but also amounts to nothing more than legitimate and permissible competitive behavior by Bracco.” *Id.* at 24–25. Quoting the Federal Circuit, the Commission posits that “there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor’s product from the market.” *Id.* at 25 (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988)).

The problem with the Commission’s argument is that the Commission has already conceded its core premise. If “[t]here is . . . no cognizable harm from the disclosure of public patent claim language and public infringement contentions in this case or any other,” Dkt. 12 at 25, then *none* of the redactions in JDI’s brief would satisfy the Commission’s two-part test for confidential treatment. But, of course, the Commission concluded that, where disclosure of public patent claim elements would reveal JDI’s design choices, that disclosure qualifies as competitive harm. The ALJ, in other words, has already determined that where a “[specific] limitation necessarily reveals . . . the [RUBY] elements in question[,] . . . that is competitive information not available to the public” and is properly withheld as confidential business

information. Dkt. 4-3 at 5 (Confidential Ex. C). As described in the prior section, the Commission has given the green light to numerous redactions. Even if the Commission now contends that those redactions were unnecessary, the ALJ clearly took the position that—with both Versions 3.1 and 4—“public infringement contentions” can, and did, constitute “cognizable harm.” That position, moreover, was a sensible one. To be sure, there is nothing wrong with Bracco using JDI’s design to seek a continuation patent that it could then use to exclude JDI from the market; but there is also nothing improper about JDI endeavoring to keep its design secret.

As the Commission has conceded that disclosure would, in fact, cause injury to JDI, the Court has little trouble concluding that the injury would be irreparable. In short, “once . . . putatively protected material is disclosed, the very right sought to be protected has been destroyed,” *In re Sealed Case No. 98-3077*, 151 F.3d 1059, 1065 (D.C. Cir. 1998) (quoting *In re Ford Motor Co.*, 110 F.3d 954, 963 (3d Cir. 1997))—that is, “once disclosed, [it] loses its confidential nature,” *Hosp. Staffing Sols., LLC v. Reyes*, 736 F. Supp. 2d 192, 200 (D.D.C. 2010). The Court, accordingly, concludes that JDI has demonstrated that it “is likely to suffer irreparable harm in the absence of preliminary relief.” *Winter*, 555 U.S. at 20.

C. Balance of Equities and Public Interest

Finally, JDI must show “that the balance of equities tips in [its] favor, and that an injunction is in the public interest.” *Winter*, 555 U.S. at 20. “The[se] last two factors ‘merge when the Government is the opposing party.’” *Guedes*, 920 F.3d at 10 (internal citation omitted). The Commission argues that the balance of equities tips in its favor because “JDI on its own initiated the inquiry and adjudication of non-infringement with respect to its Version 3.1 and Version 4 products—products which had not been accused of infringement by Bracco,” and

because “JDI had the opportunity to maintain a shroud of secrecy over its products, essentially by not seeking declaratory judgment as to them.” Dkt. 12 at 25–26. The Commission further argues that the public interest weighs against an injunction because JDI “should not be permitted to shield publicly available information and bare legal contentions from the public by simply alleging that competitive harm may result.” *Id.* at 26. JDI counters that it “had no expectation” that it would be forced to disclose confidential information, Dkt. 13 at 15, and further argues that “[t]he potential harm of a wrong decision against JDI would be substantial” and “denying relief would extinguish JDI’s right to judicial review,” whereas “the potential harm of a wrong decision against the Commission would be virtually non-existent,” Dkt. 3-1 at 19.

The Court concludes that, on balance, the third and fourth factors tip in JDI’s favor. “The primary ‘purpose of a preliminary injunction is to preserve the object of the controversy in its then existing condition—to preserve the status quo.’” *Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014) (quoting *Doeskin Products, Inc. v. United Paper Co.*, 195 F.2d 356, 358 (7th Cir. 1952)). Here, issuance of a preliminary injunction accomplishes this purpose with relatively little harm to the Commission or to the public interest. In the event that the Commission ultimately prevails, JDI will be required to disclose the redacted material in short order.

Nor is this a case in which JDI will unduly or unjustly profit from keeping this information temporarily confidential. It is undisputed that JDI’s new designs do not, in fact, infringe upon Bracco’s *existing* patents. Although the balance might shift if continued confidentiality allowed JDI to evade Bracco’s attempts to enforce its existing property rights, that is not the case. Bracco—who is not a party to this proceeding—has merely lost an opportunity to use the ongoing Commission proceedings to learn how JDI has redesigned its products so that Bracco can then seek new patents to, if possible, enjoin the new designs. Bracco

has the right to file continuation applications but does not have a statutory or regulatory right to use the Commission proceedings to gain the information it needs to file the new applications.

The Court further concludes that the public interest would be not be harmed by preserving JDI's current redactions. Although there is a "strong presumption in favor of public access to judicial proceedings," *Johnson v. Greater Se. Cmty. Hosp. Corp.*, 951 F.2d 1268, 1277 (D.C. Cir. 1991), the adjudication at issue occurs not in an Article III courthouse, but in an administrative proceeding where confidential information is often protected from public disclosure. There is, moreover, a strong "public interest" in "protecting confidential business information and trade secrets." *Council on Am.-Islamic Relations v. Gaubatz*, 667 F. Supp. 2d 67, 80 (D.D.C. 2009). The Court also notes that much of the underlying record will remain sealed regardless of whether the Commission is successful in this action. The parties agree that the Version 3.1 claims should stay redacted, and JDI represents that the Commission has sealed, in its entirety, the underlying ALJ decision granting JDI's motion for summary determination. *See* Dkt. 13 at 15. Any public interest served by the marginally increased access to additional portions of the briefing, accordingly, does not outweigh the public interest in the protection of JDI's confidential business information.

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All four factors, accordingly, weigh in favor of issuance of a preliminary injunction.

CONCLUSION

For the reasons stated above, it is hereby **ORDERED** that Plaintiff's motion for preliminary injunction, Dkt. 3, and motion to seal, Dkt. 4, are both **GRANTED**. The Commission is enjoined from disclosing any portion of JDI's motion for summary determination pending further order of the Court. The parties shall appear for a status conference on July 25, 2019 at 3:00 p.m. in Courtroom 21.

SO ORDERED.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: July 10, 2019