

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TRUSTEES OF THE UNIVERSITY : CIVIL ACTION  
OF PENNSYLVANIA :  
 :  
v. :  
 :  
ST. JUDE CHILDREN'S RESEARCH : NO. 12-4122  
HOSPITAL :

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TRUSTEES OF THE UNIVERSITY : CIVIL ACTION  
OF PENNSYLVANIA :  
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v. :  
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ST. JUDE CHILDREN'S RESEARCH : NO. 13-1502  
HOSPITAL :

MEMORANDUM

Dalzell, J.

November 13, 2013

I. Introduction

These actions concern the nature of an immunotherapy for cancer treatment that Dr. Carl June, M.D., Director of the Translational Research Program and a professor at the University of Pennsylvania ("the University" or "Penn"), developed. The parties' claims sound in patent and contract law, and the dispute centers on the question of whether Dr. June's immunotherapy (the "June Construct") contains "material" within the meaning of two Materials Transfer Agreements the University executed with St. Jude Children's Research Hospital ("St. Jude").

We here consolidate the earlier contract action (C.A. No. 12-4122) and the later patent action (C.A. No. 13-1502) and consider St. Jude's motion for partial summary judgment in the contract action and Penn's partial motion to dismiss St. Jude's counterclaims in the patent action.<sup>1</sup> We also consider St. Jude's motion for a separate trial. For the reasons discussed herein, we will deny in part the motion to dismiss, deny the summary judgment motion, and deny the motion for a separate trial. We will then set a schedule for discovery and trial.

## II. Procedural History

On April 12, 2013, we issued an opinion in which we detailed the procedural and factual history of this dispute. Trustees of Univ. of Pennsylvania v. St. Jude Children's Research Hosp., No. 12-4122, 2013 WL 1499518 (E.D. Pa. Apr. 12, 2013). Because those histories guide our consideration of the instant motions, and because the parties' recent submissions provide more information about the facts giving rise to the conflict, we will rehearse the procedural history briefly and the factual history in detail.

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<sup>1</sup> We have jurisdiction over the contract claims pursuant to 28 U.S.C. § 1332 because the parties are diverse -- St. Jude is a citizen of Tennessee and the University is a citizen of Pennsylvania, see C.A. No. 12-4122 Am. Comp. ¶¶ 1-2, and the amount in controversy exceeds \$75,000. We have jurisdiction over the patent action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

On July 11, 2012 St. Jude filed a breach of contract action against the University in the Western District of Tennessee seeking injunctive relief and damages on the ground that the University had breached two Materials Transfer Agreements ("MTAs" or "Agreements") the parties had executed. Apr. 20, 2013 Mem. at 6-7.

Eight days later, the University filed a breach of contract action here. It then submitted an amended complaint in that action in September of 2012.<sup>2</sup> On October 10, 2012 the United States District Court for the Western District of Tennessee transferred the St. Jude case to this District pursuant to 28 U.S.C. § 1404(a), and we consolidated the actions.

On March 19, 2013, the United States Patent and Trademark Office issued U.S. Patent No. 8,399,645, (the "'645 patent") entitled "Chimeric Receptors with 4-1BB Stimulatory Signaling Domain" to St. Jude. Three days later the University filed a separate action in this Court seeking a declaration that it was not infringing on that patent and that the patent was invalid, see C.A. No. 13-1502, Comp. ¶¶ 9, 34-39. St. Jude

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<sup>2</sup> The amended complaint sought damages for tortious interference with prospective contractual relations and a declaratory judgment that the University did not materially breach the 2003 and 2007 Agreements and that the 2003 Agreement had been terminated. We dismissed the tort claim in our April 2013 Memorandum.

moved to dismiss, and on June 10, 2013 the University filed an amended complaint in which it again sought our declaration of its non-infringement and the patent's invalidity. See C.A. No. 13-1502, Am. Comp. ¶¶ 34-39.<sup>3</sup>

St. Jude filed an Answer and Counterclaims, asserting that Penn is infringing and contributorily infringing on the '645 patent by using and commercializing the June Construct, and that this infringement is willful. Through its counterclaims St. Jude seeks a judgment in its favor in C.A. No. 13-1502, a declaration that the patent is valid and enforceable and that Penn is infringing upon it and that such infringement has been willful and deliberate. It also seeks an injunction from further infringement or contributory infringement, and damages. See C.A. No. 13-1502 Counterclaims ¶¶ 22-34. Penn moves to dismiss the willful infringement claim. See C.A. No. 13-1502 Penn MTD.

When the University filed the patent action, we directed the parties to show cause why we should not consolidate it with the contract action, see C.A. No. 13-1502, Docket No. 4. The University responded that it did not oppose consolidation, see April 26, 2013 epistolary submission. St. Jude responded by

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<sup>3</sup> St. Jude's motion to dismiss the original complaint is thus moot. See Fed. R. Civ. P. 15(a)(1)(B) (a party may amend its pleading once as a matter of course within twenty-one days after service of a motion under Rule 12(b)).

submitting a motion for partial summary judgment and positing that by the time the parties had submitted briefing in the patent case the contract case might be resolved by summary judgment. St. Jude Resp. to Order to Show Cause.

As an alternative to summary judgment, St. Jude moved for a separate trial on “[t]he question of whether the June Construct incorporates and was made with Material” under the MTAs. St. Jude MSJ at 23.

We thus consider here our initial suggestion of consolidation, the University’s motion to dismiss St. Jude’s counterclaim for willful infringement, and St. Jude’s motion for partial summary judgment or, in the alternative, a separate trial.

### III. Factual History

This action between the University and St. Jude concerns two MTAs between the parties, the “2003 MTA” and the “2007 MTA”. We will describe the undisputed facts as the parties have presented them.<sup>4</sup>

#### A. The Campana Construct

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<sup>4</sup> Where we draw the facts from one party’s pleading, we will note any factual dispute by the other party.

The MTAs arose out of immunotherapy research Dr. Dario Campana and Dr. Chihaya Imai<sup>5</sup> conducted at St. Jude. In the early 2000s Dr. Campana developed a protein molecule called an "anti-CD19 chimeric antigen receptor" ("CAR"). Through a genetic process we will recount below, Dr. Campana inserted the CAR into T cells, a type of white blood cell that directs immune responses and attacks infected or cancerous cells.<sup>6</sup> One end of the CAR protruded from the T cell, enabling it to latch onto a tumor cell "antigen." St. Jude MSJ at 4 (citing Declaration of Dr. John Gray, Ex. to St. Jude MSJ, at ¶ 6). When the T cell connected with the antigen, the other end of the CAR directed the T cell to "attack and destroy" the target cell. Id.

Dr. Campana reproduced this result by developing a cDNA, a DNA<sup>7</sup> molecule containing a nucleotide<sup>8</sup> sequence encoding

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<sup>5</sup> St. Jude, in its motion for summary judgment, refers to Drs. Campana and Imai collectively as "Campana". Though we recognize Dr. Imai's contributions -- and his existential independence from Dr. Campana -- we will adopt that convention here for the sake of simplicity in a matter that is already quite complex. We also note that Dr. Campana is no longer with St. Jude and now works as a professor in the Department of Pediatrics at the National University of Singapore. Campana Dec., Ex. to St. Jude MSJ, at ¶ 1.

<sup>6</sup> For more information, see, e.g., National Institute of Allergy and Infectious Diseases, "Immune System", available at <http://www.niaid.nih.gov/topics/immunesystem/immunecells/pages/tcells.aspx>.

<sup>7</sup> When James Watson and Francis Crick introduced the world to their depiction to the now-iconic double helix of DNA in their brief note in the 25 April 1953 issue of Nature, "Molecular Structure of Nucleic Acids: A Structure for Deoxyribase Nucleic Acid", they ended their short article with what is almost

the structure of the CAR, and inserting it into the DNA of a T cell. Thus, when the T cell replicated, the new T cells also included the CAR. Id. Through this process Dr. Campana "creat[ed] a population of T cell progeny that can be used to treat CD19+ B-cell cancers, such as acute and chronic leukemia and non-Hodgkin's lymphoma". St. Jude MSJ at 5. In order to insert the CAR-encoded cDNA into the T cell DNA, Dr. Campana used a "retroviral 'vector'" as a "molecular delivery vehicle". Id.

Dr. Campana presented his findings at an American Society of Hematology conference in San Diego, California, in December of 2003. St. Jude MSJ at 5; Penn Opp. at 3. After the conference, Dr. June wrote to Dr. Campana saying,

Your data at ASH with the CD19 ScFv was striking. I was wondering if you might want

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certainly the most striking understatement in the history of science: "It has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material." Their work won them the Nobel Prize in Medicine and Physiology on December 10, 1962. The Nature note and its double helix are reproduced in Horace Freeland Judson, The Eighth Day of Creation 196-98 (1979) (hereinafter "Judson").

<sup>8</sup> As Judson points out at 29, nucleic acids' "presence in all cells was as quickly demonstrated" as their chemistry was, but "[t]heir function remained unknown." By the beginning of the twentieth century "the three constituents of nucleic acids had been described," id., and the last, known as a base, was a "three-piece subassembly . . . called a nucleotide, a homely word, precise, indispensable, and ubiquitous in this science, indeed much like the word 'iamb' in poetics, for it expresses not just a particular sort of construction but a unit of length and even a category of significance." Id.

to have an inter-institutional collaboration to test this? . . . I think that retroviruses are going to be problematic as vectors due to the leukemic risk, and the higher efficiency of the lentivirus is another reason making it attractive to switch. Would you consider letting my lab create the lentiviral vector from your construct, and then I can ship you transduced T cells to compare to the retroviral vector?

Dec. 10, 2003 E-mail from June to Campana, Campana Dec., Ex. to St. Jude MSJ, Ex. 4.

In order to facilitate this exchange, the parties entered into the first MTA at issue here on December 17, 2003. Id. at ¶ 13. That Agreement defined the "Material" St. Jude was transferring as "the anti-CD19-BB-ζ chimeric T-cell receptor construct, including any progeny, portions, unmodified derivatives and any accompanying know-how or data". 2003 MTA at ¶ 1, St. Jude MSJ Ex. A. The Agreement provided that "the Material will only be used to create a lentiviral chimeric T-cell receptor construct to be used in pre-clinical studies", id. at ¶ 3, and "may not be used in humans" or "for any commercial purpose." Id. at ¶ 4. It further provided that the University would "not commercialize any product that contains Material without the prior written approval of St. Jude", id. at ¶ 8, that the University would jointly publish any "result[s] from the collaborative research study" with St. Jude, id. at ¶ 6, and that it would "notify St. Jude within sixty (60) days of filing

any patent application which claims subject matter that contains or incorporates the Material or which claims a method of manufacture or use of the Material.” Id. at ¶ 8.

Pursuant to the MTA, St. Jude sent the anti-CD19-BB-ζ chimeric receptor construct to the University, St. Jude MSJ at 7, Penn Resp. in Opp. at 7. After receiving the construct, Drs. Milone and June sent e-mails requesting information about the gene sequence to Drs. Campana and Imai. Dr. June requested a sequence of the plasmid, and he asked, “how do you detect surface expression of the scfv; do you have an antibody to [do] it?” Dec. 17, 2003 E-mail from June to Campana, Campana Dec. Ex. 5. Dr. Campana responded by sending the sequence of the anti-CD19-BB-ζ and explained, “We detect surface expression with a goat-anti-mouse F(ab)2 biotin from Jackson ImmunoResearch, followed by streptavidin PerCP from Becton Dickinson.” Dec. 17, 2003 E-mail from Campana to June, Campana Dec. Ex. 5. Dr. Milone then wrote, “I realized that the sequence for the CD19-truncated receptor is likely to have a different 3’ end compared with the other 2 constructs. We need to use PCR to transfer it to our lentivirus system. Could you tell me what sequence is at the 3’ end of the CD19-truncated?” Dec. 23, 2003 E-mail from Milone to Imai, Campana Dec. Ex. 5. Dr. Imai responded with “files containing sequence for anti-CD19-truncated and MSCV-

IRES-GFP retroviral vector." Dec. 23, 2003 E-mail from Imai to Milone, Campana Dec. Ex. 5.

Penn does not contest that St. Jude sent the construct and the gene sequence, but it argues that the sequence and the other information did not constitute "know-how" under the MTA because

The sequence of a plasmid or DNA sequence, such as the CD19-BB-z CAR sequence included in the Attachment, is readily obtainable by a person skilled in the art of molecular biology using commonly employed sequencing techniques, as were widely available at the time the materials were received from St. Jude.

Penn Resp. in Opp. at 9, citing Milone Dep., Ex. C to Penn Resp. in Opp., at ¶ 7. Dr. Milone avers that it is "common practice amongst scientific and academic research institutions that, when one institution sends biological material such as a plasmid to another, it also sends a text version of DNA sequences . . . so the recipient scientist does not have to independently sequence" the material, but that had St. Jude not provided the sequence, Dr. Milone "otherwise could have derived [the information] from [his] own sequencing of the biological materials provided by St. Jude." Milone Dep. at ¶ 7.

B. The June Construct

When Dr. June proposed using a lentiviral vector, rather than a retroviral vector, he and others at Penn,

including Dr. Michael Milone, were "the first researchers to work with a lentiviral vector (a modified form of HIV-1) for immunotherapy in cancer patients, having determined that the use of a lentivirus was the most effective way to accomplish genetic modification of human T cells". Penn Resp. in Opp. at 7. Penn contends that Drs. Milone and June could not use the St. Jude CAR cDNA because it was designed to be introduced through a retroviral vector, and it thus "lacked the required sequences at the beginning and end of the DNA anti-CD19-BB-z chain to allow it to recombine into the University's pre-existing lentiviral vector." Penn Resp. in Opp. at 8, citing Milone Dec. Ex. C, at ¶ 11. Instead, Penn avers that Dr. Milone developed a separate "primer-based polymerase chain reaction ("PCR")" that would generate a DNA sequence similar to the one that Dr. Campana had constructed but modified to contain "appropriate restriction enzyme sites on the ends to facilitate recombination into the University's lentiviral vector." Campana Dec. at ¶ 12. Thus, Penn alleges that this new sequence differed from the sequence in the Campana Construct in that it "included five nucleotide differences at the ends of the sequence" to facilitate incorporation into the lentiviral vector. Id. at ¶ 13.

Moreover, Penn contends that the new sequence differed from the sequence in the Campana Construct in that it contained a modified nucleotide in the CAR sequence leading to "an amino

acid change from the original amino acid sequence encoded by the Campana construct.” Id.

Dr. Milone also avers that “[t]he modified anti-CD19-BB-z did not contain any physical part of the Campana Construct. It was composed completely of nucleotides from Dr. June’s laboratory during the PCR reaction”, and “after the PCR process . . . the original Campana Construct physically existed as it did before the process.” Id. at ¶ 14. Drs. Milone and June completed the June Construct by incorporating the modified anti-CD19-BB-ζ sequence into a lentiviral plasmid that had been created earlier in Dr. June’s laboratory. Id. at ¶ 15. The University thus describes the June Construct as a “modified derivative” of the Campana Construct. Penn Resp. in Opp. at 7.

St. Jude’s account of the genetic makeup of the June construct appears similar to Penn’s account in fact, if not in emphasis. St. Jude describes the June Construct as a “lentiviral vector clone” consisting of “the anti-CD19 cDNA provided by St. Jude, incorporated into a lentiviral vector delivery vehicle”, St. Jude MSJ at 8. St. Jude asserts that “[t]he cDNA of the June Construct consisted of the identical approximately 1,500-base-pair sequence provided by St. Jude, with the exception of a single-base-pair difference that appears to be the kind of ‘copying error’ (or mutation) that can occur in a process called PCR amplification.” Id. (emphasis in

original). The "exception" to which St. Jude refers appears to be the difference Dr. Milone cited as causing an amino acid change. St. Jude thus concludes that "even with the base pair difference, the June Construct contains the largest possible nucleotide 'portion' -- all but one base pair out of approximately 1,500 -- of the anti-CD19 cDNA 'Material' St. Jude provided, and it was made with the accompanying data and know-how St. Jude provided." Id. at 8-9.

With regard to the five nucleotide differences at the end of the sequence, St. Jude contends that "all Penn did with the anti-CD19 CAR cDNA it received from St. Jude was to copy it exactly using common polymerase chain reaction ("PCR") techniques, and to add five nucleotide base pairs at each end so the cDNA could be spliced into a lentiviral vector." St. Jude Reply at 4<sup>9</sup>.

C. The 2007 MTA

In 2007 St. Jude sent Penn an e-mail saying that it had "reason to believe Dr. June may have sent the receptor to an investigator outside the University of Pennsylvania" and noted

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<sup>9</sup> Penn opposed St. Jude's motion for leave to file a reply brief, and it objects to our consideration of that brief on a number of grounds, including that the brief's exhibits contain hearsay statements that we may not consider in deciding a motion for summary judgment. Penn Resp. in Opp. to Reply at 5. We will grant St. Jude leave to reply, and we will consider the legal arguments it raises in that brief, but we will not consider the exhibits appended to its reply.

that it needed to determine whether "Dr. June is planning to conduct clinical trials using St. Jude materials", Jan. 11, 2007 e-mail from Hawkins to Donohue, Hawkins Dec., Ex. to St. Jude MSJ, Ex. 1.

Kurt Schwinghammer, then Director of Licensing at Penn, responded that Dr. June was planning to conduct a clinical trial, and that he had told Dr. Campana that he intended to do so. Feb. 5, 2007 E-mail from Schwinghammer to Hawkins, Hawkins Dec. Ex. 2. Three days later, St. Jude replied that Dr. Campana would not object to clinical trials moving forward, but that from St. Jude's standpoint "a new clinical trial agreement will need to be executed between the University and St. Jude before clinical trials proceed." St. Jude MSJ at 9-10, quoting Feb. 8, 2007 e-mail from Hawkins to Schwinghammer, Hawkins Dec. Ex. 3. On February 28, 2007, St. Jude again wrote to Penn that "a new MTA for clinical use must be executed between the University and St. Jude to provide St. Jude with the appropriate protections." Id.

On April 16, 2007, Donald T. Deyo, Director of Corporate Contracts in Penn's Office of Research Services, wrote, "[w]e acknowledge the necessity of a new MTA since the anti-CD19-BB-zeta receptor materials are now to be used in a clinical trial." Apr. 16, 2007 E-mail from Deyo to Hawkins, Hawkins Dec. Ex. 5.

On or about February 8, 2008, the parties executed a second MTA, dated October 2, 2007<sup>10</sup>, allowing Dr. June to proceed with clinical trials. 2007 MTA, St. Jude MSJ Ex. B; Penn Resp. in Opp. at 4. That agreement contained the same definition of "Material" as found in the 2003 agreement.<sup>11</sup> 2007 MTA at ¶ 1.

D. Penn's Alleged Breaches

In April of 2009, Dr. Campana and Dr. June, with others, co-authored an article in Molecular Therapy, Campana Dec. ¶ 6, in which they noted that "[t]he cDNA for the CARs that contain a truncated form of the TCR-ζ intracellular domain . . . were generated at St[.] Jude's Children[;]s Research Hospital. These complete CAR sequences were amplified directly from the provided plasmids by PCR."<sup>12</sup> Campana Dec. Ex. 1 at 8.

In August 2011 Dr. June described the results of his clinical trials in articles in The New England Journal of Medicine, New Eng. J. Med. 8:725-733 (2011) and Science Translational Medicine, 2011; 3(95):95ra73. See St. Jude MSJ at 12, Exs. C and D. St. Jude contends, and Penn does not dispute,

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<sup>10</sup> We refer to this agreement, as the parties do, as the 2007 MTA.

<sup>11</sup> The term in the 2007 Agreement is "Materials", rather than "Material", but the definition is the same.

<sup>12</sup> "PCR", or Polymerase Chain Reaction, is a method used to make large numbers of copies of specific DNA segments. See St. Jude MSJ at 8 n.5.

that "neither article . . . acknowledge[d] St. Jude as the source of the anti-CD19 CAR cDNA", St. Jude MSJ at 12. St. Jude wrote to Penn asking if the receptor used in the trials the articles described was the same receptor St. Jude had provided. Hawkins Dep., Ex. to St. Jude MSJ, Ex. 6. Responding to this (and other inquiries) from St. Jude, Penn's director of legal affairs, Kathryn A. Donohue, wrote to St. Jude and said, "We incorporated the cDNA from Dr. Campana/St. Jude into the vector." St. Jude MSJ at 13 (quoting Sept. 22, 2011 E-mail from Donohue to Marsh, Watts Dec., Ex. to St. Jude MSJ, Ex. 2). Donohue included a diagram, above which she wrote, "In the schema below (from the NEJM paper), the large circle represents the entire vector, and the portion of the vector that represents the St. Jude sequence is circled in blue." Id. (emphasis in original). Donohue continued that the paper in which Dr. Campana was included as a co-author was "incorporated as ref #5 of the NEJM paper, and is an acknowledgment of Dr. Campana and St. Jude." Id. The parties dispute the significance of these communications, as we will discuss below.

St. Jude points out that when other researchers asked Dr. June for the construct, he told them they needed to obtain permission from Dr. Campana and St. Jude, see, e.g., Esther Allay Dec., Ex. to St. Jude MSJ, Ex. 6 (Nov. 19, 2011 e-mail from Dr. June to Dr. Stephen Gottschalk saying, "I would be

happy to send you the BBz CAR. You would also need to get permission from dario campana [sic] at St. Jude. He sent us a retroviral plasmid in 2003, and we modified the CAR and adapted for lentivirus."); Ex. 3 (Sept. 27, 2011 e-mail from Dr. June to a researcher at the National Cancer Center in Korea saying "[i]t turns out that you also need an MTA from Dr. Dario Campana at St. Jude/Singapore [sic], or at least his permission, for me to send you the plasmid. We originally made the CD19:BB:Z lentiviral vector from a retroviral vector that Dario made.").

Dr. June's declaration suggests a different understanding. He avers that "[a]t no point have I ever understood the [MTAs] . . . to restrict the transfer of the June Construct, developed in my laboratory at the University, since the June Construct does not physically contain any of the Material provided by St. Jude under the 2003 MTA." June Dec., Ex. A to Penn Resp. in Opp., at ¶ 14. Dr. June says that before August 29, 2011 he "sent samples of the June Construct to researchers at other universities . . . without directing them to St. Jude for permission." Id. at ¶ 15.

On August 29, 2011, an Associate General Counsel for St. Jude, McGehee Marsh, sent a letter to Donohue referring to Dr. June's recent publications and saying, "[w]e simply need to know if the receptor used in the clinical trial is the one obtained from St. Jude. If it was, we would like to understand

why Dr. June did not acknowledge St. Jude's contribution . . .  
." Aug. 29, 2011 Letter from Marsh to Donohue, June Dec. Ex. 1.

After Penn received this letter, Dr. June avers that  
"solely in order to avoid a legal dispute and out of an  
abundance of caution," he "directed any researchers who wanted  
[him] to send them the June Construct to St. Jude so that St.  
Jude would not later take issue with such transfer." June Dec.  
¶ 16.

In a November 22, 2011 letter, the University informed  
St. Jude that it wished to terminate the MTA<sup>13</sup>. No. 12-4122 Am.  
Comp. Ex. F.

The University contends that it "contractually agreed  
to exclusively negotiate with Novartis regarding a ground-  
breaking collaboration that would develop Dr. June's cellular  
immunotherapy for general cancer patient use." Id. ¶ 27.  
According to the amended complaint, "The University . . .  
actively negotiated with Novartis a collaboration under which  
the University would receive funding that would allow it to  
continue with clinical trials of the Penn Immunotherapy without  
undue delay", and "[a]s of July 10, 2012, the University and  
Novartis had made substantial progress towards reaching an

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<sup>13</sup> In its amended complaint the University says this letter  
informed St. Jude it wished to terminate the 2003 MTA, but the  
letter refers to the 2007 MTA in its subject line and does not  
make clear which MTA the University sought to terminate. In any  
event, the distinction does not affect our decision here.

agreement that would allow continued development of the Penn Immunotherapy Technology.” Id. ¶¶ 28-29.

In St. Jude’s counterclaims in the patent action, St. Jude avers, and Penn does not dispute, that Penn “entered an ‘alliance’ and ‘an exclusive global research and licensing agreement’ with Novartis in August 2012 to commercialize the cells, lentiviral vectors, and CARs that Penn now calls ‘CTL019’”, St. Jude Counterclaim ¶ 15, Ex. B. See also Press Release, Perelman School of Medicine, University of Pennsylvania, “University of Pennsylvania and Novartis Form Alliance to Expand Use of Personalized T Cell Therapy for Cancer Patients” (Aug. 6, 2012) (available at [http://www.uphs.upenn.edu/news/News\\_Releases/2012/08/novartis/](http://www.uphs.upenn.edu/news/News_Releases/2012/08/novartis/)).

On January 10, 2013, in-Pharma Technologist.com, a Web site that provides “Breaking News on Global Pharmaceutical Technology & Manufacturing”, reported that Novartis had purchased a manufacturing plant with “the technological competence and equipment to support both clinical and commercial production for CTL019 as well as other therapies in the area of human autologous cellular immunotherapy products.” Id., St. Jude Answer, Ex. C, available at <http://www.in-pharmatechnologist.com/content/view/print/728836>. The article explained that “CTL019 is Novartis’ first candidate CAR therapy and is currently being studied as a test pilot at the University

of Pennsylvania.” Id. St. Jude avers that “one or more applications have been filed” with the U.S. Food and Drug Administration for the CTL019 cells, CTL019 lentiviral vectors, and CTL019 CARs. St. Jude Counterclaims ¶ 17.

St. Jude applied for a patent for the Campana Construct on July 12, 2012, and it received a patent on March 19, 2013, United States Patent No. 8,399,645, entitled “Chimeric Receptors with 4-1BB Stimulatory Signaling Domain” (the “’645 patent”). See St. Jude Counterclaims ¶¶ 8, 18, 21. According to St. Jude, “The [’645 patent] generally discloses compositions and methods for genetically modifying human immune cells to enable them to manufacture chimeric antigen receptors . . . and then to recognize and attack certain types of cancer cells.” Id. at ¶ 9.

#### IV. Consolidation

Under Fed. R. Civ. P. 42(a), we have “broad power” to consolidate cases that share “common question[s] of law or fact.” Ellerman Lines, Ltd. v. Atlantic & Gulf Stevedores, Inc., 339 F.2d 673, 675 (3d Cir. 1964). Here, the facts underlying the patent suit are almost identical to those underlying the contract action. Indeed, in the amended complaint in the patent action, Penn avers that “[t]he subject matter of the ’645 patent directly relates to the same subject

matter at issue in the [contract action].” No. 13-1502 Am. Comp. ¶ 27.

St. Jude opposed consolidation, apparently on the theory that its motion for summary judgment in the contract case was such a slam dunk that we would readily grant it, thereby clearing the path for victory in the subsequent patent case. Because, as we discuss below, we do not find that summary judgment is warranted, we are not persuaded by St. Jude’s proposed approach.

We will thus consolidate the actions.

#### V. Penn’s Motion to Dismiss

Penn moves to dismiss the allegations of willful infringement in St. Jude’s counterclaim under Fed. R. Civ. P. 12(b)(6).

##### A. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), a defendant may move the Court to dismiss a complaint on the ground that it fails to “state a claim upon which relief can be granted”, and the moving defendant bears the burden of proving that this is so, see Fed. R. Civ. P. 12(b)(6), see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005).

As the Supreme Court held in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007) and Ashcroft v. Iqbal, 556 U.S. 662

(2009), in order to survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'", Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged", Iqbal, 556 U.S. at 678.

Penn argues here that St. Jude has failed to allege sufficient facts to state a claim for willful infringement.

As our Court of Appeals has explained post-Twombly and Iqbal, when considering a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the district courts must engage in a two-part analysis:

First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief."

Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).

For the first part of this test, we refer to the facts as we have recounted them above.

In In re Seagate Technology, LLC, 497 F.3d 1360 (Fed. Cir. 2007), the Court of Appeals for the Federal Circuit held

that in the patent context “to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent”, id. at 1371. The Federal Circuit also held that if a patent holder demonstrated that the alleged infringer’s conduct had met this objective test, the holder must then show that the risk “was either known or so obvious that it should have been known to the accused infringer.” Id.<sup>14</sup>

St. Jude makes much of the issue of whether Seagate announced a new standard for pleading or for proving a claim of willful infringement, see St. Jude Resp. in Opp. at 5-7, arguing that the case “set forth a heightened standard for proving willfulness at trial, not for pleading it.” Id. at 5. Penn does not directly argue that Seagate does establish a heightened pleading standard for willful infringement claims, instead urging us to analyze St. Jude’s claim under Fed. R. Civ. P. 8, see Penn MTD at 1.

Courts applying Seagate in the motion to dismiss context have not treated it as establishing a heightened pleading standard, but have instead found it to be an

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<sup>14</sup> The Federal Circuit’s decisions on patent law are binding on our resolution of the dispute, as the Federal Circuit has exclusive appellate jurisdiction over cases in which our jurisdiction is based on federal patent law. Christianson v. Colt Industries Operating Corp., 486 U.S. 800, 807-08 (1988).

explanation of the elements of the cause of action of willful infringement. Under this reading, a plaintiff states a claim for willful infringement if it pleads sufficient factual matter, accepted as true, to allow us to “draw the reasonable inference that the defendant is liable”, Iqbal, 556 U.S. at 678, for “act[ing] despite an objectively high likelihood that its actions constituted infringement of a valid patent” where the risk was either known or was so obvious that it should have been known. Seagate, 497 F.3d at 1371. See, e.g., MONEC Holding AG v. Motorola Mobility, Inc., 897 F. Supp. 2d 225, 235-36 (D. Del. 2012) (discussing Seagate as outlining the standard a plaintiff must meet in “prov[ing] a cause of action for willful infringement” and finding, in light of Seagate, that “a plaintiff alleging a cause of action for willful infringement must ‘plead facts giving rise to at least a showing of objective recklessness of the infringement risk’”, which requires allegations of “‘factual circumstances in which the patents-in-suit are called to the attention’ of the defendants”, id. at 236 (quoting St. Clair Intellectual Prop. Consultants, Inc. v. Hewlett-Packard Co., No. 10-425, 2012 WL 1134318, at \*2-3 (D. Del. Mar. 28, 2012) (internal alterations omitted)).

We will thus apply the 12(b)(6) analysis we described above, treating Seagate as announcing the elements of the claim of willful infringement.

B. Discussion

1. Willful Infringement Claim

There can be no question that Penn knew of the patent -- Penn filed its action for non-infringement and non-enforceability on March 22, 2013, three days after the patent issued.

As we described above, St. Jude has alleged facts regarding Penn's partnership with Novartis that, if taken as true, demonstrate that Penn was commercializing CTL019 T cells, polynucleotides encoding CTL019 CARs, and CTL019 lentiviral vectors whose compositions are covered by the '645 patent. These facts suffice to state a claim that Penn acted in the face of an "objectively high likelihood" that it was infringing on a valid patent. This finding is consistent with other courts' analyses of motions to dismiss willful infringement claims. See, e.g., Medtrica Solutions, Ltd. v. Cygnus Medical, LLC, No. 12-538, 2012 WL 5726799, at \*1 (W.D. Wash., Nov. 15, 2012) ("The allegations that Medtrica has had notice of the '023 Patent since 2011 and has continued to make and sell the Appli-Kit and Revital-Ox . . . are sufficient to 'make out the barest factual assertion' to state a claim for willful infringement") (quoting IpVenture, Inc. v. Cellco P'ship, No. 10-4755, 2011 WL 207978, at \*2 (N.D. Cal. Jan. 21, 2011)); Oracle Corp. v. DrugLogic, Inc., 807 F. Supp. 2d 885, 902 (N.D. Cal. 2011) (finding that

plaintiff had stated a claim where it alleged that defendant was aware of the disputed patent and had "actual notice" of the infringement claims) (citing Milwaukee Elec. Tool Corp. v. Hitachi Koki, Ltd., No. 09-948, 2011 WL 665439, at \*5 (E.D. Wis. Feb. 14, 2011) for the proposition that the "allegation that the defendants were aware of the plaintiffs' five patents and that the defendants allegedly had infringed and continued to infringe upon, is sufficient to plead willful infringement").

Penn's filing of C.A. No. 13-1502 fortifies our assessment. In its amended complaint, Penn alleges -- as it had to in order to demonstrate the propriety of a declaratory judgment -- that "a substantial and continuing controversy exists between the University and St. Jude regarding whether the University is liable for infringing the '645 patent." No. 13-1502 Am. Comp. ¶ 33.

We will therefore deny in part Penn's motion to dismiss the claim of willful infringement.

## 2. Pre-Filing Conduct vs. Post-Filing Conduct

We deny the motion to dismiss only "in part" because the finding that St. Jude has alleged facts sufficient to state a claim for willful infringement by no means ends our analysis -- we must also consider, under Seagate, whether St. Jude's failure to seek a preliminary injunction is fatal to a

willfulness claim for the "post-filing" period, and, if so, whether the post-filing period begins to run at the date Penn filed the action or the date St. Jude filed its counterclaims.

In Seagate, the Federal Circuit explained that "in ordinary circumstances, willfulness will depend on an infringer's prelitigation conduct." Seagate, 497 F.3d at 1374. The Court noted that while "a willfulness claim asserted in the original complaint must necessarily be grounded exclusively in the accused infringer's pre-filing conduct", when an accused infringer acts willfully after a patent holder has filed a complaint, the patentee may "move for a preliminary injunction, which generally provides an adequate remedy for combating post-filing willful infringement." Id. The Federal Circuit reasoned that a patentee who does not attempt to exercise his right to prevent further infringement in this way "should not be allowed to accrue enhanced damages based solely on the infringer's post-filing conduct." Id.

Penn accurately notes that "St. Jude has made no motion to preliminarily enjoin the University from engaging in the accused infringing activities", and it argues that "[t]he absence of a motion for preliminary injunction is fatal to the viability of St. Jude's claim that the University's activities are and continue to be willful." Penn MTD at 6. Penn thus takes Seagate to mean that "an allegation of willful

infringement must either be made based on the accused infringer's pre-litigation knowledge, or be maintained only if the patentee seeks a preliminary injunction", id.

St. Jude characterizes the Seagate language as dictum, and it argues that although "[d]istrict courts are divided over whether Seagate announced a per se requirement that a preliminary injunction motion be filed . . . no such motion is necessary where willfulness is premised on pre-suit knowledge of the asserted point." St. Jude Resp. in Opp. at 9 (emphasis in original). St. Jude also points out an important distinction between the instant matter and the Seagate line -- in those cases, the patentee filed the suit alleging infringement, and so the suit itself often notified the alleged infringer of the patent. For example, in McRO, Inc. v. Namco Bandai Games America, Inc., CV 12-10322-CW (FFMx) (C.D. Cal. Jul. 11, 2013), on which Penn relies, Penn MTD Ex. A, the Court considered whether plaintiff could bring a willfulness claim where "the alleged knowledge of the patent resulted only from the filing of the original complaint in the action and the plaintiff has not sought a preliminary injunction." Id. at 9. The Court found that the plaintiff could not sustain such a claim because Seagate "drastically limit[ed] the availability of willfulness claims when notice is delivered via lawsuit." Id. at 10. McRO

Inc. does not apply here, as there is no question that Penn knew of the patent before either party filed suit.

But Seagate's reasoning is not limited to such a situation. As we noted above, Seagate also suggests that a patentee for whom a preliminary injunction remedy is available should not sleep on his rights and thereby accrue greater damages after filing suit. Seagate, 497 F.3d at 1374. See also Anascape, Ltd. v. Microsoft Corp., No. 9:06-158, 2008 WL 7182476, at \*3 (E.D. Tex. Apr. 25, 2008) (denying willful infringement claim where patentee "did not even attempt to stop any alleged infringing activity" by moving for a preliminary injunction). That logic does extend to this dispute, and we thus find that St. Jude's failure to seek a preliminary injunction limits Penn's liability for alleged willful infringement.

The question of when the "post-suit" timeline begins is complicated in this matter where Penn -- the alleged infringer -- sued first, seeking to vindicate its claim that it was not infringing on any valid patent St. Jude held, and where the willful infringement claim came later, in St. Jude's counterclaims. In a typical case, where the patentee files suit, courts have found that a patentee's obligation to seek a preliminary injunction begins upon the filing of the willful infringement claim, see, e.g., LML Holdings, Inc. v. Pacific

Coast Dist. Inc., No. 11-6173, 2012 WL 1965878, at \*5-6 (N.D. Cal. May 30, 2012); Clouding, IP, LLC v. Amazon.com, Inc., No. 12-641, 642, 675, 2013 WL 2293452 (D. Del. May 24, 2013) (finding that the "post-filing" period began when the patentee filed an amended complaint containing a willfulness claim, not when the patentee filed the original complaint).

Without acknowledging that this case diverges from the usual pattern, Penn assumes that the "post-filing" period commenced when it filed its suit, see Penn MTD at 7. St. Jude argues that the post-filing period did not begin until it filed its counterclaims alleging willful infringement, see St. Jude Resp. in Opp. at 10.

St. Jude's suggested approach is consistent with caselaw finding that the post-filing period begins at the time a patentee files a willful infringement claim. We agree. Moreover, a contrary finding would have the bizarre effect of encouraging alleged infringers to file declaratory actions immediately after the issuance of a patent so that they could infringe on valid patents with no fear of a willfulness claim. This result is inconsistent with the damages scheme the Federal Circuit established in Beatrice Foods Co. v. New England

Printing & Lithographing Co., 923 F.2d 1576 (Fed. Cir. 1991)<sup>15</sup>  
and clarified in Seagate.

We thus find that St. Jude is not entitled to damages for willful infringement for the period beginning on June 27, 2013, when it filed its counterclaims, and we will grant Penn's motion to dismiss insofar as it relates to this period.

#### VI. St. Jude's Motion for Summary Judgment

We turn to St. Jude's motion for partial summary judgment, initially filed in C.A. No. 12-4122, in which St. Jude asks us to determine, as a matter of law, that

[t]he "lentiviral vector clone" (that Penn's pleadings call the "June Construct"), which Penn made from biological material and accompanying data and know-how provided by St. Jude pursuant to the Collaboration and Materials Transfer Agreement dated December 10, 2003 (the "2003 MTA"), and which it has used in clinical trials pursuant to the Materials Transfer Agreement dated October 2, 2007 (the "2007 MTA"), contains and was made with "Material" within the plain meaning of the two MTAs.

St. Jude MSJ at 1 (emphasis added).

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<sup>15</sup> Beatrice Foods Co. established the principle that in order to receive an award of enhanced damages a patentee must make a showing of willful infringement. 923 F.2d at 1578.

A. Standard of Review

As is well-settled, a party moving for summary judgment bears the initial burden of informing the district court of the basis for its argument that there is no genuine issue of material fact by "identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact", Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

If the moving party carries this initial burden, the Rules then oblige "the nonmoving party to go beyond the pleadings and by [his] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" Id. at 324 (quoting Fed. R. Civ. P. 56).

A factual dispute is genuine

[I]f the evidence is such that a reasonable jury could return a verdict for the nonmoving party. . . . The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 252 (1986).  
A fact is "material" if it "might affect the outcome of the suit under the governing law". Id. at 248.

We "must draw all reasonable inferences in favor of the nonmoving party, and [we] may not make credibility determinations or weigh the evidence." Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000), cited in Amour v. County of Beaver, PA, 271 F.3d 417, 420 (3d Cir. 2001)).

## B. Discussion

### 1. The Parties Do Not Dispute The Physical Make-Up of the June Construct

According to Penn, we should deny summary judgment on the question of whether the June Construct contains "materials" under the MTA because there exists "a genuine issue of fact regarding the makeup of the June Construct", Penn Resp. in Opp. at 13. Penn argues that "St. Jude's motion for summary judgment is premised on the factual assertion that the June Construct has a portion of the Campana Construct in it" because St. Jude makes assertions such as, "[t]he 'lentiviral vector clone' of the CAR that Penn made pursuant to the 2003 MTA consisted of the anti-CD19 cDNA provided by St. Jude, incorporated into a lentiviral vector delivery vehicle." Id.

But the dispute as to the physical make-up of the June Construct appears to be rhetorical rather than factual. The

parties seem to agree that the June Construct contains a copy of the cDNA sequence from the Campana Construct, with one base pair difference and a change to accommodate the lentiviral vector. St. Jude refers to the June Construct as containing an "exact copy of all but one of the approximately 1,500 base pairs comprising the cDNA supplied by St. Jude", St. Judge MSJ at 20, and describes it as a "lentiviral vector clone", id. at 8 (emphases added). St. Jude thus does not appear to contend that the June Construct contains a physical portion of the Campana Construct -- instead, St. Jude argues that by using a gene sequence identical to that of the Campana Construct, except for the differences we just mentioned, Dr. June has created a construct that "contains" a "portion" of the anti-CD19-BB- $\zeta$  and is thus subject to the commercialization and crediting restrictions of the MTAs.

Thus, whether the copy of the Campana Construct sequence in the June Construct constitutes a "portion" under the MTA is a matter not of factual dispute but of contract interpretation.

## 2. Pennsylvania Contract Law

Under Pennsylvania contract law<sup>16</sup>, we seek to ascertain “the intent of the parties”, Kripp v. Kripp, 849 A.2d 1159, 1163 (Pa. 2004), and where there is a written contract whose terms are “clear and unambiguous, the intent of the parties is to be ascertained from the document itself.” Id. (citing Hutchison v. Sunbeam Coal Corp., 519 A.2d 385, 390 (Pa. 1986)).

A contract is ambiguous if “it is reasonably susceptible of different constructions and capable of being understood in more than one sense”, id. As Pennsylvania courts have made clear, “the mere fact that the parties do not agree upon the proper construction” does not render a contract ambiguous, Metzger v. Clifford Realty Corp., 476 A.2d 1, 5 (Pa. Super. Ct. 1984) (quoting Commonwealth State Highway and Bridge Auth. v. E.J. Albrecht Co., 430 A.2d 328, 330 (Pa. 1981)).

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<sup>16</sup> St. Jude assumes in its motion that Pennsylvania law applies. See St. Jude MSJ at 19-20. The University responds by arguing Pennsylvania law, but it maintains that “[s]uch response should not be construed as an admission that Pennsylvania law is the appropriate law under a choice of law analysis.” Penn Resp. in Opp. at 15 n.3. As we noted above, Penn is a citizen of Pennsylvania, see No. 12-4122 Am. Comp. ¶ 1, and it appears that Dr. June’s actions took place in Pennsylvania. St. Jude is a Tennessee citizen, see No. 12-4122 Am. Comp. ¶ 2. The MTAs contain no choice of law clause, and in our April 4, 2013 Memorandum we conducted a choice of law analysis with regard to Penn’s tort claim, and, finding no real conflict between Pennsylvania and Tennessee law, applied Pennsylvania law. Here, the only non-Pennsylvania citizen, St. Jude, has argued under Pennsylvania law and neither party has given us any reason to believe Pennsylvania law does not apply. We will thus apply Pennsylvania law here.

If a contract is unambiguous, we interpret it as a matter of law, but if we find that it is ambiguous its meaning is a question for the finder of fact. Id. See also, e.g., Ins. Adjustment Bureau, Inc. v. Allstate Ins. Co., 905 A.2d 462, 469 (Pa. 2006).

In Pennsylvania, "the course of the parties' performance under a contract is always relevant in interpreting that contract." Matthews v. Unisource Worldwide, Inc., 748 A.2d 219, 222 (Pa. Super. Ct. 2000) (citing Atlantic Richfield Co. v. Razumic, 390 A.2d 736, 741 n.6 (1978)). See also, e.g., Restatement (Second) of Contracts § 202(5) ("Wherever reasonable, the manifestations of intention of the parties to a promise or agreement are interpreted as consistent with each other and with any relevant course of performance, course of dealing, or usage of trade.").

### 3. The Language of the MTAs

St. Jude argues that the terms of the MTAs are unambiguous. According to St. Jude, "[t]he 2003 MTA and the 2007 MTA each plainly define Material to include 'any' 'portions' and 'accompanying know-how and data'", and "a 'portion' is 'a part of a whole'". St. Jude MSJ at 20 (quoting Oxford Dictionaries, available at <http://oxforddictionaries.com/definition/english/portion?q=porti>

on).<sup>17</sup> "Data" are "facts or statistics collected together for reference or analysis", id., while "know-how" is "practical knowledge or skill; expertise", id. Thus, on St. Jude's reading, "an exact copy of all but one of the approximately 1,500 base pairs comprising the cDNA supplied by St. Jude was a 'portion' of the Material", and "the data files and technical information that St. Jude's Imai sent to Penn's Milone . . . were 'accompanying know-how and data'". Id.

Penn suggests, without concluding, that the contract is ambiguous, see Penn Resp. in Opp. at 15-16, and it offers an alternative interpretation of the contract language. According to Penn, the phrase "progeny, portions, unmodified derivatives and any accompanying know-how or data" does not encompass the June Construct because the June Construct is a "modified derivative," or "a substance created from all or part of another, but . . . requir[ing] a change relative to the original substance during the creation process", Penn Resp. in Opp. at

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<sup>17</sup> We typically rely upon the peerless The Oxford English Dictionary for what Simon Winchester rightly described as The Meaning of Everything in the title of his 2003 history of the OED, but because the OED includes the similar definition, "a part of any whole", as one of nine ways of using "portion" as a noun, we defer here to St. Jude's source. XII Oxford English Dictionary 154-55, def. II.5.a (2d ed. 1989). We note that another of the nine definitions the OED offers is "[t]he part (of anything) allotted or belonging to one person; a share", id. at 154, def. I.1.a., as in, "**1772 Junius Lett.** lxviii. (1820) 338 The study of the law requires but a moderate portion of abilities." Only on this one point do we diverge from James Murray and his learned team.

16. Penn contrasts this with an unmodified derivative, which the agreement specifically includes and which Penn describes as “a substance that can be formed directly from another without a change to the original substance”. Id. Penn argues that the contract’s definition of materials “does not broadly encompass any and all derivatives of the biological materials provided”, but instead “specifies very limited types of derivatives of the biological materials to be included”, of which “modified derivatives” is not one. Id.

Reading modified derivatives as excluded from the MTA is also appropriate, Penn contends, in light of paragraph three of the 2007 MTA where Penn agreed that “the Materials are provided for the sole purpose of allowing [Penn] to use Materials to produce a molecular lentiviral vector clone incorporating Materials . . . for application in ex vivo autologous cell modification . . . .” 2007 MTA ¶ 3; Penn Resp. in Opp. at 17 (emphasis added). This passage does not refer to the lentiviral clone as itself a “material”, and the commercialization constraints in the 2003 MTA and 2007 MTA do not refer to products “incorporating Materials”, but those “contain[ing] materials” (2003 MTA) or “contain[ing] a portion of the Materials, . . . derived from the Materials, or which could not have been produced but for the use of the Materials.” (2007 MTA). Penn argues that the June Construct does not

contain a "portion" of the materials because it does not contain "a physical part of the whole provided by St. Jude", Penn Resp. in Opp. at 20, but instead contains a modified derivative.

Penn also points to paragraph five of the 2007 MTA which provides that with regard to patents "[o]wnership shall follow inventorship according to US patent law." Penn reads this as demonstrating a "clear intent . . . to allow the University to research and create a new substance in which it would presumably have its own rights", while under St. Jude's interpretation, "even a copy of a single nucleotide, molecule, or even atom from the Campana Construct would constitute a 'portion' of the Materials", Penn Resp. in Opp. at 20-21.

St. Jude and Penn reach contrary conclusions about the scope of the definition of "materials", and we find that both are reasonable. The contract is thus facially ambiguous. See, e.g., Ins. Adjustment Bureau, Inc., 905 A.2d at 469 (finding that opposing parties' interpretations were both reasonable and so "the Agreement on its face is ambiguous").

We now consider evidence of the course of performance and trade usage to determine whether these shed sufficient light on the matter to resolve the ambiguity.

#### 4. Course of Performance

St. Jude argues that “[o]ver nearly eight years, Penn repeatedly performed, acknowledged, and admitted its obligations under the 2003 MTA and the 2007 MTA Agreements in accordance with its full agreement that the June Construct contained and was made with Materials.” St. Jude MSJ at 20-21. St. Jude points to Dr. June’s crediting of Dr. Campana, Deyo’s e-mail acknowledging “the necessity of a new MTA” before proceeding with clinical trials of the June Construct, and Donahue’s e-mail diagramming the lentiviral vector, including the portion of the vector that represented the Campana Construct.

Penn argues that the fact that Dr. June occasionally gave credit to Dr. Campana does not capture the course of performance because other articles -- indeed, the articles that form the basis for St. Jude’s breach of contract action -- did not credit Dr. Campana, as we discussed above. According to Penn, Dr. June did not always credit Dr. Campana because he did not believe he had a contractual obligation to do so -- instead, he did so in order to comply with “standard practice in the field of academic research [of] identify[ing] the source of biological sequences.” Penn Resp. in Opp. at 23.

With regard to Donahue’s letter, Penn argues persuasively that the “portion” to which Donahue referred was not a “portion” of the Campana Construct within the meaning of the MTA, but the portion of the June Construct which contained

the gene sequence from the Campana Construct. That reading seems plainly accurate, and under it Donahue's statement does not shed light on Penn's understanding of whether the June Construct contained "material" within the meaning of the MTAs.

Penn does not dispute St. Jude's recounting of Deyo's e-mail.<sup>18</sup>

The evidence Penn presents -- including evidence of Dr. June's varied treatment of the June Construct in crediting St. Jude and in sharing materials -- does demonstrate a genuine dispute of fact as to Penn's understanding of the scope of the MTAs. Though Dr. June's occasional efforts to credit Dr. Campana and to seek Dr. Campana's permission before sharing the June Construct may shed light on Penn's understanding of the agreements, these efforts do not elucidate the agreements' terms. See, e.g., J.W.S. Delavau, Inc. v. Eastern America Transport & Warehousing, Inc., 810 A.2d 672, 684 (Pa. Super. Ct. 2002) ("Pennsylvania case law indicates 'course of performance' can only be used to interpret, but not to supplement, the terms of an existing agreement.").

St. Jude dismisses Penn's evidence as "self-serving declarations of undisclosed intent", St. Jude Reply at 8, but the credibility of witnesses precisely presents a question for a

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<sup>18</sup> As St. Jude puts it, Penn is "deathly silent" on this issue. St. Jude Reply at 7.

finder of fact. It is of course well-settled that we may not make credibility determinations in deciding a motion for summary judgment. See, e.g., Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004). In light of this evidence, Deyo's e-mail is insufficient to demonstrate that there is no genuine issue of material fact with respect to Penn's understanding. We thus find that the course of performance does not resolve the contracts' facial ambiguity.

#### 5. Trade Usage

Penn claims that we must read the terms of the MTAs in light of their trade usage. As the United States Supreme Court long ago explained, "[t]he proper office of a custom or usage in trade is to ascertain and explain the meaning and intention of the parties to a contract . . . which could not be done without the aid of this extrinsic evidence." Barnard v. Kellogg, 77 U.S. 383, 390 (1870). Whether a trade usage exists is a question of fact for the jury, see, e.g., Albus v. Toomey, 116 A. 917, 918 (Pa. 1922); Simon Wrecking Co. v. AIU Ins. Co., 530 F. Supp. 2d 706, 715 (E.D. Pa. 2008) (Brody, J.). See also Restatement (Second) of Contracts § 222(2) ("The existence and scope of a usage of trade are to be determined as questions of fact.").

St. Jude objects that "the mere injection of purported trade usage into a party's opposition to a motion for summary judgment will not defeat the motion", St. Jude Reply at 14, and, although we agree as a general matter, we find that here Penn has pointed to sufficient evidence to give rise to a genuine issue of material fact as to whether a trade usage affected the parties' understanding of the agreements' terms.

Penn argues that reading "materials" in the MTAs not to include the June Construct is consistent with the purpose of MTAs within the medical research field. Penn produces an affidavit of Dr. Wesley D. Blakeslee, the Executive Director of Johns Hopkins Technology Transfer at Johns Hopkins University, who avers that "[a]s a general matter, MTAs between scientific research institutions are drafted to govern the exchange of tangible materials . . . and are not intended to govern concepts, ideas or future intellectual property derived from the use of the tangible materials." Blakeslee Dec., Penn Resp. in Opp. Ex. B, at ¶ 8.

St. Jude objects that Blakeslee's Declaration is "conclusory" and "sweeping" in its opinions, and it suggests that Penn has introduced "scant factual evidence" to support its trade usage theory. St. Jude demonstrates considerable chutzpa in objecting to the volume of Penn's evidence when St. Jude moved for summary judgment before discovery, and its argument

does not accord with our role as a court reviewing a summary judgment motion. As the Supreme Court has made clear, we may not “weigh the evidence”, and we must “draw all reasonable inferences in favor of the nonmoving party”, Reeves, 530 U.S. at 150, when ruling on a summary judgment motion. We thus cannot discard the evidence Penn has provided on the ground that Penn did not provide enough support for its argument.

St. Jude next objects to Blakeslee’s interpretation on the ground that it would render the 2007 MTA “meaningless”, and so a construction based on it must fail as a matter of law. St. Jude Reply at 18. Blakeslee suggests that the MTA governed only the physically transferred materials, and St. Jude argues that if this were true there would be no need for the 2007 MTA, which did not accompany a physical materials transfer, and which the parties reached ostensibly so that Penn could use the June Construct in clinical trials. If the June Construct did not contain or was not made using “material” within the meaning of the 2003 MTA, St. Jude’s argument goes, the parties would not have needed to execute a second MTA for the materials’ use in clinical trials. But St. Jude makes this argument before conducting any discovery that would shed light on the parties’ understanding of the scope of the materials used during the clinical trials and the purpose of the 2007 MTA. Without further evidence of the parties’ understanding at the time they

entered into the second MTA, we cannot say as a matter of law that Blakeslee's interpretation would render the 2007 MTA meaningless and would thus be useless in shedding light on the question of whether there is a dispute as to trade usage.

6. Penn Has Demonstrated A  
Genuine Issue of Material Fact  
As To The Meaning of the Contract

The agreement is facially ambiguous, and the parties' conduct under it does not resolve that ambiguity. Moreover, there is a question of fact as to what the trade usage is and whether it affected the parties' understanding of the MTAs' terms. Summary judgment is thus unwarranted.

VII. St. Jude's Motion for a Separate Trial

St. Jude moves in the alternative for a separate trial on the issue of whether the June Construct contained and was made with "material" within the meaning of the 2003 and 2007 MTAs. St. Jude MSJ at 23. Penn opposes this motion on the ground that "piecemeal resolution of issues in separate trials will only serve to prolong the parties' dispute, not accelerate its resolution." Penn Resp. in Opp. at 26.

We agree with St. Jude that an expeditious resolution of the threshold question of whether the June Construct contains and was made with "material" within the meaning of the MTAs will help resolve the case. But we do not agree that separate trials

are necessary in order to accomplish this aim. Instead, in the accompanying Order, we will establish a brief discovery schedule followed by a trial on all claims. Because the case involves both legal and equitable claims, we address the parties' jury trial rights below.

The Seventh Amendment provides that "[i]n Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved." The United States Supreme Court has explained that this Amendment gives a litigant a right to a jury trial for actions "analogous to 'Suits at common law.'" Tull v. United States, 481 U.S. 412, 417 (1987). The jury trial right does not extend to suits that would have been brought in equity, and so in order to determine whether a litigant has that right courts must "examine both the nature of the action and of the remedy sought." Id.

Where a case includes both legal and equitable claims, if the issues underlying the two are common, "the legal claims involved in the action must be determined prior to any final court determination of respondents' equitable claims." Dairy Queen, Inc. v. Wood, 369 U.S. 469, 479 (1962).

Although "[d]etermination of whether a claim stated by the complaint is triable by the court or by a jury will normally not be dependent upon the 'legal' or 'equitable' character of the counterclaim", there are cases, such as one where "the

plaintiff seeks a declaration of invalidity or non-infringement of a patent, in which the relief sought by the counterclaim will determine the nature of the entire case.” Beacon Theatres, Inc. v. Westover, 359 U.S. 500, 519 n.13 (1959) (Stewart, J., dissenting) (citing Moore’s Federal Practice (2d ed.) § 38.29) (emphasis added).

Penn’s amended complaint in C.A. No. 12-4122 seeks a declaratory judgment. St. Jude’s complaint, originally filed in the Western District of Tennessee and now consolidated with C.A. No. 12-4122, contains only a breach of contract claim for which St. Jude seeks damages. Both parties included a jury demand in their complaints in that action.

In C.A. No. 13-1502, Penn seeks determinations of non-infringement and invalidity, and St. Jude counterclaims, seeking declaratory relief and damages. Both parties again include jury demands.

As our Court of Appeals has explained, a declaratory judgment action is neither legal nor equitable in nature, and if it “does not fit into one of the existing equitable patterns but is essentially an inverted law suit -- an action brought by one who would have been a defendant at common law -- then the parties have a right to a jury”, AstenJohnson, Inc. v. Columbia Cas. Co., 562 F.3d 213, 223 (3d Cir. 2009) (quoting Owens-Illinois, Inc. v. Lake Shore Land Co., 610 F.2d 1185, 1189 (3d

Cir. 1979)). In order to determine whether the action falls under this category, we are to consider "in what kind of suit the claim would have come to court if there were no declaratory judgment remedy", Owens-Illinois, Inc., 610 F.2d at 1189.

Penn's declaratory judgment claims in the contract case would have come -- and did come, in St. Jude's Tennessee complaint -- in the form of a breach of contract action. To the extent that such an action seeks damages it is a legal claim and requires a jury trial. See, e.g., 9 Charles Allen Wright & Arthur R. Miller, Federal Practice and Procedure § 2316 (3d ed., updated April 2013) ("An action for damages for breach of contract is legal in nature and therefore triable to a jury"); Wills v. Young, 255 F.2d 65, 67 (3d Cir. 1958) (contrasting "an action at law for damages for breach of contract" with "an action in equity for specific performance"). Penn and St. Jude are thus entitled to a jury determination on St. Jude's breach of contract claim for damages and Penn's declaratory judgment claims in C.A. No. 12-4122.

With regard to St. Jude's claim for a preliminary injunction, this is an equitable remedy that we will consider. See, e.g., N.A.A.C.P. v. North Hudson Regional Fire & Rescue, 707 F. Supp. 2d 520, 541 (D.N.J. 2010) (Debevoise, J.) ("a preliminary injunction is an equitable remedy, which the Court, in its discretion, considers by balancing and weighing the

various factors"). Under Dairy Queen, we will dispose of the equitable claims after a jury considers the legal claims.

Penn also seeks a declaratory judgment in the patent suit. In In re Lockwood, 50 F.3d 966 (Fed. Cir. 1995), the Federal Circuit observed that "declaratory judgment actions are, for Seventh Amendment purposes, only as legal or equitable in nature as the controversies on which they are founded." Id. at 973.<sup>19</sup> The Federal Circuit found that a declaratory judgment action by a potential infringer should be considered "as a suit for patent infringement in which the affirmative defense of invalidity has been pled", id. at 974. Lockwood looked to the nature of patent actions in the eighteenth century and found that "[i]n eighteenth-century England, allegations of patent infringement could be raised in both actions at law and suits in equity", id. at 975, and "[t]he choice of forum and remedy, and thus of the method of trial, was left with the patentee." Id. The Federal Circuit reasoned that "[u]nder both English and

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<sup>19</sup> As the Northern District of Illinois summarized, the Supreme Court vacated the Federal Circuit's decision in Lockwood after Lockwood withdrew its jury demand, American Airlines, Inc. v. Lockwood, 515 U.S. 1182 (1995); Barry S. Wilson, Patent Invalidity and the Seventh Amendment; Is the Jury Out?, 34 San Diego L.Rev. 1787, 1796 (1997), and so Lockwood is not binding, but it is persuasive as a "source of guidance" and as an indication of the Federal Circuit's likely position on the Seventh Amendment question. Pfizer Inc. v. Novopharm Ltd., No. 00 C 1475, 2001 WL 477163, at \*3 (N.D. Ill. May 3, 2001) (citing Christianson v. Colt Indus. Operating Corp., 870 F.2d 1292, 1298-99, n. 7 (7th Cir.1989)).

American practice . . . it was the patentee who decided in the first instance whether a jury trial on the factual questions relating to validity would be compelled", and so the patentee retained the option of a jury trial even when "the validity of his patents comes before the court in a declaratory judgment action for invalidity rather than as a defense in an infringement suit." Id. at 976.

In Tegal Corp. v. Tokyo Electron America, Inc., 257 F.3d 1331 (Fed. Cir. 2001), the Federal Circuit cited Lockwood's canvass of eighteenth century patent law and explained that "[i]f the patentee sought an injunction and an accounting, the patentee went to a court of equity. If, however, the patentee sought only damages, a court of law was used." Id. at 1340 (internal citations omitted).

Thus, under the Federal Circuit's jurisprudence the remedy the patentee seeks determines the nature of the action. See also, e.g., Kao Corp. v. Unilever U.S., Inc., No 01-680, 2003 WL 1905635, at \*3 (D. Del. Apr. 17, 2003) ("the patentee's infringement case is the linchpin of the Federal Circuit's Seventh Amendment analyses").

Here, where St. Jude's counterclaims seek damages, the action is necessarily legal and the parties may try their patent claims to a jury. As mentioned, we will make a determination as to the equitable relief they seek after a jury trial.

VIII. Conclusion

For the reasons stated herein, we will consolidate the actions, deny as moot St. Jude's motion to dismiss Penn's initial patent complaint, grant in part and deny in part Penn's motion to dismiss St. Jude's willful infringement counterclaim, and deny St. Jude's motion for partial summary judgment and motion for separate trial. In the accompanying Order, we set a discovery and trial schedule.

BY THE COURT:

/S/ STEWART DALZELL