

MTAS AND THE COMMON LAW OF BAILMENT: MINIMIZING MISUNDERSTANDING, AVOIDING DISPUTE, MANAGING IPR, AND ACCELERATING INNOVATION

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Abstract

Exchanges of research materials are essential to combatting rapidly emerging infectious diseases, as well as neglected tropical diseases that still wreak havoc around the world. This Note illustrates the importance of carefully managing these exchanges because the materials and any downstream products could hold great value. It advocates for greater understanding of the instruments used to facilitate these exchanges, such as Material Transfer Agreements (MTAs), to set forth ownership rights.

This Note explores misunderstandings in the sharing of research materials that could lead to dispute if MTAs do not clearly address both ownership of tangible property and intellectual property rights (IPR). It contemplates various circumstances where disputes could fall into the common law of bailment conundrum and drastically delay innovation. Furthermore, this Note discusses how MTAs should be used to protect assets and speed up scientific progress because research frequently operates in an open innovation model that calls for exchanges of materials at various stages along the path from research to innovation to commercialization.

I. Introduction

Biological research has the potential to cure diseases and provide solutions to rapidly evolving and emerging issues in the modern world.² Because of this, the materials exchanged and developed through biological research can hold high property value and the ability to commercialize the products means vast sums of money can be at stake.³ Research materials must be exchanged to promote scientific progress.⁴ Therefore, it is highly important to clearly articulate who owns the material being exchanged; who owns the material if it is

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² Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133, PLANT PHYSIOLOGY, 10, 10 (2003).

³ *Id.* at 13.

⁴ See Henry Chesbrough, *Open Innovation: Where We've Been and Where We're Going*, RESEARCH-TECHNOLOGY MANAGEMENT, 20, 23 (Aug. 2012).

substantially improved; who is allowed to seek intellectual property rights to technological advancements; and who stands to benefit from any commercial gain. Management of intellectual assets and tangible property are important for accelerating research and generating value.⁵ In order to avoid slowing down research progression, the instruments used to govern the exchange of research materials must be understood so litigation and disputes can be avoided.

The current method of using contractual bailments to govern the exchange of research materials requires that these ownership rights be clearly articulated because if they are not, then American courts cannot analyze disputes through the lens of contracts law.⁶ Courts should then turn to the ancient common law of bailments (and the related common law doctrine of accession rooted in Roman Law), which is infrequently used, not well understood, and not to mention, an ironic choice for the rapidly developing field of biotechnology.⁷

To explain this irony, the law of bailment is best demonstrated through an exchange of cattle. Consider a scenario in which a man enters an agreement with his neighbor for his neighbor to take his female Quarter Horse for a specified time period to assist the neighbor with farm work. While in the neighbor's possession, the neighbor breeds the female Quarter Horse with another male Quarter Horse and the female later gives birth to a Quarter Horse calf, a standard horse breed.⁸ The neighbor later realizes the female Quarter Horse has special

⁵ *See id.*

⁶ Tania Bubela, *Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation*, PLoS BIOLOGY, Feb. 2015 at 1.

⁷ *See* Maunulua Bay Beach Ohana 28 v. State, 222 P.3d 441, 443 (Haw. Ct. App. 2009).

⁸ American Quarter Horse, International Museum of the Horse, <https://perma.cc/L42U-T2D3>.

characteristics, consults with a horse breeder, and decides to breed the female standard Quarter Horse with a Thoroughbred Horse. The female later gives birth to a highly valued Appendix calf (a Quarter Horse-Thoroughbred cross) that proceeds to win numerous races.⁹ Who owns the standard Quarter Horse calf? Who owns the highly valued Appendix calf? Are the owners the same?

When the man entered the agreement with his neighbor that gave the neighbor a possessory interest in the female horse, a bailment was created. The man maintained title and an ownership interest in the female horse.¹⁰ When the neighbor bred the standard female Quarter Horse with another male Quarter Horse, this Note will address how the rule of increase indicates the man who owns the female horse retains ownership in this standard calf as well.¹¹ However, when the neighbor decided to substantially improve the quality of the calf born to the man's standard female Quarter Horse, the Doctrine of Accession indicates that the neighbor obtained an ownership right to the highly valued Appendix calf.¹²

To further illustrate the law of bailment and its interplay with the doctrine of accession, consider a simple hypothetical in which a man has stacks of Mahogany wood in his backyard. When the man decides to make improvements to his home, he enters into an agreement with his neighbor for the neighbor to keep the stacks of Mahogany wood safe in his yard for the duration of the man's home improvement project. The wood is placed in the neighbor's yard

⁹ What is an Appendix Quarter Horse, <https://perma.cc/6DSC-2SQS>.

¹⁰ Richard A. Epstein, *The Many Faces of Fault in Contract Law: Or How to do Economics Right, Without Really Trying*, 107 MICH. L. REV. 1461, 1474 (June 2009) (a key aspect of bailment is separation of possession and ownership).

¹¹ DANA SHILLING & CHRISTINE VINCENT, *LAWYER'S DESK BOOK* § 8.13 (2d ed. 2022).

¹² *See id.*

and soon after the neighbor realizes the high value of the Mahogany wood. The neighbor decides to use some of the wood and significantly improve it by transforming it into wooden baseball bats. The baseball bats contain material in addition to the wood and a structural design on their surface that improves the speed with which the ball leaves the bat. The neighbor files a patent application for the design and seeks to gain a great commercial profit. But who owns the baseball bats? Who should profit from their commercialization?

The law of bailment would suggest a bailment was created when the man entered into an agreement with his neighbor for the neighbor to possess the wood for safekeeping.¹³ The man maintained title to the wood though and did not give the neighbor ownership rights. However, the doctrine of accession would suggest when the neighbor transformed the wooden planks into baseball bats, he significantly improved the wood and established an ownership interest in the new and improved tangible property.¹⁴ The neighbor would be required to compensate the man for the value of the wood, but the value of the baseball bats would belong to the neighbor.¹⁵ This hypothetical segues into IP rights because once the neighbor has established title to the baseball bats, he can apply for a grant of IP right to the patentable design. The IP right, being separate and distinct from the tangible property right in the baseball bats would be acquired separately.¹⁶

In the much more involved and quickly advancing field of biological research, determining who owns what materials can be complicated and the consequences enormous. While the

¹³ ROBERT H. TANHA, *THE LAW OF BAILMENT* 6 (2019) (citing *Ashby v. Tolhurst*, 2 K.B. 242 (King's Bench Div., 1937)).

¹⁴ *See Wetherbee v. Green*, 22 Mich. 311, 315 (Mich. 1871).

¹⁵ *See id.*

¹⁶ *Moore v. Regents of Univ. of California*, 793 P.2d 479 (Sept. 2008)

highly sophisticated industry of biotechnology continues to move at an increasing pace, the contracts governing the transfer of materials between academic institutions, biotechnology companies, and pharmaceutical companies remains rooted in the Common Law of Bailments.¹⁷ The question is, how does this impact tangible property rights and intellectual property rights to the products of painstaking research endeavors.

For scientific research to continue to progress, it is widely accepted that research materials must be shared and exchanged.¹⁸ Positions vary between for-profit and non-profit institutions on how this sharing should occur, nonetheless contracts that set forth the basic principles of what is being transferred to whom and what their rights are in terms of the materials and any related IP are essential to these exchanges.¹⁹ A Material Transfer Agreement (MTA) is a legal “bailment” that provides a researcher receiving materials with a possessory interest in the materials, but maintains ownership rights in the provider of the materials.²⁰ Traditionally, the recipient is only allowed to use the materials as the provider laid out in the MTA and is to return or destroy them when the provider demands.²¹ MTAs have transformed into and should be used as more of a hybrid instrument to address ownership of tangible and intangible assets.²²

Part II of this Note discusses the policy implications behind recognizing tangible property rights in human biological materials. Part III introduces MTAs and how they are used to

¹⁷ Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133, PLANT PHYSIOLOGY, 10, 10 (2003).

¹⁸ Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 329 (Sept. 2008).

¹⁹ *Id.* at 328.

²⁰ Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 698 (2007).

²¹ *Id.*

²² *Id.*

govern the modern transfer of research materials. Part IV discusses how American courts prefer to analyze disputes involving MTAs through the law of contracts. Part V suggests how disputes involving MTAs should be analyzed through the law of bailment when the law of contracts does not provide a clear answer. Finally, Part VI concludes by emphasizing the importance of clearly articulating the terms of MTAs because management of intellectual assets and tangible property is critical to accelerate research and generate value in today's world of rapidly emerging infectious diseases.

II. Policy Implications

Courts have been hesitant to acknowledge a tangible property right in human biological materials.²³ In 1990, the Supreme Court of California avoided holding that John Moore held a tangible property right in the cells removed from his body.²⁴ Instead, focus was placed on whether Moore's treating physician fulfilled their fiduciary duty and whether Moore was able to provide adequate informed consent.²⁵ The court made a policy point by refusing to acknowledge patient property rights in biological materials removed from a patient.²⁶ However, when a biological material moves from patient to product without clearly delineated tangible property rights, devastating ethical and economic consequences can result.²⁷

In *Moore v. Regents of the University of California*, John Moore had been diagnosed with Hairy-cell Leukemia and told that a splenectomy would be the proper course of treatment.²⁸

²³ See *Moore v. Regents of Univ. of California*, 793 P.2d 479, 492 (Cal. 1990).

²⁴ *Id.* at 487.

²⁵ *Id.* at 494.

²⁶ *Id.* at 493.

²⁷ See *id.* at 481-82; The Legacy of Henrietta Lacks, JOHNS HOPKINS MEDICINE (2022) <https://perma.cc/L2T2-K3FU>.

²⁸ *Moore*, 793 P.2d at 480.

However, when Moore's treating physician informed him of the necessity of this treatment, the physician made no mention of his own intentions to conduct biological research using a piece of Moore's spleen or of his economic interest in obtaining the spleen.²⁹ The splenectomy led to development of a cell line, which was later patented and led to vast economic advantage.³⁰ Moore initially brought this case over a claim of conversion of his excised cells, claiming he owned the cell line and the products derived from it.³¹ To successfully assert a claim of conversion, there must be a property interest in the thing claimed to have been converted in the first place - in this case, Moore's extracted cells.³²

The court reasoned in *Moore* that conversion liability should not be extended based on two critical policy considerations.³³ First, it is important to protect a competent patient's right to autonomy when making medical decisions.³⁴ The court reasoned that this right is adequately protected by the well-established fiduciary duty of a physician and informed consent.³⁵ Second, it is important that the court not threaten innocent parties engaged in socially useful activities, such as scientific research, with "disabling civil liability."³⁶ The court acknowledged the importance of balancing these critical policy considerations, but ultimately determined that liability based on already existing disclosure obligations protected patients without extending conversion theory - thereby avoiding extending a tangible property right in excised cells to patients.³⁷

²⁹ *Id.* at 486.

³⁰ *Id.*

³¹ *Id.* at 493.

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 494.

Avoiding acknowledgment of patient rights in excised cells has historically placed patients at a disadvantage and prevented them from seeing any benefit from successes made possible from their contribution to scientific research.³⁸ The first human cells to be easily multiplied in a lab setting and shared among researchers were removed from Henrietta Lacks in 1951.³⁹ Henrietta Lacks was a black woman who was diagnosed with an aggressive form of cervical cancer and was treated by physicians at Johns Hopkins Hospital in Baltimore, Maryland in 1951.⁴⁰ While treating her, doctors took samples of her cells and gave some to a researcher without Henrietta Lacks' consent.⁴¹ Henrietta's cells had an ability to survive in media and replicate like no other human cells before.⁴² In the interest of scientific progress, the researcher, Dr. Gey, shared the cells extensively with fellow scientists.⁴³ The ability to use human cells as a platform to study a variety of different human diseases was viewed as groundbreaking by the scientific community.⁴⁴ Dr. Gey was known to ship tubes of Henrietta's cells via plane to fellow researchers.⁴⁵ Rumors have it that pilots or stewards would often stuff the tubes in their pockets to keep the cells at body temperature.⁴⁶ At the time, this sharing of research materials was not restricted and it was not long before Henrietta's cells were proliferating around the world.⁴⁷ The cells became known as HeLa cells and have contributed greatly in biological research, being involved in key discoveries;

³⁸ *Henrietta Lacks: Science Must Right a Historical Wrong*, 585 NATURE 7 (Sept. 2020).

³⁹ Duncan Wilson, *A Troubled Past? Reassessing Ethics in the History of Tissue Culture*, 24 HEALTH CARE ANAL 246, 247 (Aug. 2015).

⁴⁰ *Henrietta Lacks: Science Must Right a Historical Wrong*, 585 NATURE 7 (Sept. 2020).

⁴¹ *Id.*

⁴² Duncan Wilson, *A Troubled Past? Reassessing Ethics in the History of Tissue Culture*, 24 HEALTH CARE ANAL 246, 247 (Aug. 2015).

⁴³ *Id.* at 247-48.

⁴⁴ See REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* 57 (Broadway Paperbacks 2010).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

including cancer research, in vitro fertilization, and research on COVID-19 vaccines to name a few.⁴⁸ Not only is much of modern medicine rooted in research involving HeLa cells, but their use has become so common around the world that they are used by students, educators, and researchers alike in a variety of settings.⁴⁹ Along with the widespread dissemination of HeLa cells came great monetary benefit for those controlling them.⁵⁰

While a great success story for the research community at large, the woman behind the HeLa cell line, Henrietta Lacks herself, survived only a few months after her cells were removed.⁵¹ Her family continued to live in a poor rural community and were unaware for years of the lucrative success that resulted from Henrietta's cells being taken, used for research, and transformed into a beneficial cell line without her knowledge or consent.⁵² Henrietta's family continued to live poorly, while the rest of the world benefitted from the cells that were never considered Henrietta's tangible property from the second they were taken from her body.⁵³ In the Fall of 2021, the Lacks Estate sued drug company, Thermo Fisher, (a company that generates approximately \$35 billion in annual revenue) for 70 years of commercializing HeLa cells without consent.⁵⁴ However, in 1951, when Henrietta's cells were removed from her body and used without consent for research purposes, this practice was "widely seen as unproblematic."⁵⁵

⁴⁸ *Henrietta Lacks: Science Must Right a Historical Wrong*, 585 NATURE 7 (Sept. 2020).

⁴⁹ *Id.*

⁵⁰ See Henrietta Lacks' Estate Sues Drug Company that Sold her Cells, <https://perma.cc/N8PK-J9EH>

⁵¹ *Henrietta Lacks: Science Must Right a Historical Wrong*, 585 NATURE 7 (Sept. 2020).

⁵² *Id.*

⁵³ See *id.*

⁵⁴ See Henrietta Lacks' Estate Sues Drug Company that Sold her Cells, <https://perma.cc/N8PK-J9EH>

⁵⁵ Duncan Wilson, *A Troubled Past? Reassessing Ethics in the History of Tissue Culture*, 24 HEALTH CARE ANAL 246, 250 (Aug. 2015).

By 1990 when *Moore* was decided, informed consent was essential, and the court reasoned that informed consent did an adequate job of protecting patient rights.⁵⁶ The court further explained that articulating a tangible property right for a patient in their excised cells would open the door to extensive problems that would hinder socially beneficial research and not protect patient rights any better than informed consent can do on its own.⁵⁷ However, clearly articulated rights could prevent the devastating story of Henrietta Lacks from repeating itself time and again.⁵⁸ Moore claimed he suffered the tort of conversion when his cells were taken from him and that he is owed the rights to the cells and the patents resulting from them.⁵⁹ The court correctly asserts that an intellectual property right is a separate right from a tangible property right, stating that “the patented cell line is both factually and legally distinct from the cells taken from Moore’s body.”⁶⁰ Intellectual property interests, or interests in certain intangible things, is distinguished from property associated with tangible things.⁶¹ While Congress has acknowledged that Patents and Copyrights have attributes of property rights, intellectual property rights are a grant of property rights separate from that of tangible property rights.⁶² Regarding cell lines, it has been acknowledged that cells taken directly from a human body differ from any downstream patented cell line developed from the initial human cells.⁶³ A party could hold “separate and distinct” tangible and intangible rights to the patented cell line.⁶⁴

⁵⁶ *Moore v. Regents of Univ. of California*, 793 P.2d 479, 493 (Cal. 1990).

⁵⁷ *Id.*

⁵⁸ *See Henrietta Lacks: Science Must Right a Historical Wrong*, 585 NATURE 7 (Sept. 2020).

⁵⁹ *Moore*, 793 P.2d at 483.

⁶⁰ *Id.* at 492.

⁶¹ Laura Sleazinger, *What Makes Trademarks “Intellectual” Property?*, 19 J. CONTEMP. LEGAL ISSUES 7, 8 (2010).

⁶² *See id.* at 1 n.8.

⁶³ *Moore*, 793 P.2d at 492 n.35.

⁶⁴ *See id.*

In general, “people have a strong sense of ownership when it comes to their bodies,” but a sense of ownership has yet to lead to a court-articulated patient right to control tissues removed from their bodies.⁶⁵ Whether patients should have clearly articulated tangible rights in their excised cells and the ability to further specify any reach-through rights in resulting intellectual property is still highly debated.⁶⁶ But there is no question about whether human tissue research will continue to be commercialized.⁶⁷ The question is where do patients and researchers fall into this process.⁶⁸

Researchers in the UK have suggested patient informed consent should be a “continuing relational process” that merely begins when a patient consents to participate in a research endeavor.⁶⁹ The researchers do not suggest direct communication between patients and scientists would be necessary, but would require scientists to provide widespread information on their research, allowing for patients to remain informed and have an ability to maintain interaction if they choose.⁷⁰ One potential benefit of this would be that patients could choose to participate in additional studies, removing one restriction on scientific research today.⁷¹ Regarding consent today, focus is placed on the moment a patient signs a consent form.⁷² While informed consent forms of today certainly recognize patient autonomy greater than in the cases of *Moore* or Henrietta Lacks, this suggested concept is still a far cry away from a world in which patients hold tangible property rights in their biological materials, but could

⁶⁵ REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* 317 (Broadway Paperbacks 2010).

⁶⁶ *Id.*

⁶⁷ *Id.* at 322.

⁶⁸ *See id.*

⁶⁹ Graeme Laurie & Emily Postan, *Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-Related Research?*, 21 MEDICAL L. REV. 371, 412 (2013).

⁷⁰ *Id.* at 412-13.

⁷¹ *Id.* at 412.

⁷² *Id.*

provide patients with greater control over how and when their biological materials are used. If the terms of this “continuing relational process” were clearly articulated so patients and researchers understood their rights, this suggestion could serve to promote scientific progress, allowing patients to participate in more studies and dictate where their biological materials go.

In the U.S., patients do not have a say in where their biological materials go after they have signed a consent form and made a donation because they retain no ownership interest in their biological materials.⁷³ In *Washington University v. Catalona*, the 8th Circuit Court of Appeals had to determine if research participants could elect for their biological materials to be transferred from the University where they made the donation and signed the form to a new university where the lead researcher, Dr. Catalona, was transferring to.⁷⁴ While at Washington University, Dr. Catalona was the leading medical researcher, where he focused on understanding the genetic basis for prostate cancer.⁷⁵ He collected biological materials from patients beginning in 1983 and established a biorepository to store these patient samples.⁷⁶ Dr. Catalona frequently utilized MTAs to transfer materials in the biorepository to other research institutes.⁷⁷ These MTAs were signed by Dr. Catalona, but indicated that Washington University owned the biological materials.⁷⁸ When Dr. Catalona accepted a position at a different university in 2003, he requested consent from patients to transfer their materials from the Washington University biorepository to his new university.⁷⁹

⁷³ See *Washington Univ. v. Catalona*, 490 F.3d 667, 673, 676-77 (8th Cir. 2007).

⁷⁴ *Id.*

⁷⁵ *Id.* at 670.

⁷⁶ *Id.*

⁷⁷ *Id.* at 672.

⁷⁸ *Id.*

⁷⁹ *Id.*

Approximately 6,000 research participants consented to the transfer.⁸⁰ However, Washington University filed a declaratory judgment against Dr. Catalona, seeking to establish ownership of the biological materials contained in the biorepository.⁸¹ Disputes between the parties continued for two years before the case made it to the 8th Circuit Court of Appeals.⁸² The court looked to the language contained in the initial patient consent forms (indicating they were donating biological samples to Washington University) and to Dr. Catalona's behavior (signing MTAs indicating Washington University was the owner of the materials).⁸³ There was no indication in the consent forms that research participants could later transfer their samples elsewhere for research purposes.⁸⁴ The 8th Circuit concluded that Washington University owned the materials and the patients retained no right to direct a transfer of the materials.⁸⁵ However, if a "continuing relational process" of consent were adopted here, as suggested by researchers in the UK above, then perhaps the patients could have directed a transfer of their materials to remain with the researcher who had expended 20 years of effort into this project. Perhaps Dr. Catalona was the best researcher to continue this study, but the dynamics of biological tangible property rights prevented a patient-directed transfer and any future scientific discoveries or inventions.

III. Material Transfer Agreements

The goal of MTAs is to clearly articulate who owns what research materials and when so exchanges of research materials can easily occur; speeding up scientific discoveries, and

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 673.

⁸³ *Id.* at 674, 676.

⁸⁴ *Id.* at 676.

⁸⁵ *Id.* at 677.

promoting innovation.⁸⁶ While patient rights in biological materials have not been recognized, limited tangible rights in biological research materials were recognized in the 1980s when advancements in molecular genetics and advancements in the legal world combined.⁸⁷ Over the past few decades, the increasing commercial value of biological research products has led to a greater need to clearly delineate who owns what materials.⁸⁸ Historically, academia and industry have tended to view the transfer of research materials through different lenses.⁸⁹ Therefore, when academia and industry interact, clearly articulating the parties' rights to tangible property and existing IP becomes very important.⁹⁰ In academia, where the goal is more often to publish scientific results, open access to research materials is highly valued.⁹¹ In industry, these biological materials are viewed as holding direct commercial value that needs to be protected.⁹² The 1980s saw great advancements in the field of molecular genetics that simultaneously combined with three advancements in the legal world - passage of the Bayh-Dole Act, establishment of the United States Court of Appeals for the Federal Circuit, and the *Chakrabarty* decision - to create a greater need to articulate who owns what.⁹³

⁸⁶ See Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 326 (Sept. 2008).

⁸⁷ See Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133, PLANT PHYSIOLOGY, 10, 10 (2003).

⁸⁸ Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 697 (2007).

⁸⁹ *Id.* at 698.

⁹⁰ Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133, PLANT PHYSIOLOGY, 10, 11 (2003).

⁹¹ *Id.*

⁹² See *id.* at 10.

⁹³ See *id.*; *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); Paul R. Gugliuzza, *The Federal Circuit as a Federal Court*, 54 WM. & MARY L. REV. 1791, 1800 (May 2013).

The Bayh-Dole Act specifically created a greater interest in academia to contractually protect research materials.⁹⁴ In 1980, when the Bayh-Dole Act was passed, universities were newly allowed to own and manage inventions that were made through federally sponsored research.⁹⁵ These universities were just required to file a patent application and diligently attempt to further commercialize their invention.⁹⁶ Unsurprisingly, this new ability of non-profit universities to patent and commercialize products of their research efforts concerned for-profit companies.⁹⁷ For-profit companies became more protective of their proprietary materials when exchanging them with non-profit universities to a point where unrestricted transfers of material became a thing of the past.⁹⁸

Related to the ability to commercialize, is the ability to patent a particular invention.⁹⁹ In 1982, Congress granted the Federal Circuit exclusive jurisdiction over specific types of patent cases with passage of the Federal Courts Improvement Act (FCIA).¹⁰⁰ These types of patent cases included “federal district court cases ‘arising under’ the patent laws,” appeals from rejections or claims seeking a declaratory judgment of patent invalidity, and appeals from International Trade Commission (ITC) investigations.¹⁰¹ For 100 years prior to the passage of the FCIA, patent litigation appeals were heard by the court of appeals for the

⁹⁴ Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133, PLANT PHYSIOLOGY, 10, 10 (2003).

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Henry Chesbrough, *Open Innovation: Where We’ve Been and Where We’re Going*, RESEARCH-TECHNOLOGY MANAGEMENT, 20, 22 (Aug. 2012); Victor Rodriguez, *Material Transfer Agreements: Open Science vs. Proprietary Claims*, 23 NATURE BIOTECHNOLOGY 489, 489 (April 2005).

¹⁰⁰ Paul R. Gugliuzza, *The Federal Circuit as a Federal Court*, 54 WM. & MARY L. REV. 1791, 1801 (May 2013).

¹⁰¹ *Id.*

regional circuit and encourage forum shopping.¹⁰² The goal in establishing the Federal Circuit Court of Appeals was to centralize the law and thus increase decision making quality, and make deciding these highly technical cases more efficient.¹⁰³

Two years prior to the establishment of the Federal Circuit Court of Appeals, in 1980, the United States Supreme Court construed §101 of the Patent Act to permit the patentability of “human-made, genetically engineered bacterium.”¹⁰⁴ Congress has constitutional power to legislate in order to promote the “progress of Science and useful Arts” and enacted §101 with broad terms to permit anyone who has invented any “new and useful, process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” to obtain a patent for their invention.¹⁰⁵ The Supreme Court in *Chakrabarty*, acknowledged that while §101 is intentionally broad, laws of nature, physical phenomena, and abstract ideas are not patentable subject matter.¹⁰⁶ However, Chakrabarty’s bacterium did not fall into any of these categories.¹⁰⁷ The Court concluded that Chakrabarty “produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.”¹⁰⁸ This decision opened the door for the patentability of biological research materials where the discovery was the work of the researcher and not of nature.¹⁰⁹

The patent system became increasingly used in biological research with the combination of the passage of the Bayh-Dole Act, the establishment of the Federal Circuit Court of Appeals,

¹⁰² *Id.* at 1800-01.

¹⁰³ *See id.*

¹⁰⁴ *Diamond v. Chakrabarty*, 447 U.S. 303, 305, 317 (1980).

¹⁰⁵ *Id.* at 307; 35 U.S.C. § 101.

¹⁰⁶ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

¹⁰⁷ *See id.*

¹⁰⁸ *Id.* at 310.

¹⁰⁹ *See id.*

and the Supreme Court's decision in *Chakrabarty*.¹¹⁰ With this, it became more important to govern the transfer of research materials.¹¹¹ The sharing of research materials are frequently governed by MTAs, which dictate the transfer of tangible property between parties.¹¹² MTAs are legally enforceable contractual bailments that research institutions and biotech companies utilize to specify the terms by which their materials and data are to be held and used by other parties.¹¹³ In 1937, the English decision of *Ashby v. Tolhurst* articulated that for a bailment to exist, delivery of the chattel by the bailor must have occurred.¹¹⁴ The *Ashby* court further stated that to determine if a transfer of possession leading to finding a bailment has occurred, the terms of any agreement between the parties should be considered.¹¹⁵ Therefore, the law of contracts and the law of bailment overlap greatly and should be considered together.¹¹⁶ As a contractual bailment protected by law, if any provision in an MTA is not followed, the contract is breached and action can be brought against the breaching party.¹¹⁷ Ideally, MTAs should promote the sharing of data and materials while also protecting owners of discoveries and inventions.¹¹⁸ The overlap of contract and bailment seeks to achieve these goals.

¹¹⁰ See Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133, PLANT PHYSIOLOGY, 10, 10 (2003).

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ Tania Bubela, *Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation*, PLOS BIOLOGY, Feb. 2015 at 1.

¹¹⁴ ROBERT H. TANHA, THE LAW OF BAILMENT 6 (2019) (citing *Ashby v. Tolhurst*, 2 K.B. 242 (King's Bench Div., 1937)).

¹¹⁵ *Id.* at 7.

¹¹⁶ *See id.*

¹¹⁷ Victor Rodriguez, *Material Transfer Agreements: Open Science vs. Proprietary Claims*, 23 NATURE BIOTECHNOLOGY 489, 489 (April 2005).

¹¹⁸ Tania Bubela, *Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation*, PLOS BIOLOGY, Feb. 2015 at 1.

As a contract, an MTA includes language that articulates the transfer of tangible research materials between two or more parties.¹¹⁹ Tangible property and intellectual property are separate and distinct.¹²⁰ MTAs, as a bailment, were intended to govern the transfer of tangible property, existing as contracts that are separate from any downstream rights to intellectual property.¹²¹ Nonetheless, MTAs frequently function as “accessories to the patent system, and...crucial tools in the commercialization of knowledge.”¹²² The tangible property could be the subject of a patent or patent application.¹²³ When this is the case, it is important for the MTA to also account for the transfer of IP rights.¹²⁴ The majority of MTAs do address IP matters and these rights must be clearly articulated in order for the provisions to be enforceable.¹²⁵ Generally, the MTA should govern the rights of the provider of materials and the recipient with respect to the materials and their derivatives.¹²⁶

MTAs are legally considered not just a contract, but a contractual bailment.¹²⁷ Bailment law is rooted in common law and allows for a transfer of tangible property without also transferring title to that property.¹²⁸ A bailment is created when personal property is transferred from one party to another for a specific purpose and pursuant to an express or implied contract.¹²⁹ The bailor is the party who transfers the tangible property to another,

¹¹⁹ Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 699 (2007).

¹²⁰ See Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 318 (Sept. 2008).

¹²¹ *Id.* at 319.

¹²² *Id.*

¹²³ Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 699 (2007).

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ 8A AM. JUR. 2D *Bailments* § 1 (2022).

the bailee, who holds that property under a contract of bailment.¹³⁰ It has long been recognized that there is great overlap between bailments and contracts.¹³¹ With this overlap, remedies for disputes revolving around contractual bailments may follow traditional remedies for breach of contract or could turn on the law of bailment, leading to remedies in tort law.¹³² By classifying the exchange of research materials as a bailment, not only does the bailor retain ownership rights in the materials, but there is an expectation that the property will be returned if it is not expected that the property will be depleted in the course of the agreement.¹³³

A bailment is not a license.¹³⁴ The key distinction is that the relationship between the bailor-bailee relationship and the licensor-licensee relationship is that a bailment establishes the bailee has the common law duty of safekeeping.¹³⁵ By contrast, a license merely grants permission to the licensee by the licensor for the licensee to use the chattel.¹³⁶ However, MTAs, contractual bailments, may contain a variety of specific terms, including options clauses for a license on downstream research materials.¹³⁷ In this way, MTAs can contain bailment and license aspects.¹³⁸

¹³⁰ 8A AM. JUR. 2D *Bailments* § 2 (2022).

¹³¹ Graeme Laurie & Emily Postan, *Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-Related Research?*, 21 MEDICAL L. REV. 371, 402 (2013).

¹³² *Id.* at 397.

¹³³ *See id.* at 399.

¹³⁴ ROBERT H. TANHA, *THE LAW OF BAILMENT* 3 (2019).

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 323 (Sept. 2008).

¹³⁸ *See id.*

One specific additional clause bailors often seek to incorporate into their MTAs is a “reach-through” clause.¹³⁹ These clauses may stipulate that the bailor can claim any sort of IP that results from research done by the bailee with the research material governed by the MTA.¹⁴⁰ Without valid reach-through clauses, significant issues can arise when materials exchanged under an MTA have been substantially improved such that IP rights may be sought.¹⁴¹ While MTAs govern tangible property, they are not intended to govern intellectual property.¹⁴² It is well established that tangible property rights and intellectual property rights are both “legally and factually” distinct.¹⁴³ However, this does not prevent parties to an MTA from attempting to control rights to downstream intellectual property, nor should it.¹⁴⁴ A study conducted by Philip Marowski in 2005 found 38% of MTAs signed included reach-through clauses.¹⁴⁵ In this way, the bailor is attempting to claim IP rights when their only contribution was the material exchanged via MTA.¹⁴⁶ When clearly articulated, these reach-through clauses may be perfectly permissible agreements and save time and money. But, when ambiguities exist, who may seek IP rights can get murky and time-consuming disputes can result.

Consider a scenario in which Winemaker 1 enters an agreement with Winemaker 2 to store, keep safe, and experiment with Winemaker 1’s grapes.¹⁴⁷ While in Winemaker 2’s

¹³⁹ *Id.* at 328.

¹⁴⁰ *See id.* at 322.

¹⁴¹ *See id.*

¹⁴² *Id.*

¹⁴³ *See Moore v. Regents of Univ. of California*, 793 P.2d 479, 479 (Sept. 2008); Graeme Laurie & Emily Postan, *Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-Related Research?*, 21 MEDICAL L. REV. 371, 400 (2013).

¹⁴⁴ Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 322-23 (Sept. 2008).

¹⁴⁵ *Id.* at 335.

¹⁴⁶ *Id.* at 322.

¹⁴⁷ *See John Tarrant, Bailments for Work and Labour*, 6 COMMERCIAL LAW QUARTERLY (2008).

possession, Winemaker 2 uses the grapes and creates a very high quality wine that Winemaker 2 would like to develop a new brand or trademark for. Winemaker 1 thinks the new IP right should be his because the wine was developed from his grapes. If the agreement between Winemaker 1 and Winemaker 2 includes a reach-through clause that clearly articulates that Winemaker 1 may claim any resulting downstream IP rights, then Winemaker 2 is prevented from obtaining any IP rights. However, if the agreement does not account for the possibility that Winemaker 2 might produce a highly valued product and that he might seek downstream IP rights, or if the agreement does so in an ambiguous way, then time-consuming dispute over who can hold the IP right would likely result. This dispute would slow down the process of getting the wine to consumers and of making a profit – all because the agreement did not properly account for this possibility.

This Winemaker scenario plays out in biological research all too often. In the interest of speeding up scientific progress, researchers quickly enter agreements, such as the Winemaker agreement above, not realizing that the lack of clarity in the agreement could slow down scientific progress in the long run. Consider a situation where Lab 1 enters a standard agreement with Lab 2 for the exchange of a specific cell line. While in Lab 2's possession, Lab 2 inserts an additional mutation to the cell line that significantly alters the properties of the cell line, increasing its value. Lab 2 would like to patent this new cell line, but Lab 1 believes any downstream patent rights to derivatives from their initial cell line should belong to them. If not clearly articulated in the agreement, these “reach-through” rights become the subject of extensive debate and slow down any further work with this new highly valued cell line. What if this cell line has the power to help identify whether a new

cancer drug is likely to work in a particular subset of patients? The dispute over IP rights could be slowing this discovery down – all because the agreement did not clearly account for this issue.

Further complications can arise if a bailee chooses to engage in additional exchanges of biological materials governed by an MTA with a third party. If there is no mention of third-party exchanges in the MTA itself, this additional exchange would constitute an unauthorized sub-bailment.¹⁴⁸ When there is no evidence of the original contract of bailment contemplating a sub-bailment, then there is no privity of contract between the bailor and the third party.¹⁴⁹ Therefore, if the bailee provides the materials to a third party, and the third party misappropriates the materials, then the bailee may be held responsible by the bailor for the third party's action.¹⁵⁰ However, if the bailee takes reasonable care to protect the bailed materials and the third party steals them, then the bailee is not to be held responsible.¹⁵¹

To illustrate this sub-bailment complication, reconsider the Winemaker scenario above. Recall that Winemaker 1 bailed his grapes to Winemaker 2. If Winemaker 2 enters a subsequent agreement with a third Winemaker (Winemaker 3) to hold the bailed grapes in his possession and Winemaker 3 is instead the one to develop the highly valued wine, then who can assert a property right to the valuable wine? If the agreement between Winemaker 1 and Winemaker 2 did not authorize any sub-bailments, then Winemaker 2 had no authority

¹⁴⁸ Brief of Appellants at 36, *Woven Treasures, Inc. v. Hudson Capital, L.L.C.*, No. 1080296, 2009 WL 1879961.

¹⁴⁹ *Hallman v. Federal Parking Servs., Inc.*, 134 A.2d 382, 385 (D.C. 1957).

¹⁵⁰ ARMISTEAD MASON DOBIE, *HANDBOOK ON THE LAW OF BAILMENTS* 124 (1914).

¹⁵¹ *Id.*

to enter an additional bailment with Winemaker 3. Winemaker 1 can assert their ownership right against Winemaker 2 in this scenario.

This second Winemaker scenario could further play out in a research setting. As in the example above, if Lab 1 bailed their cell line to Lab 2 and Lab 2 decided to further bail the cell line to Lab 3, against the conditions of the agreement, then Lab 1 can assert their property right against Lab 2 for this misappropriation.

IV. Court Analysis of MTAs Through Contract Law

Disputes over the exchange of research materials articulated in MTAs rarely result in litigation.¹⁵² Those that are litigated tend to be decided in terms of Contract law, focusing on a claim of breach of the terms of the MTA.¹⁵³ Otherwise, MTAs that appear in litigation are sometimes used for the purpose of proving ownership over research materials, where proof of ownership is serving as a defense in patent infringement litigation.¹⁵⁴ There is no U.S. case law to date that analyzes the transfer of materials and any reach-through rights provided in terms of the common law of bailments.

To highlight one MTA dispute analyzed through the lens of contract law, *University of Pennsylvania v. St. Jude Children's Hospital* was the result of a dispute over the terms of two MTAs.¹⁵⁵ In the early 2000s, Dr. Campana conducted immunotherapy research at St. Jude and developed a protein molecule known as “anti-CD19 chimeric antigen receptor”

¹⁵² Tania Bubela, *Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation*, PLOS BIOLOGY, Feb. 2015 at 6.

¹⁵³ *See id.* at 6-7.

¹⁵⁴ *Id.* at 6.

¹⁵⁵ *Trs. of Univ. of Pa. v. St. Jude Children's Rsch. Hosp.*, 982 F. Supp. 2d 518, 522 (Dist. Ct. E.D. Pa. 2013).

(“CAR”).¹⁵⁶ In December of 2003, Dr. Campana presented his findings at the American Society of Hematology conference in San Diego, where Dr. June, a researcher at the University of Pennsylvania, was in attendance.¹⁵⁷ Dr. June contacted Dr. Campana shortly after the conference seeking to enter into an institutional collaboration to test the efficiency of different viral constructs.¹⁵⁸ On December 17, 2003, St. Jude and the University of Pennsylvania entered into the first MTA.¹⁵⁹ Key language in the first MTA defined “material” being transferred by St. Jude to the University as

“‘the anti-CD19-BB-/ chimeric T-cell receptor construct, including any progeny, portions, unmodified derivatives and any accompanying know-how or data.’ The MTA also stated ‘the Material will only be used to create a lentiviral chimeric T-cell receptor construct to be used in pre-clinical studies,’ and ‘may not be used in humans’ or ‘for any commercial purpose’ and the University would ‘not commercialize any product that contains Material without prior written approval of St. Jude’ that the University would jointly publish any ‘results from the collaborative research study’ with St. Jude and would ‘notify St. Jude within sixty (60) days of filing any patent application claiming subject matter that contains or incorporates the Material or claims a method of manufacture or use of the Material.’”¹⁶⁰

St. Jude sent the Material described in the MTA to the University.¹⁶¹ Dr. June at the University used the Material and common laboratory techniques to make slight modifications to the Material so it could be utilized in a different form.¹⁶² The second MTA was executed

¹⁵⁶ *Id.* at 522.

¹⁵⁷ *Id.* at 523.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.* at 524.

on February 8, 2008, back dated to October 2, 2007, allowing Dr. June to proceed with clinical trials involving the Material.¹⁶³ This second MTA used the same definition of Material as the first MTA.¹⁶⁴

This case exemplifies the issues that can arise when scientific progress combines with exchange of research materials, the desire to patent resulting inventions, and the hope to commercialize a product, where who owns what is ambiguous.¹⁶⁵ What began as a single MTA articulating the transfer of material to be used in further laboratory experimentation, progressed into a second MTA governing the use of the material in human clinical studies and later to the desire to partner with an industry company and seek commercialization of a patented product.¹⁶⁶ The court analyzed the dispute, over whether the patented product incorporated and was made with the Material, based on the law of contract and ultimately determined the language of the MTA defining “material” was facially ambiguous and the parties’ conduct did not resolve the ambiguity, further dragging out the dispute.¹⁶⁷

The University argued that their newly modified material used throughout this process differed from the Material in the agreement.¹⁶⁸ The court concluded that whether the copy of the Material from St. Jude in the University’s modified construct constituted a “portion” under the MTA was a matter of contract interpretation.¹⁶⁹

¹⁶³ *Id.* at 526.

¹⁶⁴ *Id.*

¹⁶⁵ *See id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 522, 537-38.

¹⁶⁸ *Id.* at 524.

¹⁶⁹ *Id.* at 533.

The court looked to the language used by St. Jude in the MTA to determine whether St. Jude described the same tangible property as the University was now claiming was different.¹⁷⁰ Ultimately, the court found the language of the MTA to be facially ambiguous, unresolved by the parties' conduct under the agreement and there was a genuine dispute of material fact as to what the trade usage was.¹⁷¹

V. MTA Analysis Through Law of Bailment?

When a dispute involving a contractual bailment, such as an MTA, cannot be resolved through the law of contracts, courts unfortunately should look to the law of bailment to determine ownership even though it requires time-consuming analysis.¹⁷² Sometimes when a contractual bailment is analyzed through the law of contracts, the bailor is left without a remedy.¹⁷³ However, when analyzed through the rules of bailment, a substantially higher burden of proof is placed on the bailee.¹⁷⁴ Bailment law favors the bailor substantially by requiring the bailee to disprove negligence.¹⁷⁵ The principle of accession should be considered here to identify if the bailee has simply increased the bailor's property or substantially improved upon it such that a new ownership right is warranted.

While an MTA is a legally binding contract, it is also a bailment.¹⁷⁶ As a bailment, the original owner of the property, the bailor, maintains title when they transfer possession of the property to another party, the bailee.¹⁷⁷ Therefore, if the bailee improves upon the

¹⁷⁰ *Id.* at 525.

¹⁷¹ *Id.* at 537-38.

¹⁷² See ROBERT H. TANHA, *THE LAW OF BAILMENT* 7 (2019).

¹⁷³ See *id.* at 3.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 318 (Sept. 2008).

¹⁷⁷ 8A AM. JUR. 2D *Bailments* § 1 (2022).

property and tries to assert rights to the property not clearly articulated in the MTA, the bailor can bring a tort action and sue for conversion.¹⁷⁸ However, based on the doctrine of accession a court could determine the bailee has established rights to the property by substantially improving upon it.¹⁷⁹ This could result in an unexpected loss in tangible rights for the bailor, leading to a loss in the ability to obtain intellectual property rights and any monetary gain available through later commercialization.¹⁸⁰

The principle of accession is an umbrella term that encompasses a variety of distinct legal doctrines.¹⁸¹ Accession is important because it grants title to property based on the relationship of that property to something already owned.¹⁸² The rule of increase is one distinct doctrine that falls under the principle of accession.¹⁸³ The rule of increase articulates that absent an alternative agreement, “the offspring of tame or domestic animals belongs to the owner of the dam or mother.”¹⁸⁴ Increase is important because it determines who owns property that exists as a new resource with a prominent connection to an existing resource, such as ownership of newborn animals being property of the owner of the biological mother.¹⁸⁵ Simply “increasing” an existing resource, such as a cow giving birth to a calf or multiplying an existing cell line, would suggest the rule of increase is at play and the owner of the initial cell line resource would maintain ownership of the new resource.¹⁸⁶

¹⁷⁸ Graeme Laurie & Emily Postan, *Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-Related Research?*, 21 MEDICAL L. REV. 371, 402 (2013).

¹⁷⁹ Peter Lee, *The Accession Insight and Patent Infringement Remedies*, 110 MICH. L. REV. 175, 199 (Nov. 2011).

¹⁸⁰ *See id.*

¹⁸¹ *Id.* at 195.

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ Thomas W. Merrill, *Accession and Original Ownership*, 1 JOURNAL OF LEGAL ANALYSIS 459, 464 (2009) (citing *Carruth v. Easterling*, 150 So.2d 852 (Miss. 1963)).

¹⁸⁵ *Id.* at 465.

¹⁸⁶ *See id.*

The doctrine of accession today is associated with the prior concepts of “specification” and “accession.”¹⁸⁷ Previously, “specification” determined who owned property when someone exerted labor or skill, using the personal property of another to create a new product, while “accession” merely covered who owned property when two or more items of different parties’ personal property remained distinguishable while joined.¹⁸⁸ The concept of “specification” plays an important role when biological materials are exchanged and improved upon and will be referred to here as the doctrine of accession to remain consistent with the modern usage of the term.¹⁸⁹

Under the doctrine of accession, when one party significantly improves upon or enhances the value of another’s property, the improver may take title to the substantially improved resource as long as they compensate the original owner for the initial resource.¹⁹⁰ Accession acts as an exception to the general rule that an original owner may recover their property when another has misappropriated it.¹⁹¹ Instead, title shifts to an improver when the improver has significantly enhanced the value of the original owner’s property, such that the property “has undergone a transformation which converts it into an article substantially different.”¹⁹² For example, in *Wetherbee v. Green*, the improver cut a strand of trees and transformed the lumber into barrel hoops, greatly increasing the value of the wood.¹⁹³ The Supreme Court of Michigan determined based on the doctrine of accession that the improver could obtain

¹⁸⁷ Peter Lee, *The Accession Insight and Patent Infringement Remedies*, 110 MICH. L. REV. 175, 196 (Nov. 2011).

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 196-97.

¹⁹¹ *Wetherbee v. Green*, 22 Mich. 311, 315 (Mich. 1871).

¹⁹² *Id.* at 317.

¹⁹³ *Id.* at 318-19.

title to the improved property as long as he paid damages to the original owner for the initial wood.¹⁹⁴ Courts must look to the extent to which an improver has transformed the original property to determine if title shifts to the improver.¹⁹⁵ This approach requires courts to carefully examine which party contributed the greater value to the improved resource and grant title to the party who made the greater contribution.¹⁹⁶

Reconsider the Winemaker scenario introduced in Part III, where Winemaker 1 bailed his grapes to Winemaker 2. Winemaker 2 then substantially improved the grapes by transforming them into a highly valuable wine. Absent terms in the agreement to the contrary, the doctrine of accession would grant title to Winemaker 2 as the improver if a court could determine Winemaker 2 contributed the greater value by inputting his labor. Similarly, in a research setting, if Lab 1 bailed their cell line to Lab 2 and Lab 2 introduced a mutation to the cell line that significantly improved the value of the cell line, then the doctrine of accession would grant title to the transformed cell line to Lab 2, absent terms in the agreement to the contrary. Discernment of who is the rightful owner of the valuable property requires weighing the relative contributions of the parties and could slow down research progress, hinder innovation, and prevent patients from benefitting from downstream results in a timely manner.

¹⁹⁴ *Id.* at 321.

¹⁹⁵ *Id.* at 318.

¹⁹⁶ Peter Lee, *The Accession Insight and Patent Infringement Remedies*, 110 MICH. L. REV. 175, 199 (Nov. 2011).

VI. Implications

MTAs are increasing in complexity as the benefits of sharing research materials are further realized and biotechnology intellectual assets continue to grow.¹⁹⁷ Where an MTA was once simply a bailment, governing the transfer of tangible property and dividing ownership and possessory interests, now MTAs tend to exhibit bailment plus license characteristics.¹⁹⁸ MTAs now reach beyond the material to data and inventions made with the material.¹⁹⁹ Therefore, MTAs are frequently “hybrid instrument[s]: covering the transfer of both tangible property (via bailment and contract) and intangible IP (via licensing of patent rights).”²⁰⁰ With this complexity, comes a greater need to clearly articulate the terms of the agreement to avoid the pitfalls noted above – the confusion, loss, and delays triggered by having to resort to the common law of bailment to determine who owns what.

The definition of “materials” in an MTA can result in extensive negotiation or future dispute if ambiguously provided.²⁰¹ As exemplified by the dispute in *St. Jude* discussed in Part IV above, where the definition of “material” in the two MTAs led to confusion over who owned what, it is important that the definition of materials be limited to the actual material being transferred and not substances or inventions created by the recipient.²⁰² The definition should

¹⁹⁷ Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 698 (2007); Gregory D. Graff, *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECHNOLOGY 989, 989 (Sept. 2003).

¹⁹⁸ See Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 698 (2007).

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *Id.* at 700.

²⁰² *Id.*; *Trs. of Univ. of Pa. v. St. Jude Children’s Rsch. Hosp.*, 982 F. Supp. 2d 518 (Dist. Ct. E.D. Pa. 2013).

not “overreach,” such that a provider (bailor) is attempting to lay claim to anything beyond what they are actually providing – modifications, derivatives, mutants, etc.²⁰³

However, MTAs may address IP rights, and arguably, they should do so.²⁰⁴ Both parties should consider the impact of overarching IP rights language contained in an MTA before they sign the agreement. This overarching language can cover past inventions of a researcher or institution, as well as future inventions that may have little to do with the materials being exchanged via the contractual bailment.²⁰⁵ The parties will likely have competing goals when considering whether to include a reach-through clause, a clause that reaches through to designate who can assert IP rights to future inventions.²⁰⁶ By including a reach-through clause, the bailor benefits in that they have a right to resulting IP even though all they did was contribute the initial materials.²⁰⁷ By contrast, excluding a reach-through clause benefits the bailee in that the bailee can conduct their research and seek downstream IP rights.²⁰⁸ If the bailor asserted reach through rights, the bailee may be hesitant to put the time, energy, and costs into any research with the materials being exchanged in the first place.²⁰⁹ And the bailor may be hesitant to enter an agreement without a reach through right because if the material being exchanged is the product of years of painstaking research, they do not want another party to come along, make a slight modification, and then receive all benefits of an IP right and commercialization.²¹⁰ Whether a reach-through right is granted in an MTA or

²⁰³ Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 700 (2007).

²⁰⁴ *Id.* at 701.

²⁰⁵ *Id.*

²⁰⁶ *See id.*

²⁰⁷ *See id.* at 702.

²⁰⁸ *See id.*

²⁰⁹ *See id.* at 701.

²¹⁰ *Id.* at 702.

not, IP must be addressed to avoid allowing the common law of bailment abyss to dictate who owns what tangible property and therefore who can lay claim to related IP rights.

Standardizing the MTA is a glamorous idea to simplify the process of entering exchanges of research materials and to encourage parties to set forth terms around the exchange to avoid later dispute.²¹¹ The Association for University Technology Managers (AUTM), in collaboration with the National Institutes of Health (NIH), began discussions in the 1990s to develop a standardized MTA.²¹² In 1995, the Uniform Biological Materials Transfer Agreement (UBMTA) was produced.²¹³ The UBMTA defines “material” very narrowly and does not include any reach through rights.²¹⁴ For a transfer of materials between universities the UBMTA can accomplish the goal of a quick transfer so research can continue.²¹⁵ However, at many universities, the UBMTA has transformed into more of a starting point for further negotiations of terms.²¹⁶ When IP rights or licenses are involved, utilizing the UBMTA would neglect some of the issues discussed through-out this Note – leaving who owns what materials a question to be determined, perhaps by the common law of bailment and the related common law doctrines of increase and accession.

The historically competing goals of academia and industry are evident in the terms of their MTAs.²¹⁷ For industry, MTAs are intended to authorize the exchange materials between

²¹¹ Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 327 (Sept. 2008).

²¹² *Id.*

²¹³ *Id.*

²¹⁴ Alan B. Bennett, *Specific Issues with Material Transfer Agreements*, Ch. 7.3 HANDBOOK OF BEST PRACTICES, 697, 703 (2007).

²¹⁵ *See id.*

²¹⁶ Philip Mirowski, *Living with the MTA*, 46 MINERVA 317, 327 (Sept. 2008).

²¹⁷ Victor Rodriguez, *Material Transfer Agreements: Open Science vs. Proprietary Claims*, 23 NATURE BIOTECHNOLOGY 489, 489 (April 2005).

companies in hope of developing a product, while prohibiting transfer to a third party (which would constitute a sub-bailment as discussed in Part III), and define how a product would be marketed.²¹⁸ Problems concerning allocation of rights to unanticipated inventions sometimes arise, but patent and ownership rights should be defined in these MTAs.²¹⁹ For academia, the goal has always been to assure association with the material is recognized and have it remain in the public domain.²²⁰ However, as noted in Part III, with the ability to obtain IPR and commercialize materials, academia should also be sure to address IPR in their MTAs.²²¹

Clearly articulating IP rights is essential in the modern world where collaboration among researchers (both in and amongst academia and industry) and exchange of research materials must occur in order to combat emerging infectious diseases and neglected tropical diseases.²²² The concept of “open innovation,” encompasses the idea that internal and external ideas together create greater value and greater efficiency in both academic and industry research.²²³ The traditional approach to innovation was a “closed system.”²²⁴ This “closed system” restricted research endeavors by only allowing projects to enter internally through a company, and exit by going into the market without input from other researchers and sources.²²⁵ However, the “open innovation” model encourages new projects being launched at various stages of the process of research and development.²²⁶ MTAs may cover

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.*

²²² See Sam Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28 ANNALS OF HEALTH LAW 101, 102 (2019).

²²³ Henry Chesbrough, *Open Innovation: Where We’ve Been and Where We’re Going*, RESEARCH-TECHNOLOGY MANAGEMENT, 20, 21 (Aug. 2012).

²²⁴ *Id.* at 22.

²²⁵ *Id.*

²²⁶ *Id.* at 23.

who owns material in biorepositories (like the one Dr. Catalona operated in *Washington v. Catalona* discussed in Part II), may restrict the ability of the receiving party to publish research results (hindering the goals of academia), or may even recategorize a research material as a prior art and render it not patentable if the MTA and exchange occurs before the patent application is filed.²²⁷ With materials being shared and exchanged at different points in the process from project initiation to product marketability all of these implications must be considered.²²⁸ This is where proper management of MTAs can greatly impact the speed with which discoveries can go to market by clearly articulating the terms of the agreement to avoid delaying disputes and creating unnecessary costs – both in terms of money and lives.

VII. Conclusion

Fundamental research and commercial development have become increasingly intertwined since 1980, and therefore, clear management of tangible property rights and IPR through MTAs is now critical to promote innovation. As demonstrated throughout this Note, MTAs are rooted in the common law of bailment, which is not easily applied to clearly identify who owns what materials. In a world where open innovation promotes exchanges of research materials throughout the process from rudimentary research to product development to commercialization, it is imperative for parties to an MTA to clearly articulate all the terms of their agreement. This should include highly valued IPR. In this way, the law of contracts can be applied and the law of bailment can be avoided. MTAs

²²⁷ Victor Rodriguez, *Material Transfer Agreements: Open Science vs. Proprietary Claims*, 23 NATURE BIOTECHNOLOGY 489, 490 (April 2005).

²²⁸ See *id.*; Henry Chesbrough, *Open Innovation: Where We've Been and Where We're Going*, RESEARCH-TECHNOLOGY MANAGEMENT, 20, 23 (Aug. 2012).

have the power to actually enhance research endeavors and speed up innovation when managed properly. The instruments governing the exchange of research materials, such as MTAs, must be well understood in order to accelerate research progression, protect IPR, and prevent inadvertent delays caused by ownership disputes due to ambiguous or overlooked terms. In a world where infectious diseases are rapidly emerging, delays in innovation due to improper management of MTAs cannot be afforded.