

Who Owns My Intellectual Property?

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Introduction

Before commencing a clinical trial, the parties sign a clinical trial agreement (CTA), which usually includes a section on the intellectual property (IP). This section, like the subject injury and indemnification sections, is very complex and must handle scenarios that are difficult to anticipate. Any ambiguity can have unforeseen consequences, especially if the terms are negotiated in haste.

The parties may sign a contract knowing that it is ambiguous (e.g., leaving governing law unspecified). Or, one or both parties may not know the language is ambiguous. In any case, if the parties enter into a legal dispute, differing interpretations of key provisions are likely.

A lawsuit between the University of Pennsylvania (UPenn) and St. Jude's Cancer Research Hospital (St. Jude) currently making its way through the Eastern District of Pennsylvania provides a good example of how ambiguous language can be problematic. While this dispute does not involve a CTA, the issues apply to CTAs.

The two parties have presented two entirely different readings of the contractual language that defines ownership rights of an immunotherapy.¹ As it presently stands, Novartis has come out in support of UPenn's understanding of the agreement, while Juno Therapeutics has come out in support of St. Jude's version.

Background

In 2003, UPenn's Dr. Carl June contacted Dr. Dario Campana of St. Jude about Dr. Campana's presentation at the American Society of Hematology Annual Meeting. At the conference, Dr. Campana presented the effects of a protein molecule he had developed called "anti-CD19 chimeric antigen receptor ('Construct 1')²" for the purpose of treating "CD19+ B-cell cancers, such as acute and chronic leukemia and non-Hodgkin's lymphoma." UPenn proposed an inter-institutional collaboration to further study Construct 1. In 2003, the parties signed a material transfer agreement (MTA) to facilitate the physical and intellectual exchange (Agreement 1).²

UPenn agreed that it would only make Construct 1 for the purpose of clinical studies and would not attempt commercialization without prior written agreement and discussion with St. Jude. UPenn further agreed to jointly publish all results with St. Jude. To help with production, UPenn requested and received several other cDNA sequences from St. Jude. Subsequent to receiving these sequences, UPenn constructed a chimeric T-cell receptor, similar in structure and mechanism to Construct 1, for testing in separate clinical trials ("Construct 2"). UPenn believed this new receptor to be a "modified derivative" and not encompassed by Agreement 1, which stated that St. Jude's IP included "any progeny, portions, unmodified derivatives [of Construct 1], and any accompanying know-how or data." In 2007, the parties signed another agreement (Agreement 2), with similar terms to the first Agreement 1 to allow St. Jude to also conduct clinical trials with Construct 1.

² Called "Construct 1" and "Construct 2" in this article.

Shortly thereafter, UPenn began sending samples of Construct 2 to other labs, upon their request, and eventually filed a patent on behalf of UPenn and Dr. June for Construct 2. Sending out samples of Construct 2 and filing the patent were done without St. Jude's express written permission, as St. Jude thought was required under the Agreements.

According to UPenn's interpretation, Construct 2 was sufficiently different from Construct 1 to be considered UPenn's own intellectual property. As such, UPenn believed it was free to disseminate, conduct trials with, patent, and profit from its invention. However, St. Jude disagreed. According to St. Jude's interpretation of the Agreements' terms, Construct 2 was St. Jude's IP and all ownership rights remained with it. The question before the court now is: Did UPenn violate St. Jude's ownership rights?

Application to Clinical Trials

The IP issues involved in this Agreement, arising from the transfer of IP from one organization to another for further study and research, could very easily be seen when a clinical research site, working under a CTA, decides to modify a sponsor's IP and/or asserts that a previously un contemplated use is now deemed to be its property. For example, a site that has received IP from a sponsor might discover a previously unintended use for the Sponsor's IP or might discover that the product works best in synergy with another commonly marketed product and then assert that these discoveries constitute its own IP. While it is entirely proper for either the sponsor or the site to own the resulting IP rights, as they may agree, the problem occurs when they both think they own the IP rights because the CTA language is ambiguous. Table 1 lists ways in which a research site might create new IP based on a study drug.

Table 1. Potential New IP Based on a Study Drug

New patient populations
New indications
New diagnostic tests
New strengths
New dosing regimens
New routes of administration
New chemical entities
New inactive ingredients
New combination products
New manufacturing methods
New study protocols

Problematic Contract Components

Three main contract components should be explicitly defined in a CTA or MTA to ensure that both parties understand and agree to the same bounds of ownership rights:

- Recitals stating the parties' intentions
- Definitions of material, know-how, data and derivatives
- Implications of course of performance and trade usage

Recitals

It would be easier to interpret the St. Jude/UPenn contract if the intentions of the parties were clearly spelled out in the recitals section. In particular, was it St. Jude's intention to allow UPenn to research, create or license *any* new substance based *in any way* on Construct 1?

Definitions of Material, Know-how, Data and Derivatives

Language

The St. Jude/UPenn Agreements defined the transferred protein molecule and the associated IP, in relevant part, as:

- “Materials” include “`any portions’ and `accompanying know-how and data.’”
- A “portion” is “a part of a whole...”
- “Data” are “facts or statistics collected together for reference or analysis.”
- “Know-how” is “practical knowledge or skill; expertise.”

Interpretation

UPenn asserted that the “Materials” term wasn’t violated, since its protein construct did not include any physical portions of the St. Jude’s Construct 1. UPenn built its protein (“construct”) using only UPenn’s materials in a UPenn laboratory. UPenn further asserted that the “know-how” requirements were not violated, as the process for protein synthesis would be expected prior knowledge for a genetic oncologist in a research setting. Despite the fact that it received additional information on constructing Construct 1, UPenn asserted that the exchange was merely a time-saving step that didn’t count as Data or Know-how, since retrosynthesis is another expected practical skill in construct development.

UPenn further asserted that the Agreements showed a “clear intent...to allow [UPenn] to research and create a new substance in which it would presumably have its own rights,” including assignability.

On the other side, St. Jude argued that, without its initial construct and related data, there would have been no retrosynthesis or derivative possibilities. It further noted that large portions of Construct 2 were identical to Construct 1 and that the origin of the amino acids in UPenn’s molecule was irrelevant.

St. Jude further asserted that the Agreements specified that “even a copy of a single nucleotide, molecule or even atom from Construct 1 would constitute a Portion of the Materials.” In other words, any intellectual property partly or wholly related to Construct 1 would remain with St. Jude and any use outside that specified by the Agreements would remain its Intellectual Property, with no rights of assignment.

These contrary interpretations arising from the metes and bounds of the terms “materials” and “know-how” illustrate the importance of clarity in contractual language.

Course of Performance and Trade Usage

Interpretation

The court considered using the course of performance and trade usage to evaluate the intent of the parties. However, it found that, while under Pennsylvania law, the course of performance does not override contract terms, if the behavior occurs without objection in full knowledge of both parties, it is a significant consideration. The court held that “Pennsylvania case law indicates `course of performance’ can only be used to interpret, but not to supplement, the terms of an existing agreement.” The court continued, “The 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.”

St. Jude cited email messages in which UPenn admitted needing Compano’s permission to move ahead with trials of any molecule (derivative or otherwise), whereas UPenn argued that a few emails do not capture the entire course of performance and that the permission required was explicitly referring to the entire Construct 1, not portions of it, or to Construct 2 as a whole.

Summary Judgment

St. Jude asked the court to issue a summary judgment in its favor. Summary judgments require the parties to agree on the facts but not on the law, since in a jury proceeding, the jury is the sole judge of the facts. In this case, the court ruled that the meaning of the Agreements was a question of fact, which would have to be decided by the jury at trial.

Conclusion

While the reader may have an opinion on whether Sr. Jude or UPenn should prevail, the legal system does not always yield results that a third-party observer would deem “fair.” It is thus far preferable to avoid disputes hinging on ambiguous contract language.

The UPenn v. St. Jude contract dispute demonstrates the importance of clarity in contracts especially when potentially valuable IP is involved. CTAs, MTAs and other contracts involving IP should employ clear definitions and explicitly describe the parties’ intentions as they relate to critical information, such as ownership, materials and know-how.

Furthermore, parties should consider whether trade use and course of performance should affect the interpretation of the contract. Research sites would typically benefit from trade usage and course of dealing being considered, since they have greater opportunity to apply modifications and derivatives arising from provided materials, but sponsors might decide to contractually disallow that as a consideration when drafting CTAs.

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