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Moore is Less: Why the Development of Induced Pluripotent Stem Cells Might Radically Upend Property Law Concerning Human Tissues As We Know It

Osagie K. Obasogie
UC Hastings College of the Law, obasogieo@uchastings.edu

Helen Theung

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MOORE IS LESS: WHY THE DEVELOPMENT OF INDUCED PLURIPOTENT STEM CELLS MIGHT LEAD US TO RETHINK DIFFERENTIAL PROPERTY INTERESTS IN EXCISED HUMAN CELLS

Osagie K. Obasogie* & Helen Theung**

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ABSTRACT

Since Moore v. Regents of the University of California*, there has been a wide-ranging debate regarding the holding of the case and its implications for property law.* Moore *stands for the notion that individuals do not have a property interest in ordinary cells taken from their bodies during medical procedures nor the commercial products that researchers might develop from them. At the same time, cases such as* Davis v. Davis *and* Hecht v. Superior Court *have asserted that individuals maintain a property interest in other types of cells—namely embryos and gametes (eggs and sperm)—once they are removed from the body. This, among other developments, has led to a fragmented regime in property law pertaining to excised biological materials that turns, in large part, on the type of*

* Associate Professor of Law, University of California Hastings College of the Law with a joint appointment at the University of California, San Francisco (UCSF) Department of Social and Behavioral Sciences; Senior Fellow, Center for Genetics and Society. B.A. Yale University; J.D. Columbia Law School; Ph.D. University of California, Berkeley. Robin Feldman, Lisa Ikemoto, Stuart Newman, Krishanu Saha, and David Winickoff kindly and thoughtfully reviewed earlier drafts of this Article, in which we are most grateful.
** Attorney, Sidley Austin LLP in Palo Alto, CA. B.A. University of California, Santa Barbara; J.D. University of California, Hastings College of the Law. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the firm, clients, or any affiliates of any of the foregoing. This Article has been prepared for informational purposes only and does not constitute legal advice.

cell in question: individuals have a diminished interest in regular somatic cells (skin, muscle, etc.) while courts have recognized that people retain a heightened property interest in reproductive cells such as sperm, eggs, and embryos. The articulated reason for the differential property interests in these two cell types is that embryos and gametes have the "potential for human life" while individuals are thought to have little use for ordinary body cells once they are excised.

This default rule has framed property law regarding excised human cells for over two decades. It exists to balance the need for scientists to have access to research materials with individuals' reproductive autonomy. To the extent that the dividing line determining the property interest in excised cells turns largely upon their "potential for human life," the recent development of induced pluripotent stem cells (iPSCs) suggests that this default rule is becoming increasingly untenable. Research has shown that iPSCs can create the ability to genetically reprogram somatic cells into a pluripotent state that may allow them to differentiate into other types of cells—including eggs and sperm—that can be used to create new organisms. While these developments have not yet been fully applied to human iPSCs, they nonetheless suggest that iPSCs may soon be able to give ordinary somatic body cells the same potential for human life as naturally produced embryos and gametes but without the corresponding property interest.

This Article argues that given this new technology, its relative success in animal models, and its impending application to human cells, the current default rules precluding individuals' property interest in excised somatic cells needs substantial reconsideration. We propose a three-part approach to manage the challenges that iPSCs create for this aspect of property law. This includes (1) a self-imposed moratorium on human applications of iPSC research that can lead to human reproduction (2) Congressional action that vests property interests in the donors of somatic cells once their cells have been reprogrammed to a pluripotent state and differentiated into reproductive cells and (3) Judicial action that distinguishes Moore and related cases by acknowledging the reversion of property interest to donors once somatic materials are reprogrammed to a state of pluripotency and differentiated into reproductive cells. This proposal offers the best way to deal with the profound legal issues created by this new technology with the least disruption to existing rules and policy preferences.

INTRODUCTION

Like *Marbury v. Madison* and *Erie Railroad Co. v. Tompkins*, *Moore v. Regents of the University of California* is one of a handful of cases that virtually every first-year law student reads as part of her introduction to the American legal system. *Moore* stands for what has become a proverbial default rule in property law: individuals do not have property interests in their own cells once they are removed from their bodies. (This default rule pertains to cells removed from living human beings during medical procedures, not (a) organs removed for transplant, (b) tissues subject to routine-removal statutes such as corneas from cadavers,[1] or (c) anatomical gifts. These transactions are governed by the National Organ Transplant Act, state level implementations of the Uniform Anatomical Gift Act, and other laws.) Thus, in *Moore*, researchers at UCLA Medical Center that used John Moore's spleen cells without his knowledge or consent to develop a profitable cell line were not liable for conversion[2] since the Court found that Moore no longer had a property interest in these excised cells. Yet, *Moore's* holding regarding individuals' diminished property interests in excised cells does not apply to *all* human cells. There are two exceptions: gametes (eggs and sperm) and embryos. Courts have found that since these cells have the potential to create or become independent human beings, individuals retain a property interest in them after being removed from the body that does not exist for somatic cells, or the ordinary non-reproductive cells that make up various parts of the body such as hair, skin, or Moore's spleen. Thus, the critical dividing line in property law with regards to individuals' interest in their excised cells is whether or not they have the "potential for human life."[3]

To the extent that the default rule regarding individuals' diminished property interest in excised human cells largely exists for policy reasons such as promoting efficient research and respecting individuals' reproductive decision-making,[4] this dividing line between gametes and embryos on one hand and ordinary non-reproductive somatic cells on the other appears coherent. Excised somatic cells that do not have any reproductive capacity are important

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1. *See* COMMITTEE ON INCREASING RATES OF ORGAN DONATION, ORGAN DONATION: OPPORTUNITIES FOR ACTION 206-07 (JAMES F. CHILDRESS & CATHARYN T. LIVERMAN eds., 2006).

2. Conversion is a tort that reflects the "unauthorized and wrongful exercise of dominion and control over another's personal property, to the exclusion of or inconsistent with rights of owner." BLACK'S LAW DICTIONARY 332 (6th ed. 1990).

3. Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992).

4. Individuals' intent and institutional informed consent play a significant role in the disposition of these cells. See discussion in Part II.

for scientific advancement and often have little value to most patients. Therefore, a default rule that gives sole property interests to scientists and research entities to the exclusion of individual patients encourages efficiency that promotes and rewards innovation. In contrast, gametes and embryos that have the potential to create independent human life may be extraordinarily valuable to individuals, which law recognizes by acknowledging a continued property interest in these types of cells once outside of the body.

However, new developments in human biotechnology are making this dividing line increasingly untenable—to the point where current default rules espousing individuals' diminished property interest in somatic cells may need substantial reconsideration. In 2007, research groups headed by Shinya Yamanaka[5] and Jamie Thompson[6] demonstrated the ability to reprogram human somatic cells into a pluripotent state. This means that regular somatic cells like those from Moore's spleen—the very types of cells that individuals have a diminished property interest in once excised—can be reverted back into a condition (pluripotency) whereby they can develop into several different types of cells—*including eggs or sperm*.[7] Known as induced pluripotent stem cells (iPSCs), these cells are hailed as offering an end-run around the ethical quagmire surrounding embryonic stem cells since they offer the promise of regenerative medicine (where such pluripotency might allow researchers to "grow" patient-specific cells to cure diseases) without the ethically fraught issue of destroying embryos.

Yet at the same time that iPSC research has been heralded as resolving a particularly thorny ethical issue, it has created a profound challenge for property law that has gone almost wholly unnoticed. If the legal justification for diminishing individuals' property interests in their own somatic cells and acknowledging scientists' claims to own such material is that these cells do not have the "potential for human life," then the impending ability to reprogram such cells into a pluripotent state where they can then differentiate into reproductive cells with the potential to become autonomous human beings radically upends this logic. In short, human iPSCs, if they achieve the same potential as has already been demonstrated in animal experiments, can become a profound game changer in that *every somatic cell would have the "potential for human life*"; the proverbial spleen cells from John Moore and any other ordinary cells removed during medical procedures would potentially be just a few steps away from being turned into gametes that could then be used for reproductive purposes. This suggests that this new technology might blur the

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5. Kazutoshi Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861, 861 (2007).

6. Junying Yu et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 SCIENCE 1917, 1917 (2007).

7. While iPSC research with mice has shown the ability to induce somatic cells into a pluripotent state that can then differentiate into reproductive cells, this research has not yet been done with humans though it is considered to be feasible. See Part III.

dividing lines and default rules in property law and that serious reconsideration may be needed.

Despite the wide-ranging post-*Moore* discussion of property rights in excised human cells, this Article is the first to identify and articulate the profound challenges raised by iPSCs for property law. These challenges are likely to have important implications. Given an estimated 270 million human tissue samples held in domestic biobanks, the development of iPSCs adds a new and qualitatively different dimension to an endearing question in property law: who can own your body (in terms of excised cells and tissues) and under what circumstances?

This Article proceeds in three parts to address these issues. Part I assesses existing rules pertaining to individuals' property interests in excised somatic cells as well as gametes and embryos. Part I also examines key cases in the development of this jurisprudence to identify and substantiate a basic underlying premise in property law pertaining to excised human cells: in the absence of a contract or preexisting agreement, default property interest in excised human cells is given to researchers and scientists *except* in the case of eggs, sperm, and embryos, whereby individuals retain a property interest since these cells have the "potential for human life." Thus, Part I highlights how this potentiality is a key dividing line in establishing differential property interests in excised human cells. Part II discusses the development of iPSCs and how this technology might complicate the logic of this dividing line by giving human somatic cells the potential to become life through cellular reprogramming that reverts them to a pluripotent state where they can differentiate into many types of cells, potentially including eggs and sperm. Part III situates this issue in the landscape of the current scholarly debate on property interest in human cells to highlight the transformative nature of this technology; existing conversations have entirely missed the significance of iPSC research for property law. We then offer a three-part proposal for how law and science should respond to the challenges raised by iPSCs. We argue that (1) the scientific community should engage in a self-imposed moratorium on human applications of iPSC research that may lead to human reproduction; (2) that Congress should enact legislation that vests property interests in excised somatic cells in donors once these cells have been reprogrammed to a pluripotent state and differentiated into reproductive cells; and (3) that courts should acknowledge the heightened property interest that vests in excised somatic cells once they are reprogrammed to a pluripotent state and differentiated into reproductive cells. After discussing various objections some may have with this proposal and offering rebuttals, we conclude with a brief discussion of this Article's significance for the future of property law.

I. PROPERTY LAW REGARDING SOMATIC CELLS, GAMETES, AND EMBRYOS: A BRIEF OVERVIEW

Since *Moore v. Regents of the University of California*, the law regarding individuals' property interests in excised cells has been fragmented and unevenly developed. Starting with *Moore*, this section discusses key cases that have laid the broad foundations for the current default rules that confer differential property interests to human cells in a manner that depends heavily on their potential to create or become human life. Although the case law on this topic is scarce and dispersed, courts have consistently concluded that individuals have little to no property interests in excised somatic cells while also acknowledging individuals' significant property interests in gametes and embryos that exist outside the body. The potential to create or become full human beings plays a large role in the court's justification for these rules.

A. *Somatic Cells*

Discussions about property rights and the human body are not new.[8] However, recent developments in new reproductive and genetic technologies have given rise to novel questions about the rights individuals have in excised tissues and cells. *Moore v. Regents of the University of California* represents one of the earliest judicial considerations of this question, and its disposition has had cascading effects on how the law understands individuals' property interests in their own cells once they are disconnected from their bodies.

John Moore was a patient at UCLA Medical Center in the mid 1970's, where he received treatment for hairy-cell leukemia. In the course of this treatment, Dr. David Golde, Moore's physician, took "extensive amounts of blood, bone marrow aspirate, and other bodily substances" all while knowing—

8. *See generally* ALAN HYDE, BODIES OF LAW (1997). Radhika Rao offers an interesting discussion of an early theory of the body as property as articulated by John Locke: "The image of the body as a form of property possessed by its 'owner' dates back at least to John Locke, whose influential theory of property derived all ownership from the property possessed by individuals in their own persons. In his treatise "Of Property," written around 1690, Locke asserted: "Though the Earth and all inferior Creatures be common to all Men, yet every Man has a Property in his own Person. This no Body has any Right to but himself." According to Locke, individual ownership of the physical body entailed ownership of those external things that are the product of the body's labor. Yet Locke apparently envisioned the body as property of a special sort, held in trust rather than as an individual owner. As a result, he believed that a person's rights to life and liberty were inalienable because they were not his own, but belonged to another. These limits upon bodily property followed from the fact that ultimate ownership rested with the deity. Thus Locke apparently viewed individuals as stewards over their bodies, possessing themselves in trust rather than as outright owners. Therefore, despite his reliance upon property rhetoric, his image of the rights individuals possess in their bodies clearly does not rise to the level of complete ownership." Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. REV. 359, 367-68 (2000).

and without disclosing to Moore—that these biological materials "were of great value in a number of commercial and scientific efforts," that could provide "competitive, commercial, and scientific advantages."[9] Moore also had his spleen removed at Golde's recommendation. While Golde received consent for the splenectomy, he did not disclose to Moore that his spleen and other biological materials would be used for research. Between 1976 and 1983, Moore travelled to UCLA Medical Center from his home in Seattle to give more samples of blood and other tissues because "he had been told that the procedures were to be performed only there and only under Golde's direction."[10]

Little did Moore know that Golde was working with others to develop a cell line from T-lymphocytes derived from Moore's tissues. Golde, Shirley Quan, and the Regents of the University of California patented the cell line and shared in the royalties while excluding Moore from any compensation.[11] Moore brought suit, claiming a breach of fiduciary duty and lack of informed consent. Moore also brought a claim for conversion, or that the defendants interfered with his interest in his personal property—his blood, cells, etc.—and that he subsequently had an interest in the products derived from his bodily materials.[12] While the Court found that Dr. Golde did not fulfill his fiduciary duty to Moore and impermissibly failed to obtain informed consent by not disclosing his financial interests, it ruled against Moore's conversion claims. As a descriptive matter, the Court stated that current law simply did not support Moore's claim that he *owned* these excised biological materials, which is a predicate to making any successful claim that they were illegally subject to conversion.[13] The Court refused to extend the principle of conversion to this

9. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 481 (Cal. 1990).

10. *Id.* at 482.

11. "With the Regents' assistance, Golde negotiated agreements for commercial development of the cell line and products to be derived from it. Under an agreement with Genetics Institute, Golde 'became a paid consultant' and 'acquired the rights to 75,000 shares of common stock.' Genetics Institute also agreed to pay Golde and the Regents 'at least $ 330,000 over three years, including a pro-rata share of [Golde's] salary and fringe benefits, in exchange for . . . exclusive access to the materials and research performed' on the cell line and products derived from it. On June 4, 1982, Sandoz 'was added to the agreement,' and compensation payable to Golde and the Regents was increased by $ 110,000. '[T]hroughout this period, . . . Quan spent as much as 70 [percent] of her time working for [the] Regents on research' related to the cell line." *Id.* at 482.

12. "Moore also attempts to characterize the invasion of his rights as a conversion – a tort that protects against interference with possessory and ownership interests in personal property. He theorizes that he continued to own his cells following their removal from his body, at least for the purpose of directing their use, and that he never consented to their use in potentially lucrative medical research. Thus, to complete Moore's argument, defendants' unauthorized use of his cells constitutes a conversion. As a result of the alleged conversion, Moore claims a proprietary interest in each of the products that any of the defendants might ever create from his cells or the patented cell line." *Id.* at 487.

13. Quoting *Del E. Webb Corp. v. Structural Materials Co*, the *Moore* Court noted that "to establish a conversion, plaintiff must establish an actual interference with his

novel area of excised cells for three reasons. First, the Court noted that this analogy—treating excised biological materials like personal property—had not been supported by any other court, suggesting a general consensus that individuals did not retain an ownership interest in cells akin to personal property once removed from the body. Second, state statutes limited what individuals could do with excised biological materials, which suggested that any ownership interest in them has been significantly curtailed.[14] Lastly, with regard to Moore's claim that he had a property interest in the cell line derived from him, the Court reasoned that "[it] cannot be Moore's property . . . . because the patented cell line is both factually and legally distinct from the cells taken from Moore's body."[15]

But the Court also made a series of *normative* claims regarding whether a property interest in excised cells *ought* to be recognized to support Moore's conversion claims, which allowed the Court to discuss various policy issues implicated by this situation in a manner that has substantially affected this area of law. The Court cited three policy reasons to explain why the use of excised cells in medical research did not constitute conversion. First, the Court explained that these issues are better handled by legislatures. Second, the Court acknowledged that a tort of conversion is not necessary to affirm or protect the rights of patients. But the Court seemed most disturbed by the third reason: that potentially adverse impacts might follow from extending the tort of conversion into the area of biomedical specimens. The Court noted:

> Research on human cells plays a critical role in medical research. This is so because researchers are increasingly able to isolate naturally occurring, medically useful biological substances and to produce useful quantities of such substances through genetic engineering. These efforts are beginning to bear fruit. Products developed through biotechnology that have already been approved for marketing in this country include treatments and tests for leukemia, cancer, diabetes, dwarfism, hepatitis-B, kidney transplant rejection, emphysema, osteoporosis, ulcers, anemia, infertility, and gynecological

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ownership or *right of possession* . . . Where plaintiff neither has title to the property alleged to have been converted, nor possession thereof, he cannot maintain an action for conversion." *Id.* at 488.

14. "Pursuant to Health and Safety Code section 7054.4, '[n]otwithstanding any other provision of law, recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste following conclusion of scientific use shall be disposed of by interment, incineration, or any other method determined by the state department [of health services] to protect the public health and safety.' Clearly the Legislature did not specifically intend this statute to resolve the question of whether a patient is entitled to compensation for the nonconsensual use of excised cells. A primary object of the statute is to ensure the safe handling of potentially hazardous biological waste materials. Yet one cannot escape the conclusion that the statute's practical effect is to limit, drastically, a patient's control over excised cells. By restricting how excised cells may be used and requiring their eventual destruction, the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to "property" or "ownership" for purposes of conversion law." *Id.* at 491-92.

15. *Id.* at 492.

> tumors, to name but a few . . . . [T]he extension of conversion law into this area will hinder research by restricting access to the necessary raw materials. . . . [The] exchange of scientific materials, which still is relatively free and efficient, will surely be compromised if each cell sample becomes the potential subject matter of a lawsuit.[16]

Thus, the burden that might befall the scientific community drives much of the Court's concern. For the *Moore* court, the legislature should lead such far-reaching changes rather than the judiciary since they involve policy issues far beyond individual property rights. The end result is that after *Moore*, individuals are thought to have radically diminished property interests in their excised somatic cells, although physicians and researchers still have a duty to inform patients that their biological materials may be used in research and for commercial purposes.

Subsequent cases have further discussed and reaffirmed the *Moore* court's conclusion that individuals do not have a property interest in excised cells. *Greenberg v. Miami Children's Hospital Research Institute*, a 2003 decision by the United States District Court for the Southern District of Florida, involved the disposition of human tissues given to researchers for the purpose of identifying the genes responsible for Canavan diseases and developing carrier tests that would permit prenatal screening. This collaboration, where affected patients gave tissues and other biological materials to researchers, led to a breakthrough that identified the Canavan-associated gene. While the plaintiffs expected that any developments stemming from research using their blood and tissues would be offered in an affordable and accessible manner that stayed in the public domain, the researchers patented the gene. This gave the researchers and the hospital "the ability to restrict any activity related to the Canavan disease gene, including without limitation: carrier and prenatal testing, gene therapy, and other treatments . . . ."[17] Soon after, the hospital allegedly threatened other hospitals that infringed their patent through unauthorized testing and began negotiating licenses and royalty fees that restricted the tests' availability. The tissue donors sued, saying that they were not aware of the researchers' intent to patent the research or commercialize it.

The plaintiffs made several claims in their suit, including lack of informed consent, unjust enrichment, and fraudulent concealment. The plaintiffs' conversion allegation claimed a property interest in research stemming from their donated tissues and blood. This was based on an underlying claim that they continued to possess a property interest in these biological materials once excised from their bodies. The court declined to extend conversion theory to excised tissues, stating that the tissues were "donations to research without any contemporaneous expectations of return of the body tissue and genetic

16. *Id.* at 494-99.

17. Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003).

samples . . . ."[18] Citing *Moore*, the court noted "[t]he California Supreme Court . . . held that the use of the results of medical research inconsistent with the wishes of the donor was not conversion, because the donor had no property interest at stake after the donation was made . . . . Similarly [in *Greenberg*], the property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party."[19] It is also important to note that the *Greenberg* court adopted the same consequentialist reasoning articulated in *Moore* for denying the plaintiffs' conversion claim. The Court plainly stated, "if adopted, the expansive theory championed by plaintiffs would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital."[20]

Washington University v. Catalona presented a similar issue before the Eighth Circuit Court of Appeals in 2007. Dr. William Catalona was a urologist at Washington University where his primary research area was prostate cancer. During his nearly three-decade tenure at Washington University, he amassed a large biorepository of blood and tissue for prostate cancer research—both from his patients and through larger scale recruiting.[21] Catalona accepted a new position at Northwestern in 2003 and sent letters to the research participants asking that they sign a form allowing their samples to be transferred from Washington University to his new employer. Washington University filed a declaratory action in 2003 that sought to establish their ownership of the repository amassed by Catalona and all of the biological samples that it contained.

The court held in favor of Washington University, finding that the patients' stored samples were *inter vivos* gifts donated to the university and remained its property whereby the individual donors could not re-assign the gifts to Catalona. This rationale is similar to that used by the *Greenberg* court; by framing the research participants as "donors" who made a "gift," the court

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18. *Id.* at 1074.

19. *Id.*

20. *Id.* at 1076.The *Greenberg* court uses a similar argument in rejecting the plaintiff's claim that the researchers failure to disclose their economic interests amounted to a lack of informed consent: "[D]isclosing economic interests has no support in established law, and more ominously, this requirement would have pernicious effects over medical research, as it would give each donor complete control over how medical research is used and who benefits from that research." *Id.* at 1070.

21. "At the time of the district court's permanent injunction hearing in this case, more than 30,000 [research participants] were enrolled in WU prostate cancer research studies. About 2,500 to 3,000 [research participants] had been patients of Dr. Catalona. The Biorepository contains: (1) approximately 3,500 prostate tissue samples taken from patients of Dr. Catalona and other WU physicians within the Division; (2) about 100,000 blood or serum samples donated by over 28,000 men, 75% of whom were not patients of any WU physician, but rather were volunteers recruited through the media; and (3) DNA samples provided by approximately 4,400 men, which included patients of different WU physicians and relatives of those patients." Wash. Univ. v. Catalona, 490 F.3d 667, 671-72 (8th Cir. 2007).

implicitly acknowledged that any residual property interest that the individuals might have in their excised tissue was relinquished by agreeing to participate in medical research.[22] This leads to what has now become a jurisprudentially familiar result: individuals have diminished property interests in excised somatic cells and tissues used for research purposes. Taken together, these three cases indicate the parameters of a general default rule that excised human cells and tissues used in medical research are the property of the researcher and/or research institution rather than the individual donor.

B. *Embryos and Gametes*

Courts have taken a different approach to understanding individuals' property interests in other forms of human cells, namely embryos and gametes. This section briefly describes two influential cases that highlight the way courts approach individuals' property interests in this area.

Davis v. Davis, a 1992 opinion from the Supreme Court of Tennessee, was one of the earliest judicial opinions to consider the proper disposition of frozen embryos held in a fertility clinic where there was not any preexisting agreement or contract to determine how unused embryos should be handled. The genetic parents, Mary Sue and Junior Davis, divorced; Mary Sue initially wanted to gestate the embryos and then wanted to donate them to an infertile couple while Junior wanted the embryos discarded. Not only did the couple not stipulate what should happen to any unused embryos prior to their divorce, but there was also no relevant state statute to determine the embryos' fate. Thus, the court examined a number of scientific, ethical, and legal perspectives to determine how to proceed. *Davis* remains a leading case regarding the disposition of gametes and embryos because it provides a broad framework for courts to use when assessing this issue:

> Disputes involving the disposition of pre-embryos produced by in vitro fertilization should be resolved, first, by looking to the preferences of the progenitors. If their wishes cannot be ascertained, or if there is dispute, then their prior agreement concerning disposition should be carried out. If no prior agreement exists, then the relative interests of the parties in using or not using the pre-embryos must be weighed.[23]

But what is particularly important for this Article is the court's reasoning on whether embryos are "persons" or "property" in determining progenitors' rights with regards to their disposition in the absence of any contract or other agreement. The court concluded that embryos:

> [A]re not, strictly speaking, either "persons" or "property," but occupy an interim category that entitles them to special respect because of their *potential*

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22. The court referenced the consent form and brochure distributed to research participants in coming to this decision. *See id.* at 674-75.

23. Davis v. Davis, 842 S.W.2d 588, 604 (Tenn. 1992).

> *for human life* . . . . [The Davis' interest] is not a true property interest. However, they do have an interest in the nature of ownership, to the extent that they have decision-making authority concerning disposition of the pre-embryos.[24]

Thus, the *Davis* court distinguished the property interest that individuals might have in embryos from other types of excised somatic cells and tissues, largely based upon their "potential for human life" or the capacity to develop into an autonomous human being. This potential is not enough to give individuals a standard property interest over embryos. But, it is enough, according to the court, to give the genetic parents authority to determine how the embryos will ultimately be used—which is the *precise* property interest that was sought by and denied to the cell and tissue progenitors in *Moore*, *Greenberg*, and *Catalona*.

Decided four years after *Davis*, *Hecht v. Superior Court* is significant in that it applied the same "potential for human life" rationale for giving individuals a heightened property interest in gametes and not only embryos. *Hecht* concerned the disposition of fifteen sperm vials left to Deborah Hecht by her partner, William Kane, after his death. Hecht intended to use Kane's sperm to attempt to conceive and give birth to a child. Kane's two adult children objected, leading to the suit. Central to this case is whether or not Kane "owned" the sperm vials in a manner that allowed him to give this type of property to Hecht. Relying on *Moore*, Kane's children argued that Kane could not have a property interest in his sperm or control its disposition once outside of his body much like the California Supreme Court held that Moore did not have a property interest in his excised cells. The California Court of Appeals rejected this application of *Moore* to gametes in the first of three *Hecht* decisions, noting that the "decedent had an interest, in the nature of ownership, to the extent that he had decision making authority [ ] to the sperm. . . . [that] falls within the broad definition of property."[25] Even though Kane was dead at the time of this dispute, the court's inquiry focused largely on what type of interest Kane had in his sperm while alive and whether that allowed him to give it to Hecht.[26] The court used *Davis* to distinguish *Hecht* from *Moore* to find a residual property interest in gametes that is akin to that found in embryos because of their shared potential to create life. The *Hecht* court wrote that sperm "is unlike other human tissue because it is 'gametic material' that can be used for reproduction . . . . [T]he value of sperm [as in embryos] lies in its *potential to create a child* . . . . [Therefore] decedent had an interest, in the nature of ownership . . . . [that] is sufficient to constitute 'property.'"[27] As in the embryo cases, donors' intent remains primary in determining the

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24. *Id.* at 597 (emphasis added).

25. Hecht v. Superior Court of L.A., 16 Cal. App. 4th 836, 846 (1993).

26. Kane's will also stated that his sperm should be given to Hecht after his death. *See* Hecht v. Superior Court of L.A., 50 Cal. App. 4th 1289, 1292 (1996).

27. *Hecht*, 16 Cal. App. 4th at 850 (emphasis added).

disposition of gametes and frames the nature of the property interest involved. For example, in *Estate of Kievernagel v. Kievernagel*, the court cited *Hecht* in acknowledging that "gametic material, with its potential to produce life, is a unique type of property and thus not governed by the general laws relating to gifts or personal property or transfer of personal property upon death"[28] so as to deny a widow's claim to her late husband's sperm precisely because he wanted the sperm destroyed when he died. To be sure, most cases regarding the disposition of excised embryos and gametes focus on ascertaining and giving effect (where discernable) to the intent of the parties as articulated in informed consent forms or other written agreements at the time of the procedure.[29] However, for the purposes of this Article, *Davis* and *Hecht* are important in that they exist outside of the realm of contractual or statutory interpretation to understand the residual property interests that parties retain in excised gametes and embryos as distinct from ordinary somatic cells because of their potential to become human life.

C. *Distinctions Between Cases Involving Somatic Cells and Gametes/Embryos*

There are at least two distinctions between these two sets of cases that are worth noting. First, the cases pertaining to somatic cells and tissues (*Moore*, *Greenberg*, *Catalona*) deal with disputes between patients/research participants and biomedical research entities while the embryo and gamete cases (*Davis*, *Hecht*) deal with disputes between individual litigants outside of the context of medical research. Thus, the courts' discussion of property rights occurs in two different contexts where there are different sets of competing interests. For example, the cases dealing with somatic cells and tissues each stress the adverse impact that might occur to scientific research if patients and research participants retained a controlling property interest in their excised materials and how this may work against the public interest. This broader notion of efficient use of cells and tissues to yield a wider social benefit is absent from disputes concerning gametes and embryos. Instead, the litigants are dealing with issues pertaining to reproduction that have a different set of social and legal concerns such as the appropriate dispensation of property in probate matters, privacy, the right to procreate, and the right to not be a parent. This, however, may be a distinction without much of a difference. What is of interest

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28. In re Estate of Kievernagel, 166 Cal. App. 4th 1024, 1030 (2008).

29. *See, e.g.*, Kass v. Kass, 91 N.Y.2d 554 (1998), citing *Davis* in stating that "the relevant inquiry thus becomes who has dispositional authority over [the embryos]. Because that question is answered in this case by the parties' agreement . . . we have no cause to decide whether the pre-zygotes are entitled to 'special respect.'" *Id.* at 564-65; Litowitz v. Litowitz, 48 P.3d 261 (Wash. 2002), noting that the court "based[d] [its] decision . . . solely upon the contractual rights of the parties under the pre-embryo cryopreservation contract with the Loma Linda Center for Fertility and In Vitro Fertilization." *Id.* at 271.

to the many scholarly and judicial disquisitions on *Moore* and its progeny is the specific question of what property interests individuals have in excised cells and tissue, regardless of whether the person exerting a competing claim is a scientist or an ex-spouse. The differential contexts that underlie the juxtaposition of property interests in somatic cells and tissues versus those in gametes and embryos should not disqualify such analyses as an apples and oranges comparison; indeed, it is not uncommon for courts to look across contexts to clarify the precise property interest involved.[30] Rather, these cases should be looked at broadly and comparatively to draw greater scrutiny to default rules conferring differential property interests in somatic cells and gametes/embryos.

Second, the cases pertaining to gametes and embryos place a higher premium on fulfilling the progenitors' intent at the time of removal. For example, the *Hecht* court found that Kane had sufficient interest in his sperm for it to constitute property in terms of conferring jurisdiction of the dispute to the Probate Court.[31] But much of this finding is driven by the court's acknowledgement that gametes are a special type of property that should be disposed of according to the donor's *intent*. In rejecting the trial court's order to destroy the sperm, the appellate court noted that Kane's "will evidences the decedent's intent that Hecht, should she so desire, is to receive his sperm stored in the sperm bank to bear his child posthumously."[32] The *Hecht* court relied heavily upon the test set forth by *Davis* to determine the dispensation of gametes when there is a dispute, where primacy is given to the "preferences of the progenitors."[33] Given the clarity of Kane's intent as expressed in his will, the *Hecht* court simply applied Kane's intent as articulated.[34]

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30. *See, e.g.*, Janicki v. Hosp. of St. Raphael, 744 A.2d 963, 970-71 (Conn. 1999).

31. *Hecht*, 16 Cal. App. 4th at 850.

32. *Id.* at 850-51.

33. The full test elaborated by the *Davis* court states: "[W]e hold that disputes involving the disposition of pre-embryos produced by *in vitro* fertilization should be resolved, first, by looking to the preferences of the progenitors. If their wishes cannot be ascertained, or if there is dispute, then their prior agreement concerning disposition should be carried out. If no prior agreement exists, then the relative interests of the parties in using or not using the pre-embryos must be weighed. Ordinarily, the party wishing to avoid procreation should prevail, assuming that the other party has a reasonable possibility of achieving parenthood by means other than use of the pre-embryos in question. If no other reasonable alternatives exist, then the argument in favor of using the pre-embryos to achieve pregnancy should be considered. However, if the party seeking control of the pre-embryos intends merely to donate them to another couple, the objecting party obviously has the greater interest and should prevail." Davis v. Davis, 842 S.W.2d 588, 604 (Tenn. 1992).

34. "Given the procedural posture of this case, and the fact that, for purposes of addressing real parties' arguments, we are assuming that decedent intended to allow Hecht to use his sperm for posthumous artificial insemination, it is premature for us to apply the *Davis* test. At this point, the only issue which we address is whether artificial insemination with the sperm of a *decedent* violates public policy. There is nothing in *Davis* which indicates that such artificial insemination violates public policy." *Hecht*, 16 Cal. App. 4th at 859.

Intent arguably cuts the other way in cases dealing with somatic cells and tissues. In each of these cases, litigation arose out of plaintiffs' contention that their cells or tissues were being used in a manner inconsistent with their intent or expectations at the time they donated the biological materials. Yet, courts have consistently disregarded these claims in favor of conferring a controlling property interest to researchers once the cells or tissues have been excised—even when, as in *Moore*, the court simultaneously finds that the researcher breached his disclosure obligations in a manner that may very well have altered the patient's medical decision-making.[35] The *Moore* court specifically denied the conversion claim because they concluded that Moore "clearly did not expect to retain possession of his cells following their removal"[36] and that it would be inappropriate to acknowledge any lingering property interest that legitimizes the conversion claim since such recognition had not been granted by previous courts. Such a ruling would be contrary to California statutes that restrict patient interest in excised cells. Moreover, the Court also found that the patented cell line was sufficiently different to preclude Moore's claim to ownership. Thus, the Court disregarded Moore's intent and expectations as expressed in the suit. Viewed another way, they only looked at what his intent/expectations *could legally be* at the time the cells were excised rather than taking seriously his *actual* intent/expectations as expressed during the litigation. The *Greenberg* court also articulated this comparatively thin understanding of intent in the context of somatic cells and tissues, saying that the tissues in question were donated[37] and that, following *Moore*, researchers' use of the materials in a manner inconsistent with the donors' intent or expectations was irrelevant since they no longer had a legal interest in them.[38] Where *Greenberg* used the language of "donation" to characterize the transfer of property interest in somatic tissues and to curtail any serious consideration of the plaintiff's intent, *Catalona* embraced the language of "gift" to achieve similar ends:

> Our conclusion that the [research participants] intended to make gifts of their biological samples at the time of their donation is bolstered further by the language of the brochure, which characterized the [research participants'] donations as "a free and generous gift of [biological materials] to research that may benefit society." The brochure's acknowledgment that donated materials may be shared with non-WU researchers, without any further authorization

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35. Though the *Moore* court did not allow Moore's conversion claim, they nonetheless held that "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment." Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990).

36. *Id.* at 488-89.

37. Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003).

38. *Id.* at 1074 (citing *Moore*, 51 Cal.3d 120).

> needed from the [research participants], informed the [research participants] they would relinquish or abandon the right to designate the particular destination of their biological materials upon agreeing to participate in a medical research study. Such language, considered together with the consent form, cannot reasonably be characterized as reflecting the [research participants'] intention either to entrust their samples solely to Dr. Catalona or to transfer the samples in some legal form other than a gift.[39]

Thus, the potential for gametes and embryos to develop into autonomous human beings constitutes a legally significant default rule that amplifies donors' intent so as to acknowledge a property interest that exists after removal. The inability of somatic cells and tissues to generate human beings diminishes the seriousness in which courts consider donors' intent—even when the use of these materials is so egregiously inconsistent with their desires that it generates litigation—leading courts to effectively decline any property interests that individuals have to them or any derivative product. Therefore, the type of cell or tissue in question, in terms of its ability to create or become a human being, appears to be the most legally significant variable in how the court determines whether individuals maintain a residual property interest in extracorporeal materials. Individuals' diminished property interest in somatic cells and tissues and heightened property interest in gametes and embryos are justified by what is perceived to be a clear dividing line: the potential to become human life. In the next section, we discuss how the development of iPSCs poses serious challenges to this default rule.

II. INDUCED PLURIPOTENT STEM CELLS: WHAT THEY ARE, HOW THEY WORK, AND THEIR IMPLICATIONS FOR PROPERTY LAW

A. *A Brief Description of the Technology*

The biomedical promise and excitement surrounding stem cells lies in their ability to differentiate into different types of cells. Stem cells are unlike other cells in three regards:[40] (1) they are unspecialized (i.e. they do not have tissue-specific structures that limit them to only performing particular functions[41]);

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39. Wash. Univ. v. Catalona, 490 F.3d 667, 674-75 (8th Cir. 2007). The court noted that the research participants' (RP's) options with regards to directing the use of their tissues were quite limited: "The RPs' subsequent rights to their biological materials were expressly limited to the option to discontinue participation in the study to avoid answering additional questions, donating more biological materials, or allowing their biological materials to be used for further research. Beyond these particular and limited rights, the RPs retained no greater interest with regard to their biological materials. Such rights cannot be equated with or interpreted to include the broad privileges or proprietary interests advocated by the defendants." *Id*. at 675.

40. *See generally* NAT'L INST. OF HEALTH, STEM CELL BASICS (2009), *available at* http://stemcells.nih.gov/info/basics/basics2.asp.

41. *Id.*

(2) they can divide and replicate for a long time; and (3) they can differentiate into specialized cells. Typically, stem cells come in two types: adult and embryonic. Adult stem cells are mature stem cells found in particular tissues (bone marrow, heart, etc.) of mature organisms and "are responsible for renewing and repairing the body's specialized cells."[42] Adult stem cells are *multipotent*, meaning that they ordinarily can only differentiate (become more specialized) into a limited number of cell types. Embryonic stem cells, which are coaxed from early stage human embryos, are unique in that they are *pluripotent*, meaning that they can differentiate into derivatives of any of the three main categories of human tissues—"ectoderm (skin, nerves, brain), mesoderm (bone, muscle), and endoderm (lungs, digestive system)"[43]—as well as germ cells that are the precursors for gametes.

Pluripotency is a key trait; it lays the foundation for the promise of regenerative medicine where patient-specific tissues can be developed to treat many illnesses. For example, one approach might involve treating heart disease by employing embryonic stem cells to develop patient-specific replacement cells that might be able to repair damaged heart tissue.[44] Similarly, embryonic stem cells might be used to develop patient-specific nerve tissue that might regenerate spinal cord tissues to help give movement back to paralyzed individuals.[45] Thus, many researchers believe that embryonic stem cells' pluripotency creates an avenue of research that is more promising than the limitations associated with adult stem cells, which do not exhibit this trait.

However, the promise behind embryonic stem cells is not without ethical controversy. Obtaining access to these pluripotent stem cells requires destroying embryos. Many people consider embryos to be no less a form of human life than an actual human being, making it ethically problematic to destroy one form of life to save or heal another. This has led to a form of stem cell politics that mirrors abortion politics, where competing definitions of when life begins often determines how individuals understand the legitimacy of this medical technique.

It is in this context that the 2007 discovery of iPSCs was heralded as a new technology that might resolve this ethical and political problem. By adding a handful of genes to somatic cells and providing the right laboratory environment, these cells can be "induced" or "reprogrammed" to revert back to a pluripotent state that exhibits the same characteristics as embryonic stem

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42. Insoo Hyun, *Stem Cells*, *in* FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS, 159, 159 (Mary Crowley ed., 2008).

43. *Id.*

44. *See generally* Siamak Davani et al., *Can Stem Cells Mend a Broken Heart*, 65 CARDIOVASCULAR RESEARCH 305, 310 (2005).

45. *See generally* M.A. Woodbury, *Hans Keirstead Can Make Mice Walk Again (and Humans Too?)*, ESQUIRE MAGAZINE, Nov. 17, 2009, *available at* http://www.esquire.com/features/best-and-brightest-2009/human-embryonic-stem-cell-research-1209.

cells—all without having to destroy an embryo.[46] These reprogrammed cells can, in effect, give rise to an entirely new organism from somatic cells—which has not yet been done with humans but was demonstrated by two separate teams in 2009 with mice.[47] Using somatic cells taken from the skin of adult mice, these researchers used a virus to inject four genes into mice cells, which reprogrammed the cells to a state of pluripotency, causing them to exhibit the same plasticity as embryonic stem cells. They were then implanted in the acellular surrounding material of a nonviable "tetraploid" embryo that had its own cells modified; the new embryo with the reprogrammed somatic cells then developed into new baby mice. iPSCs have also been used to reprogram mouse somatic cells into pluripotent cells that were then differentiated into precursor germ cells that were used in fertilization.[48] While these mouse experiments pertaining to reproduction via iPSCs have not yet been demonstrated with human somatic cells, there is growing evidence that human applications are feasible and a logical extension of these animal experiments.[49]

B. *Potential Applications of iPSC Research With Human Cells*

There are several potential applications of iPSC research with human cells that might directly implicate the property interests of individual cell and tissue donors. It has been estimated that there are over 270 million tissue samples stored in U.S. biobanks alone, with an additional 20 million samples being added every year.[50] While some of these biobanks contain eggs, sperm, and embryos, millions of these samples are ordinary somatic cells and tissues used by scientists to conduct research that may lead to new therapies and treatments. While there is a robust debate regarding biobank governance to manage their disposition and to protect patients from privacy intrusions or from other harms

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46. *See generally* Takahashi et al., *supra* note 5; Yu et al., *supra* note 6.

47. *See generally* Lan Kang et al., *iPS Cells Can Support Full-Term Development of Tetraploid Blastocyst-Complemented Embryos*, 5 CELL STEM CELL 1, 1-4 (2009); Xiao-yang Zhao et al., *iPS Cells Produce Viable Mice Through Tetraploid Complementation*, 461 NATURE 86, 86-89 (2009).

48. Masanori Imamura et al., *Induction of Primordial Germ Cells From Mouse Induced Pluripotent Stem Cells Derived from Adult Hepatocytes*, 77 MOLECULAR REPROD. & DEV. 802, 808 (2010); Natalie de Souza, *Gametes from Stem Cells*, 8 NATURE METHODS 789, 789 (2011).

49. *See* Charles A. Easley IV et. al., *Direct Differentiation of Human Pluripotent Stem Cells into Haploid Spermatogenic Cells*, 2 CELL REPORTS 440, 443-44 (2012) (evidencing advances in using iPSC technology to turn human somatic cells into gametes); Rosa Silverman, *Scientists Create Sperm from Skin Sample*, UK TELEGRAPH, Aug. 29, 2012, http://www.telegraph.co.uk/science/science-news/9505267/Scientists-create-sperm-from-skin-sample.html. The study's lead author told the UK Telegraph "[n]o one has been able to make human sperm from pluripotent stem cells . . . in the lab, but this research indicates it might be possible."

50. Susanne B. Haga & Laura M. Beskow, *Ethical, Legal, and Social Implications of Biobanks for Genetics Research*, 60 ADVANCES IN GENETICS 505, 506 (2008).

that may lead to having their tissues identified,[51] the possibility that somatic cells in biobanks might be used for iPSC research raises important questions for property law that have not even been articulated yet alone addressed.

Although iPSC research has been touted as resolving debates regarding the ethics of destroying embryos to harvest pluripotent stem cells, some commentators have pointed to new ethical problems created by this emerging technology. One looming ethical issue is the notion of consent. It is common practice that individuals provide written consent to physicians and researchers to use their excised cell and tissue samples for research. However, patients and research participants often do this with an implicit understanding that there are certain biological limitations regarding what can be done with their somatic cells and tissues. The advent of iPSCs, however, suggests radically different possibilities—including the reprogramming of somatic cells into precursor germ cells that can mature into gametes that can be fertilized and grow into a living person.

Standard informed consent forms typically do not contemplate this possibility. To use somatic cells obtained under existing informed consent processes for iPSC research without raising the new possibilities to patients and research participants is ethically problematic for the obvious reasons that many people would object to their cells being used in a manner that may indiscriminately create new life that would be genetically related to them.[52]

Another concern is privacy. iPSC lines derived from a living individual contains genetic information about the donor and his/her relatives that may be sensitive. De-identification may not always be desirable in the context of iPSC research for both clinical and technical reasons.[53]

The third major ethical issue with iPSC research is that it is a relatively straightforward process that is not difficult to replicate.[54] In short,

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51. *See generally* David E. Winickoff & Richard N. Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 NEW. ENG. J. MED. 1180, 1182-83 (2003).

52. *See generally* Katriina Aalto-Setälä et al., *Obtaining Consent for Future Research with Induced Pluripotent Cells: Opportunities and Challenges*, 7 PLOS BIOLOGY 204, 207 (2009).

53. Amy Zarzeczny et al., *iPS Cells: Mapping the Policy Issues*, 139 CELL 1032, 1033 (2009). "One way for researchers to address these [privacy] concerns is to de-identify or anonymize the data at the time of donation. However, there are various problems with this approach. First, there are clinical, research, and policy reasons why anonymization (that is, de-linkage from identifiable information) may not be an ideal approach. For instance, future clinical applications (e.g. transplantation) may necessitate obtaining follow up information about the donor's health status. Second, with the advent of large-scale genome-wide association studies, technology now exists to detect a specific individual's single nucleotide polymorphism, even when de-identified and in a pooled data set."

54. David Cyranoski, *5 Things to Know Before Jumping on the iPS Bandwagon*, 452 NATURE 406, 406 (2008). Although the process is rather straightforward, iPS cells can be rather difficult to develop. Nature's David Cyranoski reports that "as simple as this procedure might seem, iPS cells are not easy to make. Kathrin Plath at the University of California, Los Angeles estimates that each of the reprogramming genes (she used six) has

reprogramming somatic body cells into a pluripotent state only requires inserting four genes in culture to trigger the process of de-differentiation that turns a regular somatic cell (e.g. skin) into a pluripotent state[55] that can differentiate into reproductive cells. Shinya Yamanaka, who led one of the first teams to discover iPS cells stated "we are presenting new ethical issues, maybe worse ones, because many people can do this—and without telling anybody."[56] As an editorial from *Nature* noted, "the facility with which iPS cells can be derived could make it easier to derive gametes from any person, living or dead."[57] This combination of (a) a transformative technology that is (b) straightforward to conduct with (c) widely accessible raw materials (somatic cells and tissues) stored by the millions in biobanks and (d) a legal regime whereby the progenitors of these raw materials have no legal interest in their own cells and tissues (while also remaining vulnerable to third party usage that could be quite damaging) might produce disputes and unwanted outcomes of an order of magnitude that was previously unimaginable. Put bluntly, any person who has had a tissue biopsy stored in a biobank may now, at least theoretically, become a genetic parent without their consent.

One particularly sensitive area of research is the use of iPSCs for reproductive medicine. The specter of this type of research draws attention not only to the fraught nature of iPSC research in the current bioethical and biomedical environments but also to its legally problematic dynamics. The advent of iPSCs implicate property interests in ways that obliterate the rationale for the existing default rules that apportion differential property interests according to cells' potential to create new human beings. For example, to the extent that iPSC research might be able to reprogram and differentiate somatic cells into reproductive cells that can become mature gametes, researchers may find iPSC-derived gametes "useful both for understanding gametogenesis and as a potential infertility treatment [whereby] gametes derived from iPS cells would have virtually the same DNA as the somatic cell donor."[58] A less scrupulous researcher could use iPSC methods and readily available somatic cells and tissues to pursue human cloning—even in jurisdictions that ban reproductive cloning by other means.[59] Beyond notions of privacy and consent,

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only a 15% chance of making it into a given cell. Even if they all make it, the cell has only a 5% chance of being fully reprogrammed. The low efficiency presents a riddle for scientists, but with millions of cells available in a biopsy sample, it is not a roadblock."

55. Justin Lowenthal et al., *Specimen Collection for Induced Pluripotent Stem Cell Research: Harmonizing the Approach to Informed Consent*, 1 STEM CELLS TRANSLATIONAL MED. 409, 409 (2012). "Although recent evidence has tempered the hope that translating these technologies toward new therapies will be easy, there is great interest in using iPSC lines to advance translational goals. A broad range of human tissue types are currently being procured to facilitate the generation of iPSC lines."

56. Cyranoski, *supra* note 54, at 408.

57. *New Sources of Sex Cells,* 452 NATURE 913, 913 (2008)

58. Aalto-Setälä et al., *supra* note 52, at 206.

59. "In theory, injecting human iPSCs into a human tetraploid blastocyst could create

it is likely that scenarios such as these would be quite troubling to the somatic cell donor if they came to pass for the precise reasons that law has recognized a residual property interest in gametes and embryos: the potential to create new individuals intuitively gives donors a heightened interest in how their cells are used, lest a genetically related version of themselves be created without their knowledge or against their wishes. Yet, in the existing legal regime, donors of somatic cells and tissues would have no recourse to even prevent a scientist from pursuing the most questionable types of research with their biological materials.

III. NORMATIVE PROPOSALS

iPSCs pose a dramatic challenge to this default rule in property law, which recognizes an individual's property interests in excised gametes and embryos based on their "potential for human life" while refusing any corollary property interest in excised somatic cells. While research with iPSCs in humans is in its early stages, the developments with mice cells suggest that it may soon be possible for excised human somatic cells to be reprogrammed and differentiated into reproductive cells, which would have the very potential for life that courts have identified as a prerequisite for having a residual property interest in excised cells. Therefore, iPSCs can make it technically feasible for any regular somatic cell—from an individual's hair, skin, or Moore's storied spleen—to be reprogrammed in a manner that can create life. Somatic cells now arguably have the same potential to become new human beings that embryos and gametes do, but without a corresponding property interest to prevent misuse or to respect individuals' wishes concerning the disposition of such cells. While the development of iPSCs have led to important reconsiderations regarding informed consent[60] and intellectual property,[61]

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a child who is a clone of the somatic cell donor and whose placenta comes from the donor(s) of the blastomeres. . . . [M]any current policies ban only human reproductive cloning by somatic cell nuclear transfer (SCNT)." Bernard Lo et al., *Cloning Mice and Men: Prohibiting the Use of iPS Cells for Human Reproductive Cloning*, 6 CELL STEM CELL 16, 16 (2010).

60. *See* Lowenthal et al., *supra* note 55. The development of iPSCs creates important questions regarding informed consent, i.e. how can a patient consent to donating tissues that may be subject to iPSC research when it is not yet entirely clear what that research might entail. It is interesting to note that while they do not speak to the exact issues discussed in this Article, existing regulations for human embryonic stem cells do not give donors downstream control over their usage. For example, the NIH Guidelines on Human Stem Cell Research only states that donors "should have been informed that they retained the right to withdraw consent for the donation of the embryo" and that they should also be informed that "the results of research using [human embryonic stem cells] may have commercial potential, and that the donor(s) *would not* receive financial or any other benefits from any such commercial development." NATIONAL INSTITUTES OF HEALTH GUIDELINES ON HUMAN STEM CELL RESEARCH, II(A)(3)(d)(iii), II(A)(3)(e)(vi) (2009) (emphasis added), *available at* http://stemcells.nih.gov/policy/2009guidelines.htm. Guidelines from the California Institute

scholars have not identified nor discussed the tensions created for property law. This section fills this void by first discussing the existing relevant literature. We then offer a three-part proposal that addresses the challenges posed by iPSCs for property law and then discuss concerns that may be raised by our recommendations.

A. *Existing Literature*

Legal scholars have not discussed the transformative challenges that iPSCs pose for property law. The scholarly literature regarding property interest in human cells and tissues has largely focused on exploring different theoretical or doctrinal bases to rethink the default rules established by *Moore*—i.e., that individuals do not have a property interest in their excised somatic cells. Scholars have been largely critical of *Moore's* holding and have offered alternative paradigms as solutions. For example, Robin Feldman has recently argued that "[i]t defies common sense to say that an individual lab can hold property rights in the tangible cells removed from a person's body while the person whose body supplied the cells cannot."[62] This intuitive understanding that *Moore* was incorrectly decided leads Feldman to urge courts to revisit the issue in light of the knowledge gleaned through decades of experience since the initial decision.[63] Pilar Ossorio shares a similar normative sensibility[64] in arguing that a formal transfer (gift, sale, etc.) should be needed before a researcher can use someone else's tissues for their own purposes.[65] Radhika

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of Regenerative Medicine (CIRM)—the largest state level program for stem cell funding – note that "donor[s] will have no legal or financial interest in any commercial development resulting from the research" and that "a donor must be given the opportunity to impose restrictions on future uses of donated materials [but that] researchers may choose to use materials only from donors who agree to all future uses without restriction." CAL. CODE REGS. tit. 17, § 100100(b)(1)(I), § 100100(b)(2)(2012).

61. *See* Robin Feldman & Deborah Furth, *The Intellectual Property Landscape for iPS Cells*, 3 STAN. J.L. SCI. & POL'Y 16 (2010).

62. Robin Feldman, *Whose Body Is It Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law*, 63 STAN. L. REV. 1377, 1384 (2011).

63. "Our enthusiasm and appreciation for the miraculous advances of science should not blind us to the necessity of thinking through the interests of the people whose cells provide the raw materials, nor should it obviate the necessity of ensuring that those raw materials are properly obtained. Perhaps courts in the appropriate jurisdictions will feel moved to revisit these issues, now that we have decades of experience with this type of scientific research." *Id.* at 1385.

64. "If one accepts the proposition 'my body belongs to me,' then I think there is a strong argument that extracorporeal bodily materials should be considered, initially, the property of the person from whom it was derived. . . . Does changing the location of bodily material from within my body to outside my body change my property rights in that material? I do not think so." Pilar N. Ossorio, *Property Rights and Human Bodies*, *in* WHO OWNS LIFE?, 223, 234-35 (David Magnus, Arthur Caplan, & Glenn McGee eds., 2002).

65. Ossorio states that "the individual from whom bodily materials are derived [should be] the initial owner of those materials, and that legitimate transfers from them to scientists

Rao examines the overlapping legal regimes of property, contract, and privacy to tease out the incoherence that law applies to individuals' rights and relationships to excised cells and tissues. She suggests a model of property in the human body as stewardship, where individuals collectively possess themselves in a public trust, rather than being outright owners.[66]

Not all commentators find the default rules established by *Moore* and subsequent cases troubling. For example, Hakimian and Korn argue that the *Moore* regime of diminished individual property interest in excised cells is justifiable:

> Because the benefits of medical knowledge derived from tissue research potentially accrue to all individuals and future generations, society may justify the expansive use of these valuable resources based on the principle of justice. Human tissue specimens are a unique and irreplaceable research resource, and society's strong interest in the advancement of medical knowledge deserves a coherent and internally consistent legal, regulatory, and ethical framework to govern specimen use.[67]

Similarly, Russell Korobkin argues that *Moore* correctly established an important default rule—one based on contract rather than property—of no compensation for transactions pertaining to human tissues.[68] Nevertheless, much of the literature surrounding *Moore* has expressed dissatisfaction with both the outcome and default rules established by the case, which has led to proposals for alternative models. For example, Charlotte Harrison has suggested a hybrid approach that falls between notions of altruism and private property, such that there would be "a general rule of donation for research tissue at the time it is acquired" which would "provide an objective, non-market mechanism for compensation after research use for unusual cases in which samples prove to have significant commercial utility."[69] Donna Gitter

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must take place before scientists can rightfully possess, use, or sell those materials, or exclude others from doing so." *Id.* at 241.

66. Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body*, 35 J.L. MED. & ETHICS 371, 379-80 (2007). *See also* Rao, *supra* note 8.

67. Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens for Research*, 292 JAMA 2500, 2504 (2004).

68. Korobkin notes "[i]n the twenty-first century, biotechnology is becoming increasingly important in medical research. If biomedicine is able to fulfill the hopes of the scientific community by creating a new paradigm for the treatment of disease – one in which biological agents regenerate diseased or dead tissues – disembodied tissues could become the cures for a variety of ailments. It is likely that scientists around the world will need a tremendous amount of human tissues of all types just to mount the research effort, regardless of whether the promise is ever actually fulfilled. In the new era of biomedical technology, it is critically important for the law to facilitate tissue transactions efficiently. This, in turn requires understanding and embracing the underlying wisdom of *Moore*." Russell Korobkin, *"No Compensation" or "Pro Compensation":* Moore v. Regents *and Default Rules for Human Tissue Donations*, 40 J. HEALTH L. 1, 27 (2007).

69. Charlotte H. Harrison, *Neither* Moore *nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 78 (2002).

takes a different approach in proposing that Congress recognize individuals' enduring property interest in excised human tissues by enacting legislation that not only allows research participants to sell human tissues for research purposes but also expressly provides for a tort of conversion if researchers wrongly use such materials.[70]

Despite these wide ranging perspectives, there has been no conversation in the literature—legal, biomedical, or otherwise—on how the development of iPSCs significantly complicates the existing conversation on property interests in excised human cells and tissues.[71] What is needed is a discussion of how iPSCs might shift the empirical footing underneath these theoretical, policy, and doctrinal conversations by making the existing logic behind the differential treatment of somatic cells and gametes/embryos largely incoherent. Prior to the development of iPSCs, the default rule regarding individuals' property interests in excised cells worked reasonably well by efficiently giving scientists access to research materials without exposing donors to the risk that their cells could be used by third parties to create new humans with a genetic tie to them. The default rule acts as a firewall in acknowledging a residual property interest in gametes and embryos outside of the body so that progenitors can control their disposition. But iPSC research disrupts the protections afforded by this default rule by giving somatic cells the potential to create human life without extending a residual property interest to donors so that they may limit the use of somatic cells for reproductive purposes. A model is needed that allows the law to co-evolve with technology in a manner that is least disruptive to the existing default rules. Yet it is also important to maintain the sensibilities of promoting efficient research with somatic cells and tissues while also giving donors a heightened property interest in excised cells with reproductive abilities. Here, we propose a three-part approach.

B. *A Three-part Proposal*

1. *Self-imposed moratorium on using iPSCs for human reproduction*

To address the jurisprudential instability in property law created by iPSCs, we first argue that the research community should implement a self-imposed moratorium on applications of iPSC research that pursue human reproduction

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70. Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257, 339-41 (2004).

71. Zarzeczny et al. come the closest to raising these issues (albeit in a non-legal journal article) by discussing the possibility of "reach through rights" stemming from iPSC research, whereby donors may have a controlling interest in the use of cell lines resulting from their tissues. However, this does not speak to the issue identified in this Article, i.e. that iPSCs complicate existing default rules pertaining to individuals' property interest in excised biological materials. *See* Zarzeczny et al., *supra* note 53, at 1034.

with somatic cells from individuals who have not specifically given informed consent for their biological materials to be used in this manner. We are not the first to suggest that certain types of iPSC research should not proceed. Bernard Lo et al. have argued for a moratorium in relation to the potential use of iPSCs for reproductive cloning purposes, citing both safety and ethical concerns.[72] However, the manner in which iPSC research potentially destabilizes the existing default rules pertaining to property law suggests that this provides another important reason to stop human reproductive applications with somatic cells from individuals who have not specifically consented to this use until further legal and policy deliberations can take place.

We do not suggest that iPSC research pertaining to animal models should stop. Nor do we necessarily suggest that all iPSC research with human cells should cease. We do, however, find the safety and ethical concerns pertaining to human reproductive cloning raised by Lo and his colleagues to be quite persuasive. Accordingly, we specifically tailor this first part of our proposal to the indeterminate property interest raised by using somatic cells from non-consenting individuals for iPSC research,[73] to the extent that this technology may give somatic cells the same potential to become human life as gametes and embryos, where progenitors retain a property interest after excision. We believe that the scientific community should take a leadership role in assessing and resolving the tensions regarding the ownership of excised biological cells created by iPSC research. This should start with a self-imposed moratorium on the most questionable aspect of this technology—research that results in the creation of reproductive cells that have the potential to create life and whose donors did not specifically consent to this purpose. While some may argue that a self-imposed moratorium would not be effective in stopping this research, we believe that research institutions and funding organizations can provide the appropriate combination of incentives and disincentives to require clear consent from donors that unequivocally demonstrates their understanding that their cells will be used for iPSC research and that they appreciate the full range of potential outcomes. For the scientific community to not take the lead with this

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72. "There continue to be compelling safety reasons to ban human reproductive cloning. Existing laws and professional guidelines should be carefully revised to cover tetraploid complementation with iPSCs and other technologies in addition to [somatic cell nuclear transfer], thereby broadening the ban on attempts at reproductive cloning to existing and future technologies." Lo et al., *supra* note 59, at 20.

73. Aalto-Setälä et al. discuss the importance of consent in iPSC research, noting that "iPS cells are an exciting new approach to developing pluripotent stem cell lines that are genetically identical to people with known phenotypes. While they avoid the ethical issues inherent in embryonic stem cells, they do raise some ethical concerns regarding consent for future research. Obtaining consent for fundamental downstream research with iPS cells, together with offering the options of allowing recontact by researchers and giving permission for additional sensitive types of future research, will show respect for somatic cell donors, promote public trust in stem cell research, and allow optimal use of scientific discoveries." Aalto-Setälä et al., *supra* note 52, at 207.

rather nominal proposal risks creating the perception that they are more interested in preserving the unadulterated commercial potential of iPSC research rather than respecting the law's concern with preserving individuals' property interests in excised cells with the potential to create human life. This perception, if fostered by the research community's reluctance, may lead to distrust among potential research participants. This may stifle development of human applications of this technology as well as others. We believe that this moratorium should only be in place for a limited period, at least until the proposal's second part is in place.

2. *Legislative action*

Second, we argue that Congress should consider legislation that acknowledges a property interest in excised somatic cells that vests back to the progenitor once these cells are reprogrammed to a state of pluripotency and differentiated into reproductive cells. Since the characteristic that destabilizes the existing default rules is induced pluripotency that can lead to the creation of reproductive cells—the outermost point at which a somatic cell has the potential to create an independent human organism—it makes clear legal and scientific sense to protect individuals' property interests at this point like any other excised reproductive cell with this potential. To the extent that this has been the key rationale for the differential property interests given to these cells, Congress can quickly and logically bring uniformity to this area of property law by extending existing property interests in gametes and embryos to somatic cells at the moment they cease to function as ordinary body cells and obtain reproductive capacity through the processes of induced pluripotency and differentiation. Such Congressional action would provide the most protection to potential research participants and encourages iPSC researchers to specifically seek informed consent from the progenitors of somatic cells and tissues.

3. *Judicial action*

Lastly, in light of these scientific developments and proposed Congressional actions, we argue that courts should distinguish *Moore* to clearly identify a property interest in excised somatic cells that are reprogrammed and differentiated into reproductive cells through the processes of induced pluripotency. This will add further consistency to the existing jurisprudence by demonstrating that the acknowledgement of a property interest in somatic cells that have been reprogrammed and differentiated into reproductive cells is not a departure from the existing default rules. Rather, it is consistent with the court's longstanding emphasis on protecting individuals' interests in excised biological materials that have the potential to create autonomous human beings. To the extent that iPSCs may not be the last technique to confer pluripotency to somatic cells, such judicial pronouncements can create a stable paradigm that protects individual property interests. It can also provide a predictable research

environment for researchers seeking consistency in how to handle excised cells and tissues and how to assess the commercial viability of their research.

C. *Three Possible Objections*

There are at least three different concerns to this proposal that merit discussion. First, there is the argument that the proposed approach is overly broad. Many in the research community may argue that iPSC research can go forward without any type of self-imposed moratorium, Congressional action, or judicial affirmation as scientists can be trusted to not abuse donors' samples, the public's trust, or existing ethical guidelines. However, we argue that this issue is too important to allow human applications of iPSC research to exist within the status quo default rules as this may lead to the existing paradigm's perversion. Scientists are given a default property interest in excised somatic cells because they are ostensibly of little use to most individuals. Yet, this rule can now "lock out" individuals from any property interest in their own cells once they are reprogrammed and differentiated into reproductive cells with the potential to become life. Our proposal is a logical extension of the current default rules. We simply argue that law should extend the same property interest to somatic cells that are conferred to gametes and embryos once these somatic cells are reprogrammed and differentiated to exhibit traits that are substantially similar to those of ordinary reproductive cells—and therefore have the potential to become new human beings.

A second concern is that the vesting feature of our proposal—where Congressional action would confer a property interest to somatic cell donors once their cells have been reprogrammed and differentiated into reproductive cells—is too burdensome to be functional; it would require each and every somatic sample to be tracked in light of the possibility that it might be used for iPSC research. However, this concern overstates the issue. Our proposal is designed to incentivize the creation of separate biobanks where somatic cell and tissue donors have specifically consented to the use of their samples for iPSC research. Thus, the point of Congressional action of this nature is for the market and scientific community to develop a workable model outside of requiring the tracking of all banked biological samples on the off chance that they may be useful to iPSC researchers. The creation of separate biobanks with donors fully consented about the prospects of their samples being used for iPSC research can create new efficiencies in that researchers can have confidence that they are using samples in an ethically appropriate manner and that donors are fully aware of the potential use of their samples.

A third objection that may be raised by this proposal is that it introduces unnecessary instability in this area of law and threatens the established property interests conferred to researchers through the default rules established by *Moore*, *Davis*, *Hecht*, and other cases. Put differently: leave well enough alone. This possible objection both understates and overstates the significance of the proposal being made. It understates it in that what might be considered "well

enough" for the research community may not be the case for individual cell and tissue donors. Yet, it also overstates things in that the proposal does not take anything away from researchers, nor does it change the existing default rules. Indeed, the default differential property interests are preserved. Our proposal simply addresses the new middle ground created by somatic cells that are reprogrammed to a pluripotent state, and conservatively errs on the side of individual donors to the extent that reprogrammed pluripotency and subsequent cell differentiation can give somatic cells the very potential to become life that the existing default rules acknowledge as a key reason for extending property interest to donors. Rather than destabilizing the existing regime, this proposal respectfully adheres to the preferences and concerns embedded in the existing default rules.

CONCLUSION

Discussions concerning property rights in the body have been ongoing for hundreds of years. *Moore v. Regents of the University of California* was a watershed moment in establishing the foundation for the current default rules concerning the type of property interests individuals have in excised somatic cells, with subsequent cases adding the bricks and mortar. This Article has shown the evolving nature of these property interests, especially in the context of new genetic technologies such as iPSCs. By giving somatic cells the potential to become life, iPSCs challenge the entire modern regime concerning property interests in excised human cells and tissues and create new opportunities for rethinking this area of law. Our proposal provides a coherent framework to deal with the implications iPSCs might have for property law without upending this entire jurisprudence. By granting the same property interest in gametes and embryos to somatic cells that are reprogrammed and differentiated into reproductive cells, the current legal framework, policy preferences, and expectations among scientists and research participants are preserved. In addition, this recognition of property interests creates an incentive for the iPSC research community to develop separate biobanks composed of samples from donors who fully consent to their cells and tissues being subjected to this new technology. This provides a viable means by which the integrity of both the iPSC research agenda and cell and tissue donors can be preserved.