IN THE COURT OF COMMON PLEAS OF MONTGOMERY COUNTY, PENNSYLVANIA
CIVIL ACTION – LAW

INOVIO PHARMACEUTICALS, INC.	:	NO. 2020-06554
v.	:	
GENEONE LIFE SCIENCE INC and VGXI, INC	:	

MEMORANDUM AND ORDER

This matter is both exceedingly timely and exceedingly difficult. The nation and the world are in the midst of the COVID-19 pandemic — the most destructive pandemic in over a century. In its Petition for a Preliminary Injunction, Plaintiff Inovio Pharmaceuticals, Inc. ("Inovio"), claims that it has developed a vaccine that can end the pandemic, but only if the Court compels Defendant VGXI, Inc. ("VGXI"), to transfer its proprietary DNA manufacturing process to as many as ten other manufacturers. The Court recognizes the compelling interest in the commercial development of an effective COVID-19 vaccine. Nevertheless, after consideration of all the evidence presented, the Court concludes that the factual basis for Inovio's claim is too speculative to support the extraordinary remedy of a mandatory preliminary injunction.

Inovio commenced this action against VGXI and its parent, Defendant GeneOne Life Science, Inc., by Writ of Summons on June 1, 2020. It filed its Complaint and Petition for a

Preliminary Injunction on June 3, 2020. A hearing was held on the Petition on June 18 and 22, 2020.[1] The facts set forth below are based on the evidence presented at that hearing.[2]

Inovio is a biotechnology company engaged in developing DNA medicines. It is party to a Supply Agreement dated June 25, 2008, and amended September 4, 2013, with VGXI, which is engaged in the manufacture of DNA plasmids through a proprietary manufacturing process. The Supply Agreement provides that Inovio shall treat VGXI as its "Most Favored Supplier" for DNA plasmids and that VGXI shall treat Inovio as its "Most Favored Customer," as those terms are defined in the Agreement. Section 2.9(a)(iii) of the Agreement, as amended, provides that under certain circumstances, generally involving VGXI's inability to manufacture or refusal of a "production project," VGXI must deliver to Inovio a "transfer documentation package to enable Inovio to transfer the manufacturing process to a location of Inovio's choosing."

Inovio is in the process of developing a DNA vaccine for COVID-19. Although the vaccine is still in Phase I testing, the results thus far are promising enough that Inovio desires to begin large-scale commercial production of the vaccine now, in the expectation that it will eventually obtain final regulatory approval. Specifically, Inovio seeks the manufacture of one million doses by the end of 2020 and one hundred million doses by the end of 2021. It asserts that VGXI is unable to meet these manufacturing requirements and that VGXI is therefore required to proceed with its technology transfer obligations under section 2.9(a)(iii). Inovio's Petition seeks a preliminary injunction requiring VGXI to transfer its DNA manufacturing technology under that section.

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[1] Fittingly, the need for social distancing required that the hearing be held by remote video technology.

[2] In the interest of issuing a prompt ruling, the Court has not taken the time that would be required to engage in a complete discussion of the evidence and the applicable law. Instead, this Memorandum is limited to a concise explanation of the principal factual and legal bases for the Court's ruling.

The "essential prerequisites" for a preliminary injunction are as follows:

> First, a party seeking a preliminary injunction must show that an injunction is necessary to prevent immediate and irreparable harm that cannot be adequately compensated by damages. Second, the party must show that greater injury would result from refusing an injunction than from granting it, and, concomitantly, that issuance of an injunction will not substantially harm other interested parties in the proceedings. Third, the party must show that a preliminary injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct. Fourth, the party seeking an injunction must show that the activity it seeks to restrain is actionable, that its right to relief is clear, and that the wrong is manifest, or, in other words, must show that it is likely to prevail on the merits. Fifth, the party must show that the injunction it seeks is reasonably suited to abate the offending activity. Sixth and finally, the party seeking an injunction must show that a preliminary injunction will not adversely affect the public interest.

Summit Towne Ctr., Inc. v. Shoe Show of Rocky Mount, Inc., 828 A.2d 995, 1001 (Pa. 2003) (citations omitted). "The burden is on the party who requested preliminary injunctive relief . . . ," *Warehime v. Warehime*, 860 A.2d 41, 47 (Pa. 2004), and the failure to satisfy "any one of the . . . 'essential prerequisites'" is a sufficient basis for denial of a preliminary injunction, *Summit Towne Ctr.*, 828 A.2d at 1001.

This burden is enhanced when the preliminary injunction that is sought is mandatory rather than prohibitory. As our Supreme Court has cautioned:

> Generally, preliminary injunctions are preventive in nature and are designed to maintain the status quo until the rights of the parties are finally determined. There is, however, a distinction between mandatory injunctions, which command the performance of some positive act to preserve the status quo, and prohibitory injunctions, which enjoin the doing of an act that will change the status quo. This Court has engaged in greater scrutiny of mandatory injunctions and has often stated that they should be issued more sparingly than injunctions that are merely prohibitory. Thus, in reviewing the grant of a mandatory injunction, we have insisted that a clear right to relief in the plaintiff be established.

Mazzie v. Commonwealth, 432 A.2d 985, 988 (Pa. 1981); *see Summit Towne Ctr.*, 828 A.2d at 1005 n.13.

To start with the easiest factor, it is clear that the requested injunction would not harm the public interest. It is unnecessary to state in any detail the incalculable cost that the COVID-19 pandemic has imposed and will continue to impose, on the nation and the world, in lost lives, injury to health, and economic hardship. Any positive step toward the prompt development of an effective vaccine would plainly be in the public interest.

Whether Inovio has shown a likelihood of success on the merits of its contract claim is a much closer call. It does appear from the evidence that VGXI is "unable to manufacture" Inovio's vaccine requirements under section 2.9(a)(iii) of the Supply Agreement. VGXI's current large-scale manufacturing capacity is limited. Section 4.6 of the Agreement generally prohibits it from delegating or subcontracting its contractual obligations, although it appears to have done so, without objection from Inovio, on an earlier project several years ago, when VGXI brought in Richter-Helm BioTec as an "overflow manufacturer." Further, VGXI's professed willingness to dramatically expand its manufacturing capacity in a short time is largely aspirational. On the other hand, VGXI notes that the technology transfer provision of section 2.9(a)(iii) applies only to a "production project." That term is not defined in the Agreement, but Inovio's own witnesses acknowledged that as used between the parties, the term requires the issuance of a purchase order, which did not occur in this case. Inovio counters that the submission of a purchase order under the circumstances would be a futile ritual and that its failure to do so does not preclude application of the technology transfer provision. On balance, Inovio probably has the better of the argument, but that balance is a close one. It is uncertain whether Inovio has established the "clear right to relief" required for a mandatory preliminary injunction. *Mazzie*, 432 A.2d at 988. Even if it has done so, however, several other factors counsel against the issuance of an injunction.

First, Inovio has not established that "an injunction is *necessary* to prevent immediate and irreparable harm." *Summit Towne Ctr*, 828 A.2d at 1001 (emphasis added). To the contrary, Inovio's witnesses testified that there are other manufacturers that are capable of manufacturing DNA plasmids. It therefore does not appear "necessary" that VGXI transfer its own manufacturing technology in order that Inovio's needs are met. It is true that the alternative manufacturing processes of other companies *might* not be suitable for Inovio's vaccine. But the evidence was that Inovio is still investigating that issue and has not reached a definitive answer. Thus, the assertion that a technology transfer is "necessary" to enable the large-scale manufacture of Inovio's vaccine is, at least for now, inherently speculative. In assessing the harm that is asserted to justify the issuance of a preliminary injunction, "speculative considerations" are insufficient. *See, e.g.*, *Novak v. Commonwealth*, 523 A.2d 318, 320 (Pa. 1987).

It is equally speculative, if not more so, that the public interest in the development of an effective COVID-19 vaccine as soon as possible necessitates the immediate large-scale production of *Inovio's* vaccine. There are more than a hundred other potential vaccines in development, any one of which may be the silver bullet (or one of multiple silver bullets) that can end this pandemic. Inovio has presented evidence that the results of its product thus far are very encouraging. But the history of pharmaceutical research contains countless examples of treatments that initially showed promise but ultimately failed to prove themselves safe and effective. Again, the speculative nature of Inovio's predictions weighs against the issuance of an injunction.

Further, the requested technology transfer would "substantially harm" VGXI, *Summit Towne Ctr*, 828 A.2d at 1001, by placing at risk its proprietary rights in its manufacturing

technology. Inovio has stated its intention to transfer the technology to as many as ten other manufacturers, including some in countries with weak enforcement of intellectual property rights, and has not yet identified all of those alternate manufacturers. Certainly in assessing the balance of harms, the protection of private property is outweighed by the saving of hundreds of thousands of lives. But in view of Inovio's inability to show that such a saving of human lives will occur only if a preliminary injunction is issued, VGXI's proprietary interests cannot be ignored. Inovio has argued that any harm to VGXI's intellectual property is a consequence that VGXI should have foreseen in agreeing to section 2.9(a)(iii). It is not at all clear, however, that the Supply Agreement contemplates such a consequence — one that is serious enough that it would likely have been specifically expressed if that were the intention. Indeed, in VGXI's prior technology transfer to Richter-Helm BioTec (which Inovio states was made pursuant to section 2.9(a)(iii) but VGXI claims was made outside of that provision), VGXI was provided with protection from misappropriation of its intellectual property rights.

Finally, enforcement of a mandatory preliminary injunction would be impeded by an inherent difficulty in determining exactly what is required of VGXI in effectuating a technology transfer. Exhibit II to the Supply Agreement, a two-page list of the documentation to be furnished by VGXI, specifically states that it is necessarily incomplete: "An exact list of documents can not be supplied in advance, as it is expected that the documentation system of VGXI will continue to expand and evolve over time." During the course of the hearing, significant issues arose over what would be required of VGXI if an injunction were granted. For example, the parties were at odds over the provisions of section 2.9(a)(iii) requiring that "VGXI will further provide a project plan and personnel required to facilitate transfer of the manufacturing methods to [Inovio's] selected location. A fee will be agreed between the Parties

for this service and will be based upon industry standard fees for similar services." It is unclear how many personnel — and how many hours of service from such personnel within what time frame — VGXI would be obligated to supply under this provision. That uncertainty is especially stark because the section contemplates transfer to "*a* location of Inovio's choosing" (emphasis added) but Inovio seeks a transfer to approximately ten alternate manufacturers. Additional pitfalls are likely present in the many "SOP" documents (presumably Standard Operating Procedures) that are referred to in Exhibit II to the Agreement but have not been provided to the Court. A preliminary injunction should not be entered when "such an injunction would be difficult, if not impossible, to administer." *Maritrans GP Inc. v. Pepper, Hamilton & Scheetz*, 602 A.2d 1277, 1287 (Pa. 1992). To be sure, if Inovio had shown its entitlement to an injunction under the six *Summit* factors, problems of enforcement, standing alone, might not preclude the issuance of an injunction. Where that burden has not been sustained, however, difficulties in framing and administering an injunction provide yet an additional basis for denial.

In the face of the devastation that the COVID-19 pandemic has caused and will continue to cause, it may be tempting to conclude that even the *possibility*, however uncertain, that Inovio's vaccine may be the best and fastest way to bring the pandemic to an end is a sufficient basis for granting its Petition. But following that temptation would be a misuse of the extraordinary power of the Court to order injunctive relief. That power is granted because it is constrained by guardrails — the legal principles developed by our Supreme Court that govern the issuance of a preliminary injunction. Applying those principles to the evidence presented, this Court concludes that Inovio has failed to sustain its burden and that its Petition must be denied.

An appropriate Order follows.

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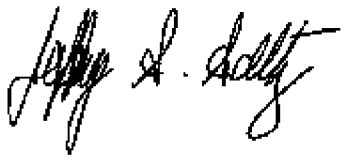
ORDER

AND NOW, this 25th day of June, 2020, upon consideration of the Plaintiff's Petition for a Preliminary Injunction and all other written submissions, and after a hearing held on June 18 and 22, 2020, and for the reasons set forth above, it is hereby **ORDERED** that the Petition is **DENIED**.

BY THE COURT:



JEFFREY S. SALTZ, J.

efiled on 6/25/20