IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HEMOSTEMIX, INC., Plaintiff; v. ACCUDATA SOLUTIONS, INC. and ASPIRE HEALTH SCIENCE, LLC, Defendants.	Civil Action No. 20-881-RGA

MEMORANDUM OPINION

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March 30, 2021

/s/ Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before the Court is Plaintiff's Motion for a Preliminary Injunction (D.I. 6). Both Defendants oppose. (D.I. 17, 33). I have reviewed the parties' briefing. (D.I. 7, 17, 20, 28, 33, 37). I heard oral argument. (D.I. 35).

I. BACKGROUND

Plaintiff Hemostemix filed suit against Defendant Accudata seeking a declaratory judgment and specific performance under the Hemostemix-Accudata Consulting Agreement ("Consulting Agreement") and alleging breach of contract. (D.I. 1 at 10-14). Plaintiff is a clinical-stage biotechnology company and Accudata is a biostatistics firm. This action concerns the underlying clinical trial data and analysis for the Midpoint Analysis of Plaintiff's clinical trials for its product ACP-01. Shortly after filing suit, Plaintiff filed the instant motion. (D.I. 6). Plaintiff's motion requests that the Court order Accudata to return Plaintiff's clinical and statistical data and be forbidden from sharing the data with third parties. (*Id.*). Defendant Aspire, a Contract Research Organization (CRO), filed a motion to intervene (D.I. 23), which the Court granted (D.I. 38).

Related litigation between Hemostemix and Aspire was initiated in both Calgary, Canada, and in state court in Florida before this suit was filed. Trial in Florida was set for "the trial period beginning January 10, 2022." (D.I. 52-1 at ¶ 4). The Canadian litigation was dismissed in June 2020 (D.I. 35 at 16), and "recently ended without a decision on the merits" after an appeal by Hemostemix (D.I. 48 at 4).

II. LEGAL STANDARD

"The decision whether to enter a preliminary injunction is committed to the sound discretion of the trial court." *Duraco Prods., Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1437

(3d Cir. 1994) (quoting *Merchant & Evans, Inc. v. Roosevelt Bldg. Prods. Co.*, 963 F.2d 628, 633 (3d Cir. 1992)). The Third Circuit has cautioned that a preliminary injunction is "an extraordinary remedy" to be granted "only in limited circumstances." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002) (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989)).When seeking a preliminary injunction, a movant "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 v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The movant must establish the first two requirements before a court considers, to the extent relevant, the remaining two prongs of the standard. *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x 135, 138 (3d Cir. 2019). Further, "where the relief ordered by a preliminary injunction is mandatory and will alter the status quo, the party seeking the injunction must meet a higher standard of showing irreparable harm in absence of an injunction." *Bennington Foods, LLC v. St. Croix Renaissance, Grp., LLP*, 528 F.3d 176, 179 (3d Cir. 2008). In such cases "the burden on the moving party is particularly heavy." *Punnett v. Carter*, 621 F.2d 578, 582 (3d. Cir. 1980).

III. ANALYSIS

Plaintiff moves for a preliminary injunction to compel Accudata to return all of Plaintiff's clinical trial data and to enjoin Accudata from divulging or disclosing such information to third parties. (D.I. 7 at 2). Accudata contends that Plaintiff's motion for a preliminary injunction is moot to the extent that it seeks Accudata's Midpoint Analysis, as Plaintiff received the analysis on July 5, 2020 from Aspire. (D.I. 17 at 10). Accudata argues that since Plaintiff is in possession of the Midpoint Analysis from Aspire, there is no need to compel disclosure from Accudata.

(*Id.*). Aspire argues that Plaintiff has not met its burden in demonstrating the need for a preliminary injunction. (D.I. 33 at 10).

A. Likelihood of Success on the Merits

Plaintiff argues that it is likely to succeed on the merits because, under the Consulting Agreement, it owns the clinical and statistical data at issue and Accudata was required to return the data, which it did not do. (D.I. 7 at 15). Plaintiff asserts that it has made a breach of contract claim as the Consulting Agreement was between itself and Accudata, and by withholding the data, Accudata has breached, and is continuing to breach, the agreement. (*Id.* at 16). Plaintiff argues that as a direct result of Accudata's breach it is unable to complete its clinical trials. (*Id.*). Plaintiff contends that for these reasons, it is likely to prevail on the merits of the breach of contracts claim, as well as the specific performance and declaratory judgment claims. (*Id.*).

Aspire contends that Plaintiff has not shown a likelihood of success on the merits on its specific performance claim. (D.I. 33 at 11-12). Aspire argues that Plaintiff has not established the elements of specific performance. (*Id.*). Aspire contends that Plaintiff has not established that there was a breach of contract. (*Id.*). Aspire asserts that the Consulting Agreement was not breached, as Accudata and Hemostemix were not acting pursuant to that contract. (*Id.* at 12). Aspire also contends that even if the parties were acting pursuant to that agreement, there still was no contract breach because Plaintiff does not own the Midpoint Analysis and the ownership rights to the clinical trial data are disputed. (*Id.* at 14). Lastly, Aspire argues that the balance of equities does not tip in Plaintiff's favor as Plaintiff "dragged" Accudata into this dispute, and Plaintiff could seek access to the clinical trial data in the other ongoing action between Plaintiff and Aspire in Florida. (*Id.* at 16).

Plaintiff has shown that there was a breach of contract. For breach of contract under Delaware law, a plaintiff must establish "(1) the existence of a contract; (2) the breach of an obligation imposed by the contract; and (3) resulting damage to the plaintiff." *Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 394 (D. Del. 2019). Plaintiff has established that it had a contract (the Consulting Agreement) with Accudata, that Accudata breached the contract when it refused to return Plaintiff's data, and that Plaintiff is damaged by not having access to the original Midpoint Analysis and the underlying clinical trial data. (D.I. 8 at 5-7 of 9; D.I. 36-1, Exh. 1 at 5 of 344).

However, establishing a breach of contract does not bear Plaintiff's "particularly heavy" burden, *Punnett*, 621 F.2d at 582, of proving a likelihood of success on the merits. There are many different agreements at play in this dispute. In particular, Aspire points to its own Contractor Agreement with Accudata, which provides that Accudata will perform an analysis of the data for the clinical trials and that all information should be returned to Aspire upon expiration or early termination of the agreement. (D.I. 24-2, Exh. C at 2, 4 of 6). Aspire contends that under this agreement it has the rights to the data as it paid for the data analysis pursuant to its Contractor Agreement with Accudata. (D.I. 35 at 18 ("Aspire owns the data."); *id*. at 23 ("the data is 100 percent owned by Aspire")). There are conflicting agreements and conflicting claims to the Midpoint Analysis and underlying clinical trial data. Based on the record, it is not clear that Plaintiff is likely to succeed on the merits.

B. Irreparable Harm

Plaintiff argues that it would suffer irreparable harm without the granting of a preliminary injunction as its lack of access to the clinical trial data and Midpoint Analysis will impede the ongoing clinical trials. (D.I. 7 at 17-18). Plaintiff contends that its lack of access to the data could

cause "potential termination of the clinical trials," causing a loss of money, time, and patient access to ACP-01. (*Id.* at 17). Plaintiff also argues that without access to the data it could be subject to "potential significant regulatory ramifications," as it is legally responsible for the clinical trials and the data serves as a critical means of information so that Plaintiff can oversee the trials. (*Id*. at 18).

Aspire argues that Plaintiff has not met its burden of showing that it would suffer irreparable harm without a preliminary injunction. Aspire contends that Plaintiff is requesting a mandatory injunction and must meet a higher standard of showing irreparable harm. (D.I. 33 at 10). Aspire asserts first that Plaintiff is seeking final relief on its specific performance claim, which would change, not preserve, the status quo as the clinical trial data would be given to Plaintiff. (*Id.* at 16). Aspire then argues that Plaintiff's "purported" irreparable harm is negated by its delayed request for the clinical trial data from Accudata and delay tactics in the Florida Action. (*Id.* at 17-18).

Here, Plaintiff seeks the return of its data and Midpoint Analysis from Accudata. This relief will "alter the status quo" as it will change who is in possession of the data. Therefore, Plaintiff must meet a "higher standard of showing irreparable harm in the absence of an injunction." *Bennington Foods*, 528 F.3d at 179. Plaintiff argues that it will suffer irreparable harm as its lack of access to the data could result in two theoretical situations: "potential termination of the clinical trials" and/or "potential significant regulatory ramifications." Beyond these assertions, Plaintiff does not show a likelihood of suffering irreparable harm.

Plaintiff currently has access to the Midpoint Analysis. Aspire's counsel transmitted the Midpoint Analysis to Plaintiff on July 5, 2020. (D.I. 17 at 10; D.I. 20 at 4). This negates Plaintiff's arguments that it could not provide effective oversight to the clinical trials; it has the

information that was contained in the Midpoint Analysis. While Plaintiff continues to seek a signed copy of the Midpoint Analysis and the data upon which the analysis relies (D.I. 18 at 3-5; D.I. 22 at ¶ 18), it nevertheless has access to the Midpoint Analysis and will continue to have such access throughout this litigation. Further, the Midpoint Analysis and the other clinical trial data in Accudata's possession is not at risk of being destroyed in the interim, as it is under court order for preservation. (*See* D.I. 30; D.I. 35 at 28, 50).

Granting Plaintiff's motion for a preliminary injunction would be granting Plaintiff final relief for its specific performance claim. It would change, not preserve, the status quo, as it would alter who is in possession of the Midpoint Analysis and the underlying clinical trial data. Such a mandatory injunctions requires a particularly heavy burden to show its necessity. *See Punnett*, 621 F.2d at 582. Here, Plaintiff has not borne that burden. Plaintiff has access to the Midpoint Analysis and there is no risk of destruction of the underlying clinical data. Should Plaintiff succeed on the merits it would receive the analysis and clinical trial data that it seeks. For these reasons, Plaintiff has not established the likelihood of irreparable harm.[1]

IV. CONCLUSION

For the foregoing reasons, Plaintiff's Motion for a Preliminary Injunction (D.I. 6) is denied.

[1] As Plaintiff has not established a likelihood of success on the merits or that it would suffer irreparable harm without preliminary relief, the Court will not assess the balance of equities or whether granting a preliminary injunction will further the public interest. *See Cipla*, 778 F. App'x at 138.

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ORDER

For the reasons stated in the accompanying memorandum opinion, Plaintiff's motion for a preliminary injunction (D.I. 6) is **DENIED**.

IT IS SO ORDERED this 30th day of March 2021.

/s/ Richard G. Andrews
United States District Judge