IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC., Plaintiff, v. HOLOGIC INC., GRIFOLS DIAGNOSTICS SOLUTIONS, INC., and GRIFOLS, S.A., Defendants.	)	C.A. No. 16-894-LPS-CJB REDACTED - PUBLIC VERSION

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MEMORANDUM OPINION

September 26, 2018
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court is Defendant Grifols, S.A.'s ("GSA" or "Defendant") Motion to Dismiss for Lack of Personal Jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(2). (D.I. 56) For the reasons set forth below, the Court will deny Defendant's motion.

I. BACKGROUND

Plaintiff Enzo Life Sciences, Inc. ("Enzo" or "Plaintiff") filed this patent infringement action, alleging initially that defendant Hologic, Inc.'s ("Hologic") Procleix®, Aptima®, and Progensa® product lines infringe U.S. Patent No. 6,221,581. (D.I. 1 ¶ 26) Later, the Court granted Enzo's unopposed motion for leave to amend its complaint to add GSA and Grifols Diagnostic Solutions Inc. ("GDS") as defendants. (*See* D.I. 28-1, 39) The first amended complaint ("FAC") alleges that GSA is a Spanish corporation with its principal place of business in Barcelona, Spain, and GDS is a Delaware corporation with its principal place of business in Emeryville, California. (D.I. 28-1 ¶¶ 3, 4)

According to the FAC, GDS is a wholly owned subsidiary of GSA, and GSA "transacts substantial business, either directly or through its affiliates, such as [GDS] or agents, on an ongoing basis in this judicial district and elsewhere in the United States." (*Id.* ¶ 4) The FAC further alleges that GDS "has acquired all assets and liabilities of Hologic's NAT (nucleic acid testing) blood screening business, which includes the Procleix® product line ["Accused Products"] accused of infringement . . . [and] a plant in San Diego, California as well as development rights, licenses to patents, access to product manufacturers and research and development activities." (*Id.* ¶ 9)

II. LEGAL STANDARDS

Pursuant to Federal Rule of Civil Procedure 12(b)(2), a party may move to dismiss a case based on the Court's lack of personal jurisdiction over that party. Determining the existence of personal jurisdiction requires a two-part analysis – one statutory and one constitutional. First, the Court analyzes the long-arm statute of the state in which the court is located.[1] *See IMO Indus., Inc. v. Kiekert AG*, 155 F.3d 254, 259 (3d Cir. 1998). Next, the Court determines whether exercising jurisdiction over the defendant in that state comports with the Due Process Clause of the Constitution. *See id.* Due process is satisfied if the Court finds the existence of "minimum contacts" between the non-resident defendant and the forum state, "such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal quotation marks omitted).

When a defendant moves to dismiss a lawsuit for lack of personal jurisdiction, the plaintiff bears the burden of showing the basis for jurisdiction. *See Power Integrations, Inc. v. BCD Semiconductor*, 547 F. Supp. 2d 365, 369 (D. Del. 2008). If no evidentiary hearing has been held, a plaintiff "need only establish a prima facie case of personal jurisdiction." *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007). A plaintiff "presents a prima facie case for the exercise of personal jurisdiction by establishing with reasonable particularity sufficient contacts between the defendant and the forum state." *Mellon Bank (E) PSFS, Nat'l Ass'n v. Farino*, 960 F.2d 1217, 1223 (3d Cir.1992). On a motion to dismiss for lack of personal

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[1]With regard to the statutory inquiry, the Court applies the law of the state in which the district court is located; as to the constitutional inquiry, in a patent case the court applies the law of the Federal Circuit. *See Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1016 (Fed. Cir. 2009).

jurisdiction, "the plaintiff is entitled to have its allegations taken as true and all factual disputes drawn in its favor." *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004).

"To survive a motion to dismiss in the absence of jurisdictional discovery, plaintiffs need only make a prima facie showing of jurisdiction." *Nuance Commc'ns, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1231 (Fed. Cir. 2010). A court is always free to revisit the issue of personal jurisdiction if it later is revealed that the facts alleged in support of jurisdiction are in dispute. *See Metcalfe v. Renaissance Marine, Inc.*, 566 F.3d 324, 331 (3d Cir. 2009).[2]

III. DISCUSSION

GSA moves to dismiss on the ground that the Court lacks personal jurisdiction over it because, as a foreign corporation, it has no relevant jurisdictional contacts, i.e., it has no presence and does not make, use, offer for sale, or sell any Accused Products in this District. (D.I. 57 at 1) Enzo counters that GSA' involvement in the manufacture, sale, and distribution of the Accused Products, either directly or indirectly, in the United States provides a basis for the Court to

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[2]GSA writes:

> If the Court decides the motion based on written submissions [as it is doing], then Enzo must make a *prima facie* showing of personal jurisdiction over GSA. Because GSA has submitted declarations refuting the jurisdictional allegations in the FAC, the Court cannot accept the bare formulaic accusations of the FAC and Enzo must submit declarations or other evidence sufficient to create a factual dispute regarding GSA's forum-state contacts.

(D.I. 57 at 4-5) (internal citations and quotation marks omitted) Enzo has met this obligation by citing to evidence sufficient (at minimum) to create a factual dispute, as explained in this Memorandum Opinion.

exercise specific jurisdiction over GSA.[3] (D.I. 63 at 7-8) (citing D.I. 28-1 ¶¶ 8-13) Enzo relies on both the Delaware long-arm statute (D.I. 63 at 7) (citing10 Del. C. § 3104 (c)(1) and (c)(3)), and the Federal long-arm statute (*id.* at 16-17) (citing Fed. R. Civ. P. 4(k)(2)), to establish jurisdiction.

GSA counters Enzo's allegations with declarations from the President of GDS (*see* D.I. 58) and GSA's Chief Financial Officer ("CFO") (*see* D.I. 59) to the effect that "[GSA] itself has never made, used, advertised, marketed, offered for sale, or sold any of the Accused Products in Delaware or anywhere else in the United States," "has no role with respect to the distribution channel of the Accused Products in the United States" beyond a "general oversight . . . that is typical of a corporate parent-subsidiary relationship," and "maintains corporate separateness with GDS." (D.I. 57 at 3-4, 7-8, 9-10)

At this stage of the case, Enzo is "entitled to have [its] allegations viewed as true and have disputed facts construed in [its] favor." *Metcalfe*, 566 F.3d at 331. Additionally, Enzo does not "merely rest on [its] . . . pleadings but rather submitted a [declaration] . . . and other documentary evidence in support of . . . personal jurisdiction." *Id.*; *see also generally* D.I. 64. Accepting this evidence as true and construing the disputed facts in Enzo's favor, the Court finds that Enzo has established a prima facie case of jurisdiction over GSA consistent with the Delaware long-arm statute, Federal long-arm statute, and constitutional due process.

A. The Delaware Long-Arm Statute – 10 Del. C. § 3104

The Delaware long-arm statute, in relevant part, states that:

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[3]Enzo does not contend the Court may exercise general personal jurisdiction over GSA. (*See* D.I. 57 at 5-7)

> (c) As to a cause of action brought by any person arising from any of the acts enumerated in this section, a court may exercise personal jurisdiction over any nonresident, or a personal representative, who in person or through an agent:
>
> > (1) Transacts any business or performs any character of work or service in the State; . . .
> >
> > (3) Causes tortious injury in the State by an act or omission in this State . . . .

10 Del. C. § 3104. "[J]urisdiction under either (c)(1) or (c)(3) requires a showing that the plaintiff's claim arises from the defendant's activity, [and] that there is a nexus between the cause of action and the conduct used as a basis for jurisdiction." *McDonough v. Gorman*, 2017 WL 3528846, *3 (D. Del. Aug. 16, 2017) (internal quotation marks and brackets omitted).

It is uncontested that "Delaware's long arm statute . . . is to be broadly construed to confer jurisdiction to the maximum extent possible under the Due Process Clause." *Robert Bosch LLC v. Alberee Prod., Inc.*, 70 F. Supp. 3d 665, 675 (D. Del. 2014); *see also* D.I. 57 at 5. Consistent with the Due Process Clause, a party may be subject to personal jurisdiction when that party does "something more than simply placing a product into the stream of commerce." *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 889 (2011) (internal quotation marks omitted); *see also Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 112 (1987) ("The substantial connection between the defendant and the forum State necessary for a finding of minimum contacts must come about by an action of the defendant purposefully directed toward the forum State.").

GDS – the wholly-owned subsidiary of GSA – has not challenged the jurisdiction of this Court. There is no dispute that GDS has relevant jurisdictional contacts arising from its

commercial activities, such as the "manufacturing, advertising, marketing, offering for sale, and selling of the Accused Products in the United States," and this District.[4] (D.I. 57 at 7) Thus, the issue before the Court is whether Enzo has met its burden to show with "reasonable particularity" that GSA also participates in such commercial activities sufficient to meet the jurisdictional requirements of the Delaware long-arm statute. *Mellon Bank*, 960 F.2d at 1223.

Plaintiff has established a prima facie case that GSA plays a direct role in the commercial operations relating to the Accused Products in the United States, including in this District.[5] Contrary to GSA's arguments, the government filings and public statements in the record support the plausible inference that GSA participates in the development, sales, and marketing of the

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[4]*See also* D.I. 58 ¶ 6 (GDS' President noting that GDS is "responsible for the advertising, marketing, sale and distribution of the Accused Products in the United States"); *id.* ¶ 7 (same noting that GDS carries out "[a]ll aspects of the commercialization of the Accused Products in the United States" such as soliciting sales, operating U.S.-facing website, handling online product orders, and creating product and marketing materials); D.I. 59 ¶ 17 (GSA's CFO noting that "[e]ven if the activities and business of GDS in the State of Delaware were imputed to [GSA] or aggregated with [GSA], they represent only a small percentage of [GSA'] global business").

[5]GSA does not distinguish between commercial activities occurring in the United States and in Delaware. Instead, GSA argues that whatever relevant jurisdictional contacts necessary to confer specific jurisdiction in Delaware are associated with GDS, not GSA. (*See* D.I. 68 at 1 (arguing that evidence submitted by Enzo "shed no light on the issue of [GSA's] own jurisdictional contacts with the State of Delaware because they concern Grifols' business as a whole, without distinguishing between the parent corporation [GSA] and its various subsidiaries"); *see also generally* D.I. 58, 59) Thus, the evidence showing the commercial activities targeting the United States is also relevant to Delaware, as there is no showing that GSA or GDS attempted to exclude the Accused Products from reaching the Delaware market. *See Robert Bosch*, 70 F. Supp. 3d at 675 ("A non-resident firm's intent to serve the United States market is sufficient to establish an intent to serve the Delaware market, unless there is evidence that the firm intended to exclude from its marketing and distribution efforts some portion of the country that includes Delaware.").

Accused Products in the United States.[6] The record also shows that [redacted] (*See* D.I. 64-9 (Collaboration Agreement [redacted]); D.I. 64-10 (Supply Agreement [redacted]).[7] Taken together, Enzo has met its burden to show the Court may exercise specific jurisdiction over GSA.

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[6]*See, e.g.,* D.I. 64-6 at pp. 2-3 of 6 (GSA publication noting that "Grifols entered into an agreement to acquire Hologic's . . . interest in their existing joint-business under which Grifols owns all customer facing activities" and "based on the existing agreement with Hologic, ***Grifols is marketing the aforementioned [NAT] assays and instruments worldwide***") (emphasis added); *id.* at 5 of 6 ("Grifols is a leading company in the NAT technology business (Procleix® NAT Solutions) . . .; ***in the United States, its market share reaches 79%*** . . . . In addition, Grifols . . . ***continues to make strides in the U.S. market, which is both relevant and very much a consolidated market.***") (emphasis added); D.I. 64-3 at p. 3 of 5 (GSA's 2017 SEC filing, noting that "[p]rior to the Hologic Transaction, we and Hologic jointly operated this business, with Hologic responsible for research and development and manufacturing of the Procleix® blood screening products and ***Grifols responsible for their commercialization worldwide***") (emphasis added); D.I. 64-8 at p. 3 of 5 (GSA's 2015 SEC filing, noting that "***[t]he Procleix® assays we added to our portfolio as a result of the Novartis Acquisition are developed in collaboration with Hologic*** . . . . We have an agreement with Hologic through 2025 to distribute and sell these Procleix® assays . . . .") (emphasis added).

[7]GSA argues that Enzo has failed to show a nexus between Enzo's patent infringement claim and GSA's conduct used as a basis for jurisdiction based on GSA's agreements with Hologic. (*See* D.I. 68 at 3) But drawing reasonable inferences from these agreements, [redacted], and viewing them in Enzo's favor, the Court concludes that these agreements plausibly relate to the Accused Products.

Enzo further argues that GDS' actions, including sales of the Accused Products, as GSA's agent are attributable to GSA. (D.I. 63 at 10) "Under agency theory, a defendant company may be subject to personal jurisdiction under Delaware's long-arm statute by virtue of the court's personal jurisdiction over the defendant company's affiliate." *Robert Bosch*, 70 F. Supp. 3d at 678-79. "The agency theory may be applied not only to parents and subsidiaries, but also to companies that are 'two arms of the same business group,' operate in concert with each other, and enter into agreements with each other that are nearer than arm's length." *Id.* "Among the factors for determining whether an agency relationship exists are: '[1] the extent of overlap of officers and directors, [2] methods of financing, [3] the division of responsibility for day-to-day management, and [4] the process by which each corporation obtains its business.'" *Id.* The Court agrees that Enzo has made a sufficient showing that GDS is GSA's agent. *See Waters v. Deutz Corp.*, 460 A.2d 1332, 1337-38 (Del. Super. Ct. 1983) ("10 Del. C. § 3104 authorizes jurisdiction over a foreign manufacturer . . . based on the commercial marketing activities of its subsidiary.").

GSA has made numerous representations through "government filings, public statements made by its own CEO, and press releases" that "describe Grifols as the architect and driving force behind the manufacturing, marketing and sales operations for the accused Procleix products in the United States." (D.I. 63 at 11) It is undisputed that GDS is the entity that acquired the relevant assets, including the Accused Products, from Hologic. While GSA structured this acquisition through GDS, Enzo has produced competent evidence showing GSA's purpose was to enter the United States market and gain control over the commercial activities of the Accused Products in the United States. GSA's then-Chairman and CEO explained that "we knew ***we***

needed a significant presence in United States" to achieve "our vision to become a world leader also in the diagnostics field." (D.I. 64-1 at p. 3 of 5) (emphasis added) He further noted that Hologic has been a "strategic partner of Grifols since 2014," adding that the acquisition of Hologic's NAT blood screening business has "contributed to our vertical integration process as we also have ***control over the production and R&D phases***." (D.I. 64-6 at 3 of 6) (emphasis added)

The record further shows that the operations and management of GSA and GDS are interlinked. GSA and GDS share board members. (*See* D.I. 64-14 at 2; D.I. 64-15 at 1; D.I. 64-16 at 2) GSA combines GDS' financial information with its own when it makes required disclosures as a publicly-traded company in the United States. (*See, e.g.,* D.I. 64-3) GDS' website in the United States describes the history of GSA features the president and C.E.O. of GSA as part of GDS' leadership. (*See* D.I. 64-17; D.I. 64-18) The website also shows GSA is behind the commercialization of the Accused Products in the United States. (*See* D.I. 64-6 at p. 3 of 6 ("Until now, based on the existing agreement with Hologic, Grifols is marketing the aforementioned assays and instruments worldwide."); *id.* at p. 5 of 6 (noting that "Grifols is a leading company in the NAT technology business (Procleix® NAT Solutions) . . . in the United States, its market share reaches 79%"))

GSA argues that "'regulatory filings present[ing] the assets, liabilities, and financial earnings of its subsidiaries as one indistinguishable whole do not prove agency' for purposes of imputing jurisdictional contacts from a subsidiary to a parent." (D.I. 68 at 2) (citing *Nespresso USA, Inc. v. Ethical Coffee Co. SA*, 263 F. Supp. 3d 498, 505 (D. Del. 2017)) In *Nespresso*, however, "[t]he record indicate[d] [defendant] Nestlé had no role in the design,

manufacture, distribution, marketing, or sale of [accused products]." *Id.* at 504 (internal quotation marks omitted). By contrast, the evidence here does show GSA's involvement in the development, sales, and marketing of the Accused Products.

Additionally, as part of GSA's purchase agreement with Hologic, [redacted] (D.I. 64-19 at p. 7 of 12) [redacted] (*See id.*) ([redacted] of agreement noting [redacted]) (redaction in original)

For all these reasons, the Court concludes that Plaintiffs have met their burden to show that the requirements of the Delaware long-arm statute are satisfied.

B. Due Process

"If the Court determines that it has jurisdiction under Delaware's long-arm statute, the Court must next determine if 'subjecting the nonresident defendant to jurisdiction in Delaware violates the Due Process Clause of the Fourteenth Amendment.'" *Robert Bosch*, 70 F. Supp. 3d at 676. A defendant is subject to the jurisdiction of a federal court only when the defendant's conduct and connections with the forum state are such that it should "reasonably anticipate being haled into court there," *World–Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297, and exercising personal jurisdiction would not offend "traditional notions of fair play and substantial justice," *Int'l Shoe*, 326 U.S. at 316.

Exercising personal jurisdiction over GSA in this Court is not inconsistent with the Due Process Clause. For the reasons stated in connection with application of the Delaware Long-Arm statute, GSA has sufficient minimum contacts with Delaware. Further, GSA "could foresee being haled into court" in Delaware. *Asahi*, 480 U.S. at 109. GSA formed GDS as a wholly-owned subsidiary incorporated in Delaware to specifically serve the market, including by selling the Accused Products in the United States. (*See* D.I. 64-6 at p. 3 of 6) ("The acquisition [of Hologic's NAT blood screening business] is structured through [GDS], a U.S. incorporated, wholly owned subsidiary of Grifols, S.A.") GSA was also fully aware of this litigation when it acquired Hologic's assets. As part of the acquisition, GSA negotiated the right to participate in the defense of Enzo's claims in this case and agreed to pay a portion of any resulting monetary judgment.[8] Thus, GSA has "purposefully avail[ed] itself of the privilege of conducting activities within [Delaware], thus invoking the benefits and protections of its laws." *McIntyre*, 131 S. Ct. at 2785; *see also Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475–76 (1985) ("[W]here the defendant 'deliberately' has engaged in significant activities within a State, . . . he manifestly has availed himself of the privilege of conducting business there, and because his activities are

[8]The record supports Enzo's contention that:

> [GSA] had full knowledge of Enzo's patent infringement claims against the accused Procleix products in this case before it and GDS acquired Hologic's blood screening business unit. In fact, [GSA] entered into an indemnification agreement with Hologic that (1) permits only [GSA] – not GDS – to participate in the defense of Enzo's claims, and (2) requires [GSA] – but not GDS – to pay a portion of any award or settlement to Enzo.

(D.I. 63 at 2)

shielded by 'the benefits and protections' of the forum's laws it is presumptively not unreasonable to require him to submit to the burdens of litigation in that forum as well.").

This case also does not represent "the rare situation in which the plaintiff's interest and the state's interest in adjudicating the dispute in the forum are so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum." *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568 (Fed. Cir. 1994). GSA argues that "[b]eing haled into court in Delaware imposes a significant burden on [GSA], a Spanish corporation with no presence in this State." (D.I. 57 at 11) But GSA has not shown that participating in this litigation would be "so gravely difficult and inconvenient" that it would be at a "severe disadvantage" when compared to Enzo. *Burger King Corp.*, 471 U.S. at 478.[9] GSA has not, for example, sought "a change of venue" or identified any other forum in the United States where personal jurisdiction would be appropriate. *Id.* at 477. GSA's purported burden of litigating in this Court is no greater that any other judicial district. While GSA "will be required to submit itself to a foreign nation's judicial system," GSA, through its efforts to commercialize the Accused Products using GDS, "cannot profess complete ignorance of the judicial system of the United States." *Beverly Hills*, 21 F.3d at 1569. The record supports Enzo's observations that GSA "is a global company that has subsidiaries across the world, including in Delaware" and, further, that GSA "shares litigation counsel with Hologic and GDS, which have not challenged

[9]As GSA recognizes, at "this prong of the analysis, the burden shifts to the defendant to 'present a compelling case that the presence of some other considerations would render jurisdiction unreasonable under the five-factor test articulated by the Supreme Court.'" (D.I. 57 at 10) (quoting *Autogenomics*, 566 F.3d at 1018)

personal jurisdiction." (D.I. 63 at 16) Thus, the burden on GSA "is not sufficiently compelling to outweigh" Enzo's and Delaware's interests. *Id.*

C. The Federal Long-Arm Statute – Rule 4(k)(2)

Enzo argues in the alternative that the Court should exercise jurisdiction over GSA under Federal Rule of Civil Procedure 4(k)(2), also known as the Federal long-arm statute. (D.I. 63 at 16-19) "Pursuant to Rule 4(k)(2), personal jurisdiction over a foreign defendant exists when: (1) the case arises under federal law and is not pending before the court pursuant to the court's diversity jurisdiction; (2) the foreign defendant lacks sufficient contacts with any single state to subject it to personal jurisdiction in any state; and (3) the foreign defendant has sufficient contacts with the United States as a whole to comport with constitutional notions of due process." *Robert Bosch*, 70 F. Supp. 3d at 680.

GSA challenges only the third prong, arguing that "even considering [GSA's] contacts with the entire United States, [GSA] does not have sufficient minimum contacts to satisfy due process because GDS, not [GSA], is responsible for the manufacturing, marketing, and sale of the Accused Products in the United States." (D.I. 68 at 6) However, the Court has already concluded that the evidence of record shows GSA has purposely directed its commercial activities to the United States through its role in the sales and marketing of the Accused Products. Hence, Rule 4(k)(2) provides an additional reason for the Court to exercise jurisdiction over GSA.

IV. CONCLUSION

For the foregoing reasons, the Court will deny GSA's motion to dismiss for lack of personal jurisdiction.[10] An appropriate Order follows.

[10]Enzo also requests jurisdictional discovery from GSA, if the Court concludes that a more substantial showing of facts is necessary to determine whether the exercise of personal jurisdiction over GSA is proper. (D.I. 63 at 19) Because the Court has already concluded that it may properly exercise personal jurisdiction over GSA, Enzo's request for jurisdictional discovery is moot.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 16-894-LPS-CJB
	)	
HOLOGIC INC.,	)	
GRIFOLS DIAGNOSTICS	)	
SOLUTIONS, INC., and GRIFOLS, S.A.,	)	
	)	
Defendants.	)	
	)	

ORDER

At Wilmington this **26th** day of **September, 2018**:

For reasons discussed in the Memorandum Opinion issued this same date,

IT IS HEREBY ORDERED that:

1. GSA's Motion to Dismiss for Lack of Personal Jurisdiction (D.I. 56) is **DENIED**.

2. As the Memorandum Opinion was filed under seal, the parties shall meet and confer and shall, no later than **September 27, 2018**, submit a proposed redacted version. Thereafter, the Court will issue a public version of its Memorandum Opinion.

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE