



**IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE**

THERAVECTYS SA, )  
)  
Plaintiff, )  
)  
v. ) **C.A. No. 9950-VCN**  
)  
IMMUNE DESIGN CORP., )  
)  
Defendant. )

**MEMORANDUM OPINION**

Date Submitted: January 14, 2015

Date Decided: March 9, 2015

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Todd C. Schiltz, Esquire of Drinker Biddle & Reath LLP, Wilmington, Delaware, and Steven F. Barley, Esquire, Steven P. Hollman, Esquire, Scott R. Haiber, Esquire, and Marc A. Marinaccio, Esquire of Hogan Lovells US LLP, Baltimore, Maryland, Attorneys for Defendant.

NOBLE, Vice Chancellor

Plaintiff Theravectys SA (“TVS”) and Defendant Immune Design Corp. (“IDC”) are two biotechnology companies, each of which has conducted clinical trials of lentiviral vector vaccines in humans. Both companies used a common manufacturer to produce many of their lentiviral vectors despite the fact that TVS’s contract, which was entered into first, contained an exclusivity provision restricting the manufacturer’s work for third parties and confidentiality provisions protecting TVS’s confidential information. TVS asserts claims of tortious interference with contractual relations and misappropriation of trade secrets against IDC. It seeks a preliminary injunction halting IDC’s continuing use of its allegedly ill-gotten gains. IDC defends, in part, that it had no knowledge of the manufacturer’s obligations to TVS and that it never received any TVS trade secret.

## **I. BACKGROUND<sup>1</sup>**

### *A. TVS Contracts with Henogen*

TVS is a privately-held biotechnology company based in Paris, France. The company specializes in the development of a new generation of therapeutic vaccines based on lentiviral vector (“LV”) technology. Lentiviruses are infectious

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<sup>1</sup> This section provides a broad overview of the facts. Other facts are developed when appropriate in the analysis section. Exhibits submitted by TVS, attached to the Transmittal Affidavit of Albert J. Carroll, are cited as “TVS Ex. \_\_\_.” Exhibits submitted by IDC, attached to the Transmittal Affidavit of Todd C. Schiltz, are cited as “IDC Ex. \_\_\_.” Portions of some witnesses’ testimony were given through interpreters. In addition, some record documents have been translated into English. The accuracy of such translations has not been questioned.

agents that can serve as instruments, *i.e.*, vectors, to deliver genes into cells.<sup>2</sup> They are “adept at gene delivery because they can cross the intact membrane of the nucleus of the target cell and thus infect both dividing and nondividing cells.”<sup>3</sup> LVs are used for both gene therapy and vaccination.<sup>4</sup> “For vaccination, lentiviruses are used to introduce an antigen . . . to activate a patient’s immune response to fight the associated disease . . . .”<sup>5</sup> Currently, most LVs are developed for application to cells outside the body. While LVs developed for application to cells inside the body, *i.e.*, *in vivo*, are a promising technology, no such LV has been approved as a licensed drug.<sup>6</sup>

On October 7, 2010, TVS entered into a Services Agreement (the “TVS-Henogen Agreement”)<sup>7</sup> with Belgian contract manufacturing organization (“CMO”), Henogen SA (“Henogen”). TVS selected Henogen to produce LVs intended for *in vivo* use because of Henogen’s fully cGMP-capable facility,<sup>8</sup> its experience manufacturing LVs, and its convenient European location. TVS

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<sup>2</sup> Opening Expert Report of Dr. Farzin Farzaneh (“Farzaneh Op. Report”) (TVS Ex. A) ¶ 24.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* ¶ 25.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* ¶ 27.

<sup>7</sup> Compl. Ex. A (“TVS-Henogen Agmt.”).

<sup>8</sup> cGMP stands for “current good manufacturing practices,” *i.e.*, guidelines that relevant agencies impose on pharmaceutical companies.

negotiated (despite Henogen's reluctance) for an exclusivity provision (the "Exclusivity Provision") that provided:

For the whole duration of this Agreement, and for a one (1) year period following its termination or expiration, Henogen undertakes to inform TVS of any request made by any third party to Henogen to participate in any way to the manufacturing process of a vaccine based on lentiviral DNA Flap vectors. Henogen shall then decline such third party's request if TVS—at its discretion—asks Henogen to decline it.<sup>9</sup>

TVS bargained for the Exclusivity Provision, in addition to confidentiality provisions, to protect its "knowledge, know-how, and related trade secrets," which would necessarily be transferred under the TVS-Henogen Agreement.<sup>10</sup> Further, during the course of their collaboration, Henogen would develop additional valuable confidential information properly belonging to TVS.<sup>11</sup>

In December 2012, TVS initiated a Phase I clinical trial to test its LV vaccines in HIV patients, becoming the first company to launch clinical trials using *in vivo* LV vaccines.<sup>12</sup> TVS, as a spin-off from the Pasteur Institute, a French non-profit famous for groundbreaking HIV research, decided to focus on HIV applications. It anticipated that proving the safety and efficacy of its technology with HIV would attract investors, collaborators, and licensing opportunities,

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<sup>9</sup> TVS-Henogen Agmt. § 2.6.

<sup>10</sup> Dep. Tr. of Renaud Vaillant, Oct. 22-23, 2014 ("Vaillant Dep.") (TVS Exs. G-I) 308.

<sup>11</sup> *Id.*

<sup>12</sup> Aff. of Cécile Bauche ¶ 17. Bringing vaccines to market is a long process that requires several rounds of trials and regulatory approval. Compl. ¶ 9.

allowing it to expand into other product candidates, such as treatments for cancer. TVS has since completed its Phase I trial and reported results.

As a result of its partnership with Henogen, TVS became the first company to develop a bio-production process for the cGMP manufacture of LV vaccines.<sup>13</sup>

### B. IDC Contracts with Henogen

IDC is a public biotechnology company headquartered in Seattle, Washington, focused on developing therapeutic vaccines to treat cancers and infectious diseases. In late 2011, IDC began searching for a CMO to produce *in vivo* LVs for its own clinical trials, which would focus on a form of cancer. While IDC had already developed its own LV technology, it needed a CMO with adequate facilities to produce cGMP compliant LVs in sufficient volume for a clinical trial.

In early 2012, IDC chose Henogen as its CMO after an apparently comprehensive selection process.<sup>14</sup> Among other desirable qualities, Henogen had previously manufactured cGMP LVs for well-known companies.<sup>15</sup>

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<sup>13</sup> Dep. Tr. of Dr. Cécile Bauche, Oct. 22, 2014 (TVS Exs. K-L) 301.

<sup>14</sup> IDC's expert, Dr. Philip M. Wallace ("Dr. Wallace"), explains that IDC assessed more than eleven CMOs as potential candidates. IDC compared the CMOs based on five major factors and six minor factors. All major factors are standard considerations in the industry. Expert Report of Dr. Wallace ("Wallace Report") (IDC Ex. O) 11.

<sup>15</sup> TVS alleges that IDC's "need for speed" motivated it to select a CMO from across the Atlantic in order to exploit TVS's confidential information. Dr. Wallace

IDC's contract with Henogen provided in part:

3.3.3 [Henogen] is free to supply to IDC the [Henogen] Confidential Information and all other information to be supplied by [Henogen] to IDC under this Master Agreement, and, [Henogen] has the legal right to grant IDC the rights set forth in Section 10 of this Master Agreement;

3.3.4 to [Henogen's] best knowledge, at the Effective Date, the use by [Henogen] of [Henogen] Intellectual Property in accordance with the terms of this Master Agreement and in performance of the Work hereunder (including without limitation the manufacture of the Product), do not infringe any intellectual property rights or industrial property rights of any third party and do not involve the wrongful use of any trade secret or confidential information . . . .<sup>16</sup>

Henogen also “warrant[ed] that no Intellectual Property rights whatsoever owned by any third parties or techniques, know-how or materials that [sic] [would] be used by [Henogen] in the performance of [Henogen's] activities . . . .”<sup>17</sup>

### C. TVS Learns of the IDC-Henogen Contract

When TVS learned that Henogen was manufacturing LVs for IDC, in apparent breach of the TVS-Henogen Agreement, it demanded that Henogen cease production. When Henogen refused, TVS moved for an *ex parte* preliminary

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posits that location and primary language are generally minor factors when selecting a CMO. *Id.* at 10.

<sup>16</sup> Apr. 27, 2012, Master Agmt. between IDC and Henogen (TVS Ex. 20) §§ 3.3.3-3.3.4.

<sup>17</sup> *Id.* § 10.1. “Intellectual Property” was defined as “all intellectual property (whether or not patented), including without limitation, patents, patent applications, know-how, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions, specifications, inventions, processes, data, improvements and developments.” *Id.* § 1.13.

injunction in the Commercial Court of Charleroi in Belgium. An injunction was granted on September 10, 2013, temporarily enjoining Henogen from performing further work for IDC or shipping its product. The next day, IDC learned of this development, and it subsequently voluntarily intervened in the Belgian litigation to support Henogen's position.<sup>18</sup> The injunction was ultimately lifted effective October 22, 2013.<sup>19</sup>

Also in October, Henogen sued TVS in the Commercial Court of Paris (the "French Court"), seeking a declaration that the Exclusivity Provision was invalid. TVS filed counterclaims against Henogen, seeking, in part, an injunction to prevent Henogen from shipping IDC's LVs. IDC was aware of these proceedings, although the scope of its involvement is disputed.

In January and February 2014, while the French litigation was ongoing, Henogen agreed to produce an additional batch of LVs for IDC<sup>20</sup> and to transfer the technology involved in making IDC's LVs to a new manufacturer "with reasonable promptness."<sup>21</sup> IDC and Henogen agreed to cooperate and assist each other in relation to litigation with TVS. IDC also demanded assurances from Henogen that it would perform under the contract.

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<sup>18</sup> TVS Ex. 39 at TVS\_0000197.

<sup>19</sup> Aff. of Renaud Valliant Ex. D. TVS also sued IDC in the United States District Court for the District of Delaware, but that case was voluntarily dismissed.

<sup>20</sup> TVS Ex. 48.

<sup>21</sup> TVS Ex. 44 at 1.

On March 7, 2014, the French Court held a hearing on TVS and Henogen's dispute. Between this hearing and the French Court's ultimate ruling, Henogen shipped LVs to IDC, at IDC's request. IDC wanted to ensure that it received this material before the French Court could rule against Henogen.<sup>22</sup> On April 11, 2014, the French Court upheld the validity of the Exclusivity Provision and enjoined Henogen from performing further work for IDC.<sup>23</sup>

In May 2014, IDC initiated its own clinical trials, testing its *in vivo* LV vaccines in patients with locally advanced, relapsed, or metastatic cancer.<sup>24</sup> IDC used the LVs that Henogen had produced for those trials. While IDC no longer works with Henogen, it has a new LV manufacturer, which received the Henogen-related technology based on Henogen's technology transfer.

#### D. *Current Proceedings*

TVS filed suit against IDC in this Court on July 24, 2014, alleging tortious interference with contractual relations, unfair competition, misappropriation of trade secrets, and unjust enrichment.<sup>25</sup>

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<sup>22</sup> Dep. Tr. of Dr. Wayne Gombotz, Oct. 30, 2014 ("Gombotz Dep.") (TVS Ex. O) 113.

<sup>23</sup> TVS Ex. 51. Henogen appealed this decision, but it entered into a settlement with TVS on January 9, 2015, regarding this dispute, as well as others between the companies. See Letter to the Court from Todd C. Schiltz, Esq., dated Feb. 19, 2015, Ex. A.

<sup>24</sup> Expert Report of Dr. Gregory K. Bell ("Bell Report") (TVS Ex. B) ¶ 22.

<sup>25</sup> TVS's argument at the preliminary injunction stage was limited to its tortious interference and misappropriation of trade secrets claims.



A preliminary injunction hearing was held on January 14, 2015.<sup>26</sup> TVS argues that it has a reasonable probability of success on claims of tortious interference with contractual relations and misappropriation of trade secrets. It further asserts that absent preliminary injunctive relief, it will suffer imminent, irreparable injury based on harm to its development, partnership, and investment opportunities. IDC challenges all of TVS's claims.

## II. ANALYSIS

To earn preliminary injunctive relief, the applicant must demonstrate three necessary elements: (i) a reasonable probability of success on the merits of an underlying claim, (ii) imminent and irreparable harm in the absence of such relief, and (iii) a balance of equities in its favor.<sup>27</sup> Public interest considerations may also be highly relevant.<sup>28</sup> The party seeking such extraordinary relief faces a “considerable burden” in establishing these necessary prerequisites.<sup>29</sup>

### A. *Reasonable Probability of Success on the Merits*

Clearly, a showing of a reasonable probability of success falls below that necessary to secure post-trial final relief. Moreover, a reasonable probability is not

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<sup>26</sup> The hearing was postponed from November 13, 2014, after TVS requested a continuance.

<sup>27</sup> See, e.g., *SI Mgmt. L.P. v. Wininger*, 707 A.2d 37, 40 (Del. 1998).

<sup>28</sup> See *In re CheckFree Corp. S'holders Litig.*, 2007 WL 3262188, at \*1 (Del. Ch. Nov. 1, 2007) (treating the public interest as an independent fourth factor in the preliminary injunction analysis).

<sup>29</sup> See, e.g., *N.K.S. Distribs., Inc. v. Tigani*, 2010 WL 2367669, at \*3 (Del. Ch. June 7, 2010).

necessarily a strong probability. However, “[w]here important questions of material fact turn on the credibility of witnesses, with a focus upon actions they did or did not take based upon their subjective intent,” establishing a record capable of justifying a preliminary injunction is a difficult task.<sup>30</sup> The Court is hesitant “to resolve critical factual disputes on interlocutory injunctive motions . . . [and is] more likely to decline to find satisfaction of the probability of success prerequisite when the resolution of such disputes is necessary to the applicant’s success.”<sup>31</sup> On a paper record, the credibility of potential witnesses cannot often be determined with strong confidence.

#### 1. Tortious Interference

A threshold dispute exists regarding whether Delaware, Washington, or Belgian law governs TVS’s tortious interference claim.<sup>32</sup> TVS argues that Belgian law controls, while IDC insists that, if there is a conflict, Washington law applies.<sup>33</sup> Proving tortious interference may be somewhat easier under Belgian law, based on

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<sup>30</sup> *BBC Capital Mkt., Inc. v. Carver Bancorp, Inc.*, 2000 WL 33521113, at \*1 (Del. Ch. Feb. 16, 2000).

<sup>31</sup> Donald J. Wolfe, Jr. & Michael A. Pittenger, *Corporate and Commercial Practice in the Delaware Court of Chancery* (“Wolfe & Pittenger”), § 10.02[b][2], at 10-12 (2014).

<sup>32</sup> The parties agree that each jurisdiction’s law is substantively similar in relation to TVS’s trade secret misappropriation claim, rendering any choice of law analysis in that context academic.

<sup>33</sup> The choice between Delaware and Washington law does not present a conflict. *See infra* note 43.

that country's theory of third-party complicity.<sup>34</sup> However, at this procedural stage, the choice between Belgian and Washington law would not affect the analysis. On the current record, the evidence that IDC improperly interfered with TVS's contract can be divided between IDC's behavior before and after September 11, 2013, when it first learned that TVS was suing Henogen. Under both sets of law, TVS has not established a reasonable probability of proving tortious interference based on IDC's behavior before that date. However, also under both sets of law, TVS has established a reasonable probability of success based on IDC's subsequent conduct.

a. *Before the European Litigation*

Washington, Belgian, and Delaware law all require a plaintiff to show that the defendant had at least constructive knowledge of the contractual obligations with which it allegedly interfered.<sup>35</sup> TVS has failed to establish that IDC had actual knowledge of Henogen's contractual restrictions when it retained

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<sup>34</sup> This notion is disputed. Compare Expert Report of Prof. Dr. Arnaud Nuyts ("Nuyts Report") (TVS Ex. T) with Expert Report of Prof. Dr. Matthias E. Storme (TVS Ex. U). The differences between the experts' views do not affect the Court's conclusions.

<sup>35</sup> See, e.g., Nuyts Report ¶¶ 108-26 (describing Belgian law); *Great Am. Opportunities, Inc. v. Cherrydale Fundraising, LLC*, 2010 WL 338219, at \*9 (Del. Ch. Jan. 29, 2010) (applying Delaware law); *AR Pillow Inc. v. Maxwell Payton, LLC*, 2012 WL 6024765, at \*6 (W.D. Wash. Dec. 4, 2012) (applying Washington law).

Henogen.<sup>36</sup> Whether IDC had constructive knowledge is a closer issue, but one that TVS has not yet adequately established.

Henogen was reluctant to agree to the Exclusivity Provision<sup>37</sup> and did not include a similar provision in at least some of its other contracts.<sup>38</sup> Further, the TVS-Henogen Agreement contained a confidentiality provision that protected the existence of the contract itself as confidential information.<sup>39</sup> There is evidence that CMOs rarely agree to exclusivity, which would hinder their ability to work for many clients on many products.<sup>40</sup> IDC's expert suggests that IDC followed standard industry protocol when selecting Henogen and that it reasonably relied on Henogen's assurances regarding its ability to perform under the contract.<sup>41</sup> On this record, the Court cannot conclude with any confidence that a reasonable

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<sup>36</sup> While TVS alleges that IDC selected Henogen to exploit the knowledge it had developed with TVS, the Court cannot ascribe that subjective intent to IDC based on the current record. Even if IDC were aware of TVS (a conclusion supported by a December 2011 email from Henogen to IDC (TVS Ex. 14, at 5), as well as a brief 2009 email exchange between an IDC director and a TVS director (Aff. of Jean Pierre Kinet Ex. B)), an inference that it was aware of Henogen's contractual restrictions is not now supported. The fact that IDC wanted to ensure that its CMO had prior experience producing LVs before beginning an expensive collaboration is hardly suspicious.

<sup>37</sup> Vaillant Dep. 331-32.

<sup>38</sup> *Id.* at 333.

<sup>39</sup> *Id.* at 319.

<sup>40</sup> Dep. Tr. of Dr. Carlos Paya, Oct. 27, 2014 ("Paya Dep.") (TVS Ex. J) 58-59. *See also* Wallace Report 5-6; Gombotz Dep. 74.

<sup>41</sup> Wallace Report 15.

biotechnology company would have been on constructive notice of Henogen's contractual limitations when it retained the CMO.<sup>42</sup>

b. *After the European Litigation Began*

However, there is a reasonable probability that TVS may later establish that IDC tortiously interfered with the TVS-Henogen Agreement after September 11, 2013. The elements of tortious interference are (i) the existence of a valid contract; (ii) defendant's knowledge of the contractual relationship; (iii) intentional actions by defendant inducing or causing a breach of the contract; (iv) that defendant intervened for an improper purpose or used improper means; and (v) injury suffered by plaintiff.<sup>43</sup> On September 11, 2013, Henogen informed IDC that a Belgian court had issued a temporary injunction preventing Henogen from continuing work on or shipping IDC's LVs.<sup>44</sup> IDC learned that TVS was asserting a contractual breach against Henogen and was seeking to extend the injunction on

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<sup>42</sup> TVS previously represented that its case at the preliminary injunction stage would include "evidence of what industry practice is in entering into [CMO exclusivity] agreements. These type[s] of agreements are fairly common." Tr. of Teleconference on Pl.'s Mot. for Expedited Proceedings ("Expedited Proceedings Teleconference") 42. IDC, rather than TVS, has put forward more evidence regarding industry practice. There is no basis to conclude that mere knowledge of a contract between TVS and Henogen would have put IDC on notice of the particular provisions at issue here. The cases that TVS cited, some in the context of interference with business relations, do not direct a different conclusion.

<sup>43</sup> See, e.g., *AR Pillow*, 2012 WL 6024765, at \*6; accord *Great Am. Opportunities*, 2010 WL 338219, at \*9. Because proving tortious interference is, if anything, harder under Washington or Delaware law than Belgian, Belgian law can be set aside for the analysis in this subsection.

<sup>44</sup> TVS Ex. 37.

a permanent basis. IDC voluntarily intervened in the Belgian litigation<sup>45</sup> and later kept itself aware of the French Court proceedings.<sup>46</sup> IDC was on actual notice of TVS's claims regarding Henogen's contractual restrictions.<sup>47</sup>

While on notice, IDC negotiated for TVS to produce another batch of LVs.<sup>48</sup> Although this agreement was characterized as an addendum to IDC and Henogen's original contract, IDC provided new consideration for Henogen to undertake a new obligation. The addendum, entered into approximately four months after the Belgian litigation commenced, called for Henogen to manufacture an additional batch of LVs for IDC's research and development.<sup>49</sup> The addendum was executed in the midst of the French litigation and after TVS had filed suit against IDC in federal court in Delaware. IDC was aware that TVS claimed that Henogen was breaching the Exclusivity Provision by working with IDC.<sup>50</sup>

In its defense, IDC cites the Restatement (Second) of Torts (the "Restatement"):

One who, by asserting in good faith a legally protected interest of his own or threatening in good faith to protect the interest by appropriate means, intentionally causes a third person not to perform an existing contract or enter into a prospective contractual relation with another

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<sup>45</sup> TVS Ex. 39.

<sup>46</sup> Paya Dep. 290.

<sup>47</sup> *See, e.g.*, Paya Dep. 301 ("We were aware of the exclusivity claim . . . made by [TVS] in th[e] lawsuits in Belgium, yes.").

<sup>48</sup> TVS Ex. 48 at IDC00014396.

<sup>49</sup> Paya Dep. 297.

<sup>50</sup> *Id.* at 301.

does not interfere improperly with the other's relation if the actor believes that his interest may otherwise be impaired or destroyed by the performance of the contract or transaction.<sup>51</sup>

The Restatement offers an illustration of this limited defense:

A and B both have contracts with C for the purchase of the same horse from C. When C is about to deliver the horse to A, B in good faith demands delivery under his contract and threatens to sue C for damages if delivery is not made. C thereupon makes delivery to B and is disabled from performing the contract with A. B's interference is not improper . . . .<sup>52</sup>

IDC seeks the protection of this safe harbor for the actions it took in enforcing its contract with Henogen after September 11, 2013. However, while IDC presumably could have taken steps to enforce a contract that it had entered in good faith, its expanding on its work with Henogen, while on actual notice of TVS's contractual claims, would appear improper.

Henogen also transferred technology to IDC's new CMO<sup>53</sup> and, at IDC's request, accelerated the delivery of some of its product. Henogen recognized IDC's requested delivery schedule as "a change to the Master Agreement dated 27 April 2012,"<sup>54</sup> and IDC confirmed that it was "willing to execute a side letter to the Agreement confirming the agreed modification in respect of the conditions of

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<sup>51</sup> Restatement (Second) of Torts § 773.

<sup>52</sup> *Id.* cmt. a., Illustration 3.

<sup>53</sup> TVS Ex. 44 at IDC00180183.

<sup>54</sup> TVS Ex. 45 at IDC 00014457.

delivery.”<sup>55</sup> IDC obtained accelerated delivery of LVs to ensure that it received the product before the French Court could impose an injunction.<sup>56</sup>

Thus, IDC evidently took some actions beyond merely enforcing its own contract in good faith.<sup>57</sup> Because it entered into new agreements with Henogen while on actual notice of TVS’s claims, there is a reasonable probability that TVS will ultimately establish that IDC’s conduct after September 11, 2013, tortiously interfered with its contract.<sup>58</sup>

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<sup>55</sup> TVS Ex. 46 at IDC00180186.

<sup>56</sup> See Gombotz Dep. 217.

<sup>57</sup> The defense provided by Section 773 is construed narrowly. Restatement § 773 cmt. a.

<sup>58</sup> At the preliminary injunction hearing, IDC questioned whether TVS had adequately established that the Exclusivity Provision was in effect when IDC received shipment of LVs. The Exclusivity Provision’s duration extended only one year following the termination or expiration of the TVS-Henogen Agreement. TVS-Henogen Agmt. § 2.6. To succeed on its tortious interference claim, TVS bears the burden of establishing a valid contract.

There is a reasonable probability that TVS would establish the validity of the Exclusivity Provision at trial. The French Court concluded that the provision was valid. See TVS Ex. 51. TVS need not now prove tortious interference; it must establish a reasonable probability that it will later do so. IDC conceded: “TVS has not demonstrated a probability of proving any of th[e] prerequisites [of a tortious interference claim] except for existence of a contract.” Def.’s Opp’n to Pl.’s Mot. for Prelim. Inj. 58. In its opposition brief, IDC questioned only whether TVS could prove elements (ii)-(iv) of a tortious interference claim. *Id.*

TVS has also established a reasonable probability that it may later prove damage. See, e.g., *infra* Section II.B. The scope of TVS’s harm, although significant to the second prong of the preliminary injunction analysis, need not be evaluated here.



## 2. Trade Secret Misappropriation

### a. *Alleged Trade Secrets*

Based on the limited discovery to date, TVS has identified five pieces of confidential information that it alleges are trade secrets that IDC misappropriated. Of these, IDC has used only one, a benzonase sterilization step, in its LV manufacturing process. TVS and Henogen allegedly conceived this step to resolve a contamination problem experienced during production runs. Because benzonase is sterilized by its manufacturer, re-filtration is arguably a counter-intuitive idea. By adopting this step, IDC supposedly avoided the risk of contaminated production runs.

While TVS does not claim that IDC directly incorporated the other four alleged trade secrets into its LV development, it asserts that IDC used them to speed up its production. For example, there are multiple methods, agents, and conditions for transfection, the process by which genetic material is deliberately introduced into cells.<sup>59</sup> Although IDC and TVS ultimately used different transfection agents, IDC allegedly benefitted from quickly optimizing its process by comparing its approach to TVS's. Similarly, IDC allegedly expedited its process by comparing its and TVS's formulation buffers (materials into which

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<sup>59</sup> Farzaneh Op. Report ¶ 61.

active drugs are supplied). Knowledge of TVS's level of residual contaminants and production yield allegedly aided IDC in benchmarking its process.

b. *Reasonable Probability of Success?*

A trade secret is defined as:

[I]nformation, including a formula, pattern, compilation, program, device, method, technique or process that (a) [d]erives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (b) [i]s the subject of efforts that are reasonable under the circumstances to maintain its secrecy.<sup>60</sup>

Trade secret misappropriation consists of:

- (a) Acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or
- (b) Disclosure or use of a trade secret of another without express or implied consent by a person who:
  - (i) Used improper means to acquire knowledge of the trade secret; or
  - (ii) At the time of disclosure or use, knew or had reason to know that his or her knowledge of the trade secret was
    - (A) derived from or through a person who had utilized improper means to acquire it,
    - (B) acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use, or
    - (C) derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or

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<sup>60</sup> Wash. Rev. Code § 19.108.010(4). *Accord* 6 Del. C. § 2001(4). Both Washington and Delaware have adopted the Uniform Trade Secrets Act. The parties do not dispute that Belgian law for misappropriation of trade secrets is substantively similar.

(iii) Before a material change of his or her position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.<sup>61</sup>

TVS's confidential information does not consist of archetypal trade secrets. TVS did take efforts to maintain the secrecy of its information. It negotiated with Henogen for several contractual provisions to protect its "knowledge, know-how, and related trade secrets."<sup>62</sup> It also pursued litigation in multiple fora in order to protect its rights. In short, there is a reasonable probability that if TVS's confidential information otherwise qualifies as a trade secret, it took reasonable steps to protect it.

However, it is not immediately clear that the information "[d]erives independent economic value, actual or potential from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use." Information is less likely to qualify as a trade secret if it could be reverse-engineered from publicly available information.<sup>63</sup> This is true even if a defendant obtained secret information through improper means and the information allowed it to speed up its own operations.<sup>64</sup> However, when reverse-engineering a secret would involve more than "minimal

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<sup>61</sup> Wash Rev. Code § 19.108.010(2). *Accord* 6 Del. C. § 2001(2).

<sup>62</sup> Vaillant Dep. 308.

<sup>63</sup> *Great Am. Opportunities*, 2010 WL 338219, at \*18.

<sup>64</sup> *Id.*

expense or effort,” the fact that a defendant could have independently developed the information does not bar a misappropriation claim.<sup>65</sup>

Here, IDC wanted to manufacture its LVs as quickly as possible. A competitor’s confidential information may have allowed IDC to short-circuit its process. The fact that IDC did not use all of TVS’s allegedly confidential information in its final production process does not mean that the information was not used while optimizing that process. Further, even if IDC would not have taken the time to test its process steps against other variations if Henogen did not possess TVS’s information, it does not follow that access to that confidential information was useless. Only with the bias of hindsight would one conclude that the fact that the information was not ultimately used made it not valuable. Whether any of TVS’s confidential information is a trade secret is a close call on the current record. On balance, there appears to be a reasonable probability that at least some information may qualify for trade secret protection.<sup>66</sup>

However, as explained *supra* Section II.A.1, TVS has not yet established that IDC knew (or had reason to know) of the relevant details of Henogen and

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<sup>65</sup> *See id.*

<sup>66</sup> Further, to the extent that IDC benefitted from learning the details of a competitor’s process, that potentially valuable knowledge could not have been reverse-engineered.

TVS's contract until September 11, 2013.<sup>67</sup> Therefore, TVS cannot establish a reasonable probability of success that IDC misappropriated any trade secret until after that time.<sup>68</sup> Section 2(b)(ii)(C) of the trade secret statutes does sanction use of trade secrets when at the time of use, the alleged wrongdoer had reason to know that its knowledge of the trade secret was "derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use."<sup>69</sup> However, no alleged trade secret, besides the benzonase sterilization step, was used beyond IDC's optimization and benchmarking processes. TVS has not yet established that IDC knew of Henogen's alleged breach of duty during that time.<sup>70</sup>

On the other hand, IDC did continue to use the benzonase sterilization step after becoming aware of Henogen's claims. Yet, TVS still faces several obstacles in establishing a misappropriation claim. First, IDC asserts that it had unilaterally instructed Henogen to sterile-filter benzonase.<sup>71</sup> If true, then that step was not

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<sup>67</sup> This would include knowledge that Henogen was using TVS's confidential information in a way that may have breached the TVS-Henogen Agreement.

<sup>68</sup> No theory of trade secret misappropriation provides for strict liability. The French Court's finding that Henogen misused TVS's confidential information would not be dispositive against IDC.

<sup>69</sup> Wash Rev. Code § 19.108.010(2)(b)(ii)(C). *Accord* 6 Del. C. § 2001(2)(b)(2)(C).

<sup>70</sup> TVS does not currently allege that anything other than the benzonase sterilization step was incorporated into IDC's process. Further, TVS has not established that IDC's request for Henogen's "information relating to its experience, capabilities, and standard processes" was anything beyond acceptable due diligence. *See* Rebuttal Report of Dr. Sunil Chada ("Chada Rebuttal Report") (IDC Ex. N) 17.

<sup>71</sup> Aff. of Dr. Barbara A. Thorne in Opp'n to Pl.'s Mot. for Prelim. Inj. ¶ 47.

misappropriated. Second, even if the idea came from TVS via Henogen, based on the current record, IDC can only be charged with misappropriating the step after the knowledge it gained on September 11, 2013. However, if IDC had not initially sterile-filtered benzonase and had experienced benzonase contamination, it presumably would have been able independently to develop the step. TVS and Henogen took two months to determine the source of the contamination problem in their manufacturing process. IDC would likely have resolved a contamination issue (if it even would have experienced any) before September 11, 2013, when it had notice of TVS's claims.

Thus, while incorporating the benzonase sterilization step may have been improper, it may also have occurred while IDC was unaware of the alleged violations of TVS's rights. Assuming those facts, IDC's incorporation of the step into its process would not rise to misappropriation on IDC's behalf, and its use months later may not be misappropriation because the "economic value" of that trade secret (which presumably could have been reverse-engineered) lies in its potential to short-circuit the manufacturing process. Any short-circuiting occurred before September 11, 2013.

Nonetheless, the record may later support a finding that the continued use of this step, if in fact derived from Henogen's work with TVS, constitutes trade secret misappropriation. At this point, the record is not clear enough to determine with

confidence that TVS has a reasonable probability of success on its trade secret misappropriation claim.

### 3. Summary of the First Preliminary Injunction Prong

TVS has established a reasonable probability of proving tortious interference based on acts that IDC took after September 11, 2013. By that time, IDC had been working with Henogen for over a year and had paid the manufacturer over \$2.6 million. Even if TVS were able to prove at trial that IDC was a bad actor, a preliminary injunction, which could be devastating for IDC, would be draconian based on the current record. This observation is reaffirmed by TVS's failure to establish an imminent threat of irreparable injury. That failure, discussed next, is what ultimately convinces the Court that preliminary injunctive relief would be improper.

#### *B. Imminent Threat of Irreparable Injury*

To earn preliminary injunctive relief, TVS must establish both a threat of irreparable harm and that such harm is imminent. Imminence and irreparability are separate requirements, each worthy of independent examination.<sup>72</sup> Thus, “[w]here the injury complained of, irreparable though it might be, is speculative or remote in time, it is unnecessary for the Court to take interlocutory action, and the

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<sup>72</sup> See Wolfe & Pittenger, § 10.02[b][3], at 10-14.

application will fail.”<sup>73</sup> A preliminary injunction will only be granted if “the injury to the plaintiff is in all probability about to be inflicted.”<sup>74</sup>

While TVS has established a limited probability of success, the Court “cannot conclude [that its] level of confidence on that point overcomes [its] judgment that the record simply does not support imminent, non-speculative damages that can be stemmed only by *preliminary injunctive* relief.”<sup>75</sup> The relatively short time frame between this decision and a final hearing on the merits supports this conclusion.<sup>76</sup>

TVS asserts that IDC is causing ongoing irreparable harm to its development, partnership, and investment opportunities because TVS is no longer the “first and only” company to have tested *in vivo* LV vaccines. Further, IDC’s future announcement of its Phase I trial results will allegedly establish IDC as the leader in the development of *in vivo* LV vaccines for cancer treatment. This hypothetical market primacy will allegedly harm TVS when it eventually moves into oncology.

The universe of potential partners and investors may be limited, and arguably, some funding and opportunities that IDC obtains could come at TVS’s

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<sup>73</sup> *Id.* at 10-19.

<sup>74</sup> *Id.* at 10-14.

<sup>75</sup> *Cantor Fitzgerald, L.P. v. Cantor*, 724 A.2d 571, 586 (Del. Ch. 1998).

<sup>76</sup> *See id.* at 579. The parties have indicated that this case may be ready for trial by summer.



expense. It is understandable that TVS does not want to face the specter of competition from IDC. However, TVS has not identified a single investor or partner it has lost, or is in imminent danger of losing, because of IDC's trials.<sup>77</sup> TVS argues that it is all but impossible to determine whether, and to what extent, third parties have shied away from working with it due to IDC. According to TVS, this uncertainty actually highlights the need for preliminary injunctive relief because if it ultimately prevails at trial, its harm would be difficult or impossible to quantify.

However, while injunctive relief may be warranted when damages are uncertain, here, the very existence of imminent harm has not been established.<sup>78</sup> In

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<sup>77</sup> This observation contrasts with TVS's previous representation that at this stage in the proceedings, it would "put on very specific concrete evidence of just such harm that has occurred as a result of [IDC's] conduct." Expedited Proceedings Teleconference 44.

<sup>78</sup> TVS cites *Singh v. Batta Environmental Associates, Inc.* for the proposition that injunctive relief is appropriate when quantifying a plaintiff's harm would be extremely difficult or impossible. 2003 WL 21309115 (Del. Ch. May 21, 2003). In *Singh*, the Court enjoined a party from diverting clients from his former employer in breach of a noncompetition provision in his employment agreement. The Court observed,

How many new projects from those clients, and how many new clients [the counterclaim plaintiff] might have obtained had [the counterclaim defendant] not illegally competed, is unknown and possibly unknowable. That makes it impossible to calculate with any certainty the full extent of the damage . . . if [the counterclaim defendant] is allowed to continue violating the noncompetition provision. The inadequacy of damages as a remedy, as well as the difficulty of calculating damages—factors both present in this case—constitute irreparable harm.

other words, the harm on which interlocutory injunctive relief would be predicated is itself unknown. The fact that producing some tangible evidence is difficult (or even impossible) cannot allow the Court to assume the existence of imminent, irreparable harm based on TVS's assurances.<sup>79</sup> With no identifiable imminent harm, "the absence of present exigency . . . defeat[s TVS's] application for preliminary injunctive relief."<sup>80</sup>

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*Id.* at \*9. *Singh* is distinguishable. The plaintiff in that case brought an action to invalidate the noncompetition provision in his employment agreement with defendant. The defendant asserted counterclaims, including violation of the noncompetition provision. While the Court acknowledged the scope of the counterclaim plaintiff's harm to be "unknown and possible unknowable," trial had established the plaintiff's breach of the noncompetition agreement. There was clear factual evidence that the plaintiff was diverting clients and projects from his former employer. While the scope of this harm may have been unknowable, the existence of actual harm was proven. Not so here. Further, *Singh* dealt with the grant of a final injunction, where the Court did not consider the imminence of the harm.

<sup>79</sup> *Cf. Cantor*, 724 A.2d at 587 ("The MarketPower launch date of July 31, 1998, is certainly imminent and *may* constitute a threat that can be aggravated by [Plaintiff's] own precipitous reaction; but, I conclude the notion of actual irreparable damage from that perceived threat to be speculative at best and illusory at worst."). In *Cantor*, the Court refused to issue a preliminary injunction while acknowledging that the impending "launch of MarketPower has the potential to enrich Defendants and to harm Plaintiff." *Id.* at 585.

<sup>80</sup> *See Wolfe & Pittenger*, § 10.02[b][3] at 10-15. TVS cites *Raptor Systems, Inc. v. Shepard*, in support of the notion that conduct that "lengthens [the] odds" of consummating a deal may pose a risk of imminent, irreparable harm, despite a plaintiff's failure to identify the impending destruction of an imminent deal. 1994 WL 512526, at \*2 (Del. Ch. Sept. 12, 1994). *Raptor* did not deal with a preliminary injunction motion; rather, plaintiffs sought a status quo order temporarily designating board members pending ultimate resolution of a proceeding pursuant to 8 *Del. C.* § 225. In that case, there was evidence that venture capitalists would not deal with the company while the board's authority

Moreover, nothing in the record indicates that IDC would not be testing LV vaccines *in vivo* by now, regardless of whom it selected as its CMO. Choosing Henogen debatably allowed IDC to test its LV vaccines sooner than it otherwise would have. However, based on the estimated manufacturing timelines that three other CMOs had submitted to IDC, IDC's trial would have begun by now regardless of the identity of its manufacturer.<sup>81</sup> There is no indication that TVS would have been able to carry out its "twenty shots on goal" strategy free of competition but for IDC's wrongful conduct. TVS may have claims for past damage, but future harm is speculative.

Perhaps recognizing its inability to identify imminent, irreparable harm, TVS argues that it has lost a first-mover advantage due to IDC's wrongful conduct. Its expert, Dr. Gregory A. Bell ("Dr. Bell"), explains that pharmaceutical research and development is an expensive, risky, and lengthy endeavor and that positive early results create a virtuous circle of technology development, as strategic

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was in dispute. The company, whose creditors had already petitioned for a receiver, would not be able to continue its business without new financing. These facts, that (i) venture capitalists would not even begin negotiations with the company absent some form of temporary relief and (ii) the company was in an extremely precarious financial position, drove the Court's finding of imminent, irreparable harm. The case should not be read to eliminate the well-established imminence requirement from the preliminary injunction analysis.

<sup>81</sup> See Chada Rebuttal Report 13.

partners and investors flock toward the first mover, creating a first-mover advantage.<sup>82</sup>

Two of IDC's experts, Dr. Jeremy M. Levin ("Dr. Levin") and Dr. Arnold L. Oronsky, question Dr. Bell's grounds for concluding that a first-mover advantage exists in the pharmaceutical industry.<sup>83</sup> Dr. Levin posits that even if a first-mover advantage exists, it would be obtained by the first company to reach market rather than the first to generate clinical data.<sup>84</sup> Because of the risks and uncertainty associated with drug development, it would be highly speculative to conclude that IDC would be first to market. IDC will certainly not reach market imminently or before this matter would be tried.<sup>85</sup> Dr. Levin further concludes that "[w]hile having human clinical trial data is important to potential partners, there is no advantage to partnering activities with pharmaceutical companies to be the first to receive such human clinical trial data."<sup>86</sup> Thus, while TVS would hypothetically have been better off had IDC not conducted a trial in oncology, the experts disagree on whether there is an independent advantage to being a first mover.

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<sup>82</sup> Bell Report ¶ 11.

<sup>83</sup> Rebuttal Expert Report of Dr. Jeremy M. Levin ("Levin Report") (IDC Ex. K); Expert Report of Dr. Arnold L. Oronsky (IDC Ex. L).

<sup>84</sup> Levin Report 5-6.

<sup>85</sup> Additionally, TVS is not yet ready to test *in vivo* LV cancer vaccines; any reporting of potential results would be in the relatively remote future.

<sup>86</sup> *Id.* at 2.

TVS's first-mover advantage argument thus fails to establish a non-speculative harm. Even assuming the existence of this advantage,<sup>87</sup> when and how it would be gained is a theoretically open question. However, if TVS were to eventually earn injunctive relief, it could expect to regain a first-mover advantage. It is not clear that the intermediate harm would be irreparable.

TVS thus fails to establish that “injury is likely to occur prior to the time by which a final order following trial can be secured . . . [and a] preliminary injunction will not be granted unless the injury to the plaintiff is in all probability about to be inflicted.”<sup>88</sup>

In addition, the limited scope of TVS's reasonable probability of success cautions against an injunction that would substantially impair IDC's business. The

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<sup>87</sup> Even under TVS's theory, it is not clear whether proof of concept or application to a particular product provides a first-mover advantage. TVS is arguably the first company to establish general proof of concept. Several observations in Dr. Bell's expert report indicate that testing LV vaccines as a platform for various diseases provides an advantage that can attract investors interested in a range of other specific product categories. *See, e.g.*, Bell Report ¶ 8 (“In my experience, [a clinical study designed to show proof of concept] is a customary strategy for development stage technologies with a range of applications.”); *id.* ¶ 13 (“[Focusing on one product candidate allows a firm to achieve] preliminary proof of concept in order to attract investors, collaborators, and licensing opportunities.”); *id.* ¶ 14 (“[I]nvestments and partnership opportunities tend to feed off each other . . . mak[ing] it easier for the company to advance its development program in the initially targeted therapeutic area as well as other therapeutic area opportunities.”); *id.* ¶ 19 (“TVS expected that the bioproduction process would be able to produce a variety of therapeutic LV vaccines, irrespective of the specific antigen(s) that they might be carrying.”).

<sup>88</sup> *See* Wolfe & Pittenger, § 10.02[b][4], at 10-14.

relief that TVS currently seeks is disproportionate to the claims adequately supported by the current record.

### *C. Balance of the Equities*

The relevant issue on this prong is whether “the damage to Plaintiff if the injunction does not issue will exceed the damage to the [Defendant] if the injunction does issue.”<sup>89</sup> “[T]he impact an injunction will have on the public and on innocent third parties” also enters into the analysis.<sup>90</sup>

TVS has not produced evidence of any actual business opportunity lost, or threatened to be lost, due to IDC’s Phase I trials. The theoretical harm that TVS might suffer stands in stark contrast to the tangible and substantial harm that a preliminary injunction would cause IDC. “[T]he value of IDC is in its oncology program and most of [its] human resources are directed to that program.”<sup>91</sup> Given its product platforms, “in effect, the injunction requested by TVS would force IDC out of the business of developing cancer therapies for [its duration].”<sup>92</sup> When compared to the potential harm proffered by TVS, the more tangible harm that IDC would suffer if a preliminary injunction were improvidently granted prevents granting the requested relief. Further, if a preliminary injunction is issued, but IDC eventually prevails on the merits, or damages are deemed appropriate relief, then

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<sup>89</sup> *Cantor*, 724 A.2d at 574.

<sup>90</sup> *Id.* at 587.

<sup>91</sup> Aff. of Dr. Carlos Paya in Opp’n to Pl.’s Mot. for Prelim. Inj. ¶ 55.

<sup>92</sup> *Id.* ¶ 54.

IDC would have been needlessly prevented from developing potentially life-saving therapies. Given these circumstances, TVS fails to support the third prong of the preliminary injunction analysis.

### **III. CONCLUSION**

TVS has established a limited reasonable probability of success. The shipment of LVs in advance of the French Court's intervention is one of the more troubling aspects of this case. It seems likely that the deliberate strategy by IDC to obtain LVs that it otherwise would not have received did facilitate progress in its clinical trials. Time savings in the process of bringing a new product to market can result in substantial benefits—indeed, benefits that are difficult to quantify. When time is the ill-gotten gain, perhaps the proper remedy is delay or suspension of the development process. However, that form of remedy is more final than interim. In addition, on the present record, the appropriate duration of a court-imposed suspension is not easy to specify. Whether the proper length of any suspension would be less than the time until final judgment is, at best, uncertain. In short, a final remedy tailored to address this conduct may be warranted, but TVS's proposed relief, although TVS has tried to narrow it, is not strictly focused on maintaining the status quo and does not serve the traditional purposes for which interim injunctive relief is more frequently granted. TVS has ultimately failed to

establish an imminent and irreparable injury or that the equities tilt in its favor.

Accordingly, its Motion for Preliminary Injunction is denied.<sup>93</sup>

An implementing order will be entered.

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<sup>93</sup> IDC's unclean hands argument thus need not be considered.