

# LEGAL IMPLICATIONS OF LETTER LICENSES FOR BIOTECHNOLOGY

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## INTRODUCTION

Each new technological revolution engenders new legal problems. In response, courts try either to adapt available legal theories to the new fact situations created by the emerging technology, or to formulate new theories of law appropriate for the new problems. As the technology matures and becomes a part of the commercial sector, legislatures often codify the previously developed common law with appropriate modifications,<sup>1</sup> or create entirely new law appropriate to the new technology.<sup>2</sup>

The latest technological breakthrough, which is still in its infancy, is the biological revolution. At present, very few products based on this new technology are in commercial use.<sup>3</sup> However, a substantial amount of private research is being conducted with the goal of developing commercial products, and often, biological materials originally produced in university laboratories are used.<sup>4</sup>

A major problem arises in connection with the transfer of biological materials ("biologicals")<sup>5</sup> from a publicly-funded research institution (e.g., a university) to a private sector researcher (e.g., a corporation doing commercial research on biologicals). Universities are frequently

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1. See, e.g., 17 U.S.C. § 117 (1982) (copyright protection for software).

2. See, e.g., Semiconductor Chip Protection Act, 17 U.S.C. §§ 901-914 (Supp. II 1984) (providing special protection for semiconductor chip designs).

3. See A. BULL, G. HOLT & M. LILLY, *BIOTECHNOLOGY: INTERNATIONAL TRENDS AND PERSPECTIVES* 73 app. (1982).

4. See OFFICE OF TECHNOLOGY ASSESSMENT, UNITED STATES CONGRESS, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS* 67-69 (1984).

5. For definitions of all the biotechnology terms used in this article, see *Glossary of Biotechnology Terms*, 1 *HIGH TECH. L.J.* 253 (1986).

confronted with transfers by their faculty members of biologicals produced with university resources to recipients who are private corporations doing biological product research. This article addresses the rights, if any, of a university to the fruits of a transferee's commercial exploitation in the event transferred material becomes the basis for a commercially viable product.

First, an early case is presented to illustrate the legal problems involved in the transfer of biologicals. Then, the possible bases for recovery by the university are discussed, including contract analysis and personal and intellectual property doctrines, taking into account the special characteristics of the academic research environment. Next, the remedies the university may have under the various theories of recovery will be examined. Finally, the article will conclude that, at least under current practice, the university should not expect any recovery from the private researcher in the event the transferred biological leads to a commercially viable product.

## I. BACKGROUND

### A. An Early Case

The competing claims of universities and private researchers have sometimes been pursued through litigation.<sup>6</sup> An early case serves to illustrate the problems.

In 1978, prior to the current awareness of the commercial value of biological materials, Dr. David Golde of UCLA Medical School gave a cell line<sup>7</sup> to Dr. Robert Gallo of the National Cancer Institute ("NCI"),<sup>8</sup> a publicly-funded research body. Golde originally designated the cell line, which was obtained from a cancer patient, "KG-1."<sup>9</sup>

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6. See, e.g., *Hoffman-LaRoche, Inc. v. Golde*, No. C-80-3601-AJZ (N.D. Cal. filed Sept. 11, 1980); *Moore v. Regents of Univ. of Cal.*, No. C 513775 (Cal. Super. Ct. Los Angeles filed Sept. 11, 1984).

7. The transfer was accomplished under a written agreement under which Gallo would use the material solely for cancer research, and that Gallo would not transfer the material to anyone else. Defendant's Answer and Counterclaim for Conversion and Misappropriation of Trade Secret at 4, 5, *Hoffman-LaRoche, Inc. v. Golde*, No. C-80-3601-AJZ (N.D. Cal. filed Nov. 14, 1980) [hereinafter cited as Answer and Counterclaim].

8. *Id.* at 4.

9. Both Dr. Golde and the University of California are defendants in a second lawsuit not involving the KG-1 cell line. Cells were taken from a patient (Mr. Moore) who had hairy-cell leukemia, and the cells were established as a stable strain in Dr. Golde's laboratory for investigation. The cells were shown to be overproducers of certain lymphokines and also the carrier of a rare retrovirus. The cells became the subject matter of U.S. Patent No. 4,438,032 and also of a collaborative effort with Genetics Institute, a private company.

During his investigation, Gallo discovered that the cell line was an interferon overproducer.<sup>10</sup> Gallo subsequently gave the cell line to Dr. Sidney Pestka of the Hoffmann-LaRoche Institute of Molecular Biology.<sup>11</sup> Hoffmann-LaRoche then entered into a collaborative effort with Genentech, Inc., another private corporation, to develop a method for producing interferon in microorganisms.<sup>12</sup>

In an attempt to protect their efforts in interferon research, Hoffmann-LaRoche sued the University of California for a judgment declaring that the University had no rights in the KG-1 cell line.<sup>13</sup> Hoffmann-LaRoche admitted that Pestka had used the cell line for the production of interferon, as well as for isolating nucleic acid sequences which coded for interferon production.<sup>14</sup> However, Hoffmann-LaRoche argued that it had no obligation to the University of California,<sup>15</sup> that the University had neither a property interest in the KG-1 cell line nor any other claim against Hoffmann-LaRoche relative to its human leukocyte interferon;<sup>16</sup> and that any purported restrictions on the use of the original KG-1 cell line were of no effect as to Hoffmann-LaRoche.<sup>17</sup>

In response, the University of California filed a counterclaim based upon theories of conversion of property and misappropriation of trade secrets.<sup>18</sup> In addition, they requested that Hoffmann-LaRoche transfer to the University the KG-1 cell line, and any parts, products or inventions produced from it, and that a constructive trust for the benefit of the University be imposed on any fruits of the use of the KG-1 cell line.<sup>19</sup>

Hoffmann-LaRoche argued that it had not wrongfully obtained the KG-1 cell line, and that regardless of how the cell line had been obtained, they had not used the KG-1 cell line per se but only an organism

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Seven years after the cells were taken from Mr. Moore, Mr. Moore has sued the Regents of the University of California and Dr. Golde alleging that the University converted his spleen cells for the University's advantage. Mr. Moore also alleges that there was a lack of informed consent at the time he agreed to donate his spleen for research. Third Amended Complaint at 1-38, Moore v. Regents of the Univ. of Cal., No. C 513775 (Cal. Super. Ct. Los Angeles filed Oct. 24, 1985).

10. Answer and Counterclaim, *supra* note 7, at 6.

11. This institute is a private research foundation connected with the Hoffmann-LaRoche drug company. *Id.* at 5.

12. Third Party Complaint at 3, Hoffmann-LaRoche, Inc. v. Golde, No. C-80-3601-AJZ (N.D. Cal. filed Nov. 14, 1980).

13. Complaint for Declaratory Relief, *Hoffmann-LaRoche*, No. C-80-3601-AJZ [hereinafter cited as Complaint].

14. *Id.* at 4-5.

15. *Id.* at 7.

16. *Id.*

17. *Id.* at 8.

18. Answer and Counterclaim, *supra* note 7, at 4-8.

19. *Id.* at 8.

containing no physical portion of the cell line.<sup>20</sup> Furthermore, Hoffman-LaRoche contended that the cells which had been given to Gallo were not the same cells which had been given to Dr. Pestka.<sup>21</sup> Finally, they argued that the KG-1 cell line had no value for purposes other than research until Pestka established its commercial usefulness. Hoffman-LaRoche thus concluded that the University of California had no property or other rights in the newly-developed interferon product.

A judicial resolution of the situation was obviated by an amicable settlement between the parties. As a result, the many issues presented in the Hoffman-LaRoche case remain unresolved.

## B. The Academic Environment

Prior to the discovery of the potential value of biological materials, customs had developed in the academic community which helped delineate the obligations of the parties involved in a transfer of biologicals. The primary concern of the transferor was usually scientific recognition and this concern usually produced two demands by the transferor. First, he wanted assurances that the recipient would not compete with him in his area of investigation. Second, he wanted to be acknowledged in any subsequent publications by the recipient. After initial publication, biologicals were freely transferred in the academic environment, and the source of the biological was normally indicated in any subsequent publication. The availability of the biological material was therefore advertised not only in the transferor's articles but in the recipient's articles as well.<sup>22</sup> Generally, neither party asserted property rights in the biological.

Eventually, however, universities began to realize that transferred biologicals could be of substantial value to a commercial entity developing new products.<sup>23</sup> In trying to adapt to this new situation, universities found it very difficult to get their own researchers, who were not used to the idea of licensing biologicals to their research colleagues and were reluctant to impose new restrictions on the transfer of biologicals. In addition, universities found it impractical to enter into a formal licensing agreement with each recipient.<sup>24</sup> Instead, in an attempt to garner a share

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20. Complaint, *supra* note 13, at 4-5.

21. The cells had been replicated or "cloned."

22. See generally I. COOPER, BIOTECHNOLOGY AND THE LAW § 11.03 (1985).

23. OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 4, at 414.

24. To provide for an individually negotiated agreement governing each transfer of biological material by a university to a private researcher would be a formidable task and for the most part unnecessary and expensive. In most instances the biological has no known value at the time of the transfer. It is merely one of many biologicals which may have potential (but at the time of transfer unknown) commercial applications. Given this uncertainty, the cost of entering into a detailed, formal licensing agreement for each transfer would be prohibitive. Furthermore, in many instances the transfer may

of the financial return of the biological lead to a commercial product, universities began to routinely use standardized "letter licenses."<sup>25</sup> The licenses limit the use of the biological to "research purposes only."<sup>26</sup>

Certain essential characteristics of the academic environment are incompatible with this licensing process. The fundamental purpose of the research university is to gather and disseminate information. "Publish or perish" is frequently the standard by which tenure is achieved at a research university.<sup>27</sup> A Ph.D. thesis is predicated upon an original piece of work which is published in a journal. At the least, there will have been a substantial investment of time and effort in the development of the information included in a published article, and there may be substantial commercial value in the information as well. Yet, it is accepted that the university may not keep such information secret. The very essence of the scientific system involves disclosure—from discovery, to publication, to duplication by others and verification of the finding.<sup>28</sup> One scientist cannot verify another's results unless he has access to the same techniques and materials.

The remainder of this article will discuss the legal ramifications of the transfer of biologicals under a letter license, taking into account the special characteristics of the academic environment.

## II. CONTRACT ANALYSIS

In most situations involving a transfer of biologicals under a letter license, there will be an offer of the biological by the university with certain conditions attached<sup>29</sup> and an acceptance of the biological by the

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involve a scientific collaboration between the commercial entity and the academician, so that any interference by the licensing group (the university administration) might be rebuffed by the academician as well.

25. One of the primary reasons that biologicals are licensed by the universities rather than sold outright is to avoid problems with the implied warranty provisions of both common law and the Uniform Commercial Code. (*See infra* app. A, example 2 for an explicit recognition of this rationale.) So for very practical reasons, outside their desire to reap profits from the use of "their" biological materials, the university licenses rather than sells.

26. These licenses vary in their complexity. Some versions purport to cover new biologicals derived from the transferred biological as well as the original material, others do not mention the term "research only" but do restrict the transferee to non-commercial use. *See infra* app. A for three examples of letter licenses.

27. *See generally* M. EPSTEIN, MODERN INTELLECTUAL PROPERTY 225-26 (1984).

28. *Id.* at 225-26.

29. With letter licenses the conditions are at least twofold: first, that the biological (and sometimes derivatives of it) be used for research purposes only, and second, that the biological not be transferred to a third party without the consent of the original transferor. In addition, certain licenses explicitly require the transferee to negotiate a further license with the transferor for any other use of the biological.

commercial researcher. Therefore, although the parties have not bargained for the specific terms, they have entered into a contract.<sup>30</sup> The transfer of the biological is ample consideration for the promise by the recipient to abide by the terms of the letter license.

Thus, the letter license has the elements of a binding contract.<sup>31</sup> The real task, then, is to interpret the contract. In applying basic contract law to this particular situation, three issues arise: 1) the material covered by the license; 2) the meaning of the term research; and 3) the intent of the parties.

### A. Material Covered by the License

There is no dispute that the license covers the actual biological material transferred—the very pellet or slant of biological material given by the university to the commercial entity. A problem arises, however, because most biologicals either reproduce themselves spontaneously or may easily be duplicated in a laboratory. These “copies” of the transferred biologicals are the subject of the present controversy; either they are covered by the letter license or they are free from all restrictions.

Any licensing agreement that covers only the originally transferred biological is almost useless to the transferor, because the recipient could easily biologically duplicate the material and use this “new” biological free of any licensing restriction. For a letter license to provide any protection for the university, it must be interpreted by the courts broadly enough to cover exact duplicates of the original material. This is true because cloning a biological is relatively simple compared to developing it in the first place. For example, locating a particular gene and determining its nucleotide sequence is much more difficult than replicating the gene once it has been isolated.

One complication arises, however, when the recipient discovers a previously unknown, but valuable, property of the original biological.

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30. Obviously more is needed for a valid contract: parties capable of contracting, a legal purpose for the contract, and assent between the parties. See generally RESTATEMENT (SECOND) OF CONTRACTS §§ 1, 3, 9, 12, 17, 18, 22 (1982). However all these elements appear to be present in letter licenses.

31. Although at first glance letter licenses may appear to have some of the qualities of adhesion contracts (they are form contracts presented on a take-it-or-leave-it basis), they are not used in a consumer context but between a commercial entity and the university. The commercial entity is always free to decline the offered biological and produce it on its own, or to use a different biological from a less restrictive source.

When the potential product use is unknown, as is usually the case with transfers under a letter license, another material may suffice as well as the proffered biological. If the potential commercial use is known, then the university would probably formally license that use to the commercial entity for a set fee.

The recipient did not create the valuable property, yet the recipient may have expended considerable time and money discovering the property and creating the finished commercial product. In such a case, although the material is physically an exact duplicate of the original biological, the commercial value has been greatly enhanced.

The *Golde* case is illustrative. The University of California claimed a royalty on the grounds that its researchers created the cell line. However, it was Gallo who discovered that the cell line was an interferon producer; Pestka who developed ways to make the cells superproducers; and Genentech's scientists who made the probe and extracted the interferon gene.<sup>32</sup> In the hands of the university, the biological had little commercial value,<sup>33</sup> yet an exact duplicate had commercial value in the hands of Genentech scientists.

An even more difficult issue concerns the limits of protection provided by a letter license when the biological has been changed in the course of the transferee's research, and only the changed biological has a commercial application. Some licenses purport to cover the original material received and "any cells or DNA molecules that are replicated or derived therefrom by the [transferee] or her coworkers."<sup>34</sup> The issue then becomes interpretation of the "derived therefrom" clause.

One suggestion has been to limit the derivatives covered by such licenses to "close" derivatives created by a minor modification of the original material, and to exclude "remote" derivatives which incorporate only an unimportant or publicly available part of the original biological.<sup>35</sup> This test may be helpful at either extreme, but it is of little use in the large middle area where neither party to the agreement can predict with any degree of accuracy where a court might draw the line.

The university's claim becomes still more remote when a spontaneous mutation of the biological occurs after the transfer. At most, the license only purports to cover materials derived from the transferred

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32. See *supra* notes 7-12 and accompanying text.

33. To say that biologicals, when transferred, have no value would be incorrect. The transferee would, in most cases, be willing to pay the university an amount which would reflect the expected value (the value if a commercial product can be developed multiplied by the probability that the transferred biological will lead to that product). However, universities for the most part have not been willing to sell biologicals on this basis. Universities would rather have the chance at large returns preserved through the letter licensing technique. For the remainder of this article, where biologicals are referred to as having no value at the time of transfer, it is understood that they may have this "expectancy value," but that the actual value will be relatively small as compared to the expectancy value.

34. See *infra* app. A, examples 1 & 2.

35. Kelly & Jaworski, *Agreements Covering Exchanges of Biological Material*, 3 TRENDS IN BIOTECHNOLOGY 22 (1985) (presented at AAAS Annual Meeting, May 25, 1984).

materials by the transferee or her coworkers. This language implies that only if human agency, not nature, causes the new material to come into being will the new material be covered. Therefore, if, after a spontaneous mutation, only the new material has a commercially usable property, it appears that the transferee is not restricted by the express terms of the license.

## B. Meaning of the Term "Research"

A second prerequisite to determining how far a letter license extends is the definition of the term "research." In most instances, the transferee first realizes the commercial use or value of the biological when conducting research. Under a literal interpretation, there is no breach of a license before the transferee actually produces a commercial product. Under a more restrictive reading of the term, a breach may occur as soon as the decision is made to attempt to develop a commercial product. This interpretation is unrealistic, however, because a university must realize that a commercial transferee is not doing research merely to satisfy intellectual curiosity. In light of the obvious profit motive of the recipient, any restrictive interpretation of the "research only" clause contradicts the spirit of the letter license.

Thus, the literal language of the license is not determinative of the rights of the parties. Given the informality and sparse language of the letter license, a court will not hesitate to consider extraneous evidence to determine the intent of the parties.<sup>36</sup> This evidence could include custom in the industry.<sup>37</sup>

## C. Intent of the Parties

### 1. Reasonable Expectations

Because of the ambiguities in the express language of letter licenses, courts will need to consider extraneous evidence of the intent of the parties. The general standard of interpretation in contract law is what a reasonable person in the position of the parties would believe the contract to mean.<sup>38</sup> Courts must determine the mutual expectations of the commercial entity and the university at the time the parties entered into the agreement. The university must be held to an awareness that the recipient, a profit-seeking commercial entity, will use the material for

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36. RESTATEMENT (SECOND) OF CONTRACTS § 209 (1982).

37. U.C.C. § 1-205(2) (1976).

38. See *Lee v. State Bank & Trust Co.*, 54 F.2d 518, 521 (1931), *cert. denied*, 285 U.S. 547 (1932). See generally RESTATEMENT (SECOND) OF CONTRACTS § 203 (1982); WILLISTON, CONTRACTS § 603 (3d ed. 1961).

something other than merely satisfying intellectual curiosity. It seems apparent that the university's real desire in transferring the biological is that the recipient will find a commercial use for the material.<sup>39</sup>

By imposing the "research only" restriction, the university is attempting to establish its future rights in products developed from the transferred biologicals. If this is the university's intent, however, the letter license appears to be an "agreement to agree" which would probably be unenforceable.<sup>40</sup>

Moreover, the commercial recipient takes all the risks involved in product development. The recipient will typically invest a substantial amount of time and money in pursuit of a commercial return, in spite of the small chance of success. It is unlikely that under these circumstances the commercial recipient intended to bargain away a share in the profits from commercial development of the biological by accepting the biological under such a general license. Given that the recipient did not intend to relinquish a share of the profits to the university, and that the university merely intended to negotiate in the future, a court should be very reluctant to grant a significant remedy to the university.

## 2. *Custom in the Industry*

A further aid in determining the intent of the parties to a letter license might be custom in the industry. Although the past custom of the university was to transfer biologicals freely without asserting property rights in them,<sup>41</sup> this evidence of prior academic custom is not dispositive of custom in the research "industry" because the industry is an entirely new one. Until recently, little was known about the potential commercial value of biologicals in new product development. Thus, any analysis based on past academic custom in the transfer of biologicals

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39. Of course, the university might simply be attempting to advance pure research by distributing biologicals. However, if that were the case, a letter license would not be necessary. It would be much simpler to promote research by transferring the material free of any purported restrictions.

40. See, e.g., *Transamerica Equip. Leasing Corp. v. Union Bank*, 426 F.2d 273, 274 (9th Cir. 1970); *Yackey v. Pacifica Dev. Co.*, 99 Cal. App. 3d 776, 783, 160 Cal. Rptr. 430, 433 (1979). Agreements to agree have been held to be enforceable where the terms of the contract can be independently determined in the future by reference to commercial practice or other usage or custom. *United States v. Orr Constr. Co.*, 560 F.2d 765, 769 (7th Cir. 1977). For a discussion of the lack of uniform industry customs regarding biological research, see *infra* text accompanying note 41.

In addition, a university may be somewhat naive in hoping that a letter license will induce a commercial entity to negotiate rights in any new products developed from the transferred biologicals. If the new product has a potentially large value, the commercial entity may choose to have a court determine its rights under a vague letter license rather than negotiate large royalties with the university.

41. See *supra* text accompanying notes 22-28.

may be inappropriate to transfers involving commercial enterprises and potentially profitable materials. Until some clear custom develops in this area, reference to trade usage will not help clear up the ambiguities inherent in letter licenses.

#### D. Public Policy

Because of the problems in determining the meaning of the letter license, courts will probably be influenced by public policy considerations. Given the unique function of research universities as disseminators of information, public policy is better served by continuing the custom of transferring biologicals free of restriction. By denying the university's claim to a share of profits derived from transferred biologicals, society will benefit because private researchers will be more willing to accept and use biologicals. As a result, more socially valuable products will be developed.<sup>42</sup> The overall cost of such development to the public will be lower if the commercial researcher is not obligated to pay part of his profits to the university.<sup>43</sup>

The public has an interest in the free flow of ideas. Monopolization of ideas in our society has always been severely limited. However, there are some notable exceptions: novel and non-obvious inventions are subject to patent status;<sup>44</sup> unique expressions of an idea may be copy-rightable;<sup>45</sup> certain proprietary information may be protected under trade secret doctrine.<sup>46</sup> The rationale for intellectual property protection is to provide an incentive for innovation by allowing the creator of a new work to reap some profits from her work.<sup>47</sup>

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42. Perhaps the university is entitled to some of the commercial profits earned in part through its research efforts. At a minimum, it is arguable that more socially valuable products will be developed if the university is reimbursed for its development costs. However, universities are publicly supported and hence have already been provided with such development funds. Furthermore, universities are unlikely to cease doing research so long as public funds are available.

43. It can be argued that the public has already paid for this development by funding the university and should be entitled to a return on that investment. However, most basic research does not lead to commercial products, and is not expected to. Merely because biological materials have commercial potential is no reason for the university (or the courts) to treat them differently, if that treatment impedes the progress of technology in the bioengineering field.

44. See 35 U.S.C. §§ 101, 102 (1982) (novelty and utility); 35 U.S.C. § 103 (1982) (non-obviousness); see generally *Graham v. John Deere Co.*, 383 U.S. 1 (1965).

45. See, e.g., 17 U.S.C. § 117 (1982) (copyright protection for software).

46. See, e.g., UNIF. TRADE SECRETS ACT, 14 U.L.A. 541-51 (1980); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974).

47. See *Orderer, Economic Foundations and Considerations in Protecting Industrial and Intellectual Property*, 53 ANTITRUST L.J. 503, 506-07 (1984).

Genetic materials are in essence a form of information, as well as tangible property, in that they express the genetic code of the particular material. Thus universities are trying, through letter licenses, to get a form of intellectual property protection for the information contained in a biological. Courts should be very reluctant to extend such protection to universities outside the established statutory schemes.<sup>48</sup>

There has been ample indication by statute and public pronouncement that the Federal government has an interest in the continued expansion of technology in the United States.<sup>49</sup> For example, Public Law 96-517, Patent Rights in Inventions Made With Federal Assistance,<sup>50</sup> was enacted to encourage the private sector to develop government supported inventions by granting exclusive proprietary rights to the government's licensee, particularly where that licensee was the developer of the invention.

In many instances, the university has developed the original biological either directly or indirectly with government funds. The university has received substantial government support for its research program, which benefits all the researchers at the university.

Given this prior public support in developing the original biologicals, and the policy expressed by Congress, it is difficult to see how it might be in the public interest for universities to restrict the use of the biologicals by commercial entities. The commercial entity may, because of uncertainty about future liability, choose to redevelop the original biological if possible. The waste of time, resources and energy caused by duplication of this sort is obvious. In addition, if duplication of the biological is impossible and no substitute materials (not subject to the licensing restrictions) are available, the commercial entity may entirely abandon the use of the material, thereby foreclosing a potentially valuable project that could ultimately benefit society. Commercial recipients should therefore have limited, if any, liability to the university/transferor, even if the transferred material eventually leads to a commercial product, when the product has applications which benefit the general public.<sup>51</sup>

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48. For a discussion of the applicability of statutory intellectual property protection to biologicals, see *infra* text accompanying notes 94-115.

49. See, e.g., U.S. CONST. art. I, § 8, cl. 8; *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

50. Patent Rights in Inventions Made With Federal Assistance, ch. 18, 96 Stat. 816 (1982) (transferred from ch. 38, 94 Stat. 3019) (codified as amended at 35 U.S.C. §§ 200-221 (1981 & 1985)).

51. Of course, there is the countervailing public policy of providing economic support to the educational system. If the commercial use of biological materials could provide revenues to fund further research, this policy might also be a consideration. However, in the absence of a more specific licensing agreement providing for the university to

In summary, if the letter license is enforceable, it should be restricted to cover the actual material transferred, and even exact duplicates of the material created by cloning or culture. If the recipient sells such materials it has obviously used the transferred biological for a purpose not contemplated by the phrase "research purposes only" and a breach of the contract has taken place. However, any further restriction would appear to be unwarranted under general principles of contract law and public policy. Thus, if the recipient changes the material, or if the material changes by itself, or if the recipient discovers some previously unknown property of the material which has commercial application, the university should not have a claim to a share of the recipient's profits.

It is simply not practical for the university to rely on vague terms like "research purposes only" and "derivatives" when a more detailed agreement could be used. The university can no longer rely on the informal traditions of scientific exchange. If the university expects the courts to protect its rights, it must make those rights clear in the license.

### III. BIOLOGICALS AS PERSONAL PROPERTY

Apart from the rights in biologicals created by contract, the actual cell line or culture transferred is also tangible property. The biological can be owned by an individual or other legal entity, and its transfer can trigger common law doctrines dealing with the transfer of tangible property, such as bailment, accession, and specification. These doctrines may provide the original owner of the biological with rights in the property distinct from those rights determined under a contract analysis of the letter license.

#### A. Bailment

The transfer of a biological to a commercial entity under a letter license could be considered a bailment.<sup>52</sup> Under basic common law principles, the right of a bailee to use the bailed property ordinarily depends upon the bailment contract. Where the contract specifies a particular kind of authorized use, any other use is improper.<sup>53</sup>

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share in future profits, this policy of supporting further research should not be sufficient, by itself, to give the university significant rights in the developed product.

52. A bailment is a contractual relationship consisting of the delivery of a tangible property in trust for a special object or purpose, upon a contract, express or implied, to conform to the object or purpose of the trust. *Sturm v. Boker*, 150 U.S. 312, 329-30 (1893). See also R. BROWN, *THE LAW OF PERSONAL PROPERTY* § 10.5 (3d ed. 1975).

53. *First State Bank of Monroe v. Connoley*, 131 Va. 479, 481, 109 S.E. 301, 303 (1921) (citing *Walker v. Smith*, 4 U.S. (4 Dall.) 389 (1804)).

A bailment requires all of the elements of binding contract, including assent, consideration and legality.<sup>54</sup> Assuming that a letter license is sufficiently specific to be a valid contract,<sup>55</sup> the basic elements of a binding contract are present. In addition, it is essential that the duties and obligations of a bailee be voluntarily assumed.<sup>56</sup> However, a bailment may arise constructively, may be implied from the circumstances of the possession,<sup>57</sup> or may occur by operation of law.<sup>58</sup> Usually, the bailee must return or account for the identical bailed object or the product thereof, or substitute for that object, together with all increments and gains, when the use to which it is to be put is completed or performed or the bailment has otherwise expired.<sup>59</sup> A bailee who uses bailed property for purposes other than the trust is a convertor.<sup>60</sup> In the event of a commercial use of a biological by the recipient under a letter license, the university may be able to maintain a cause of action under a theory of conversion.<sup>61</sup>

To determine whether the law of bailment applies to the transfer of biologicals, the initial question to be asked is whether a letter license creates a bailment contract. It appears that neither party to a letter

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54. *Barnett v. Casey*, 124 W. Va. 143, 145, 19 S.E.2d 621, 623 (1942).

55. See *supra* notes 30-31 and accompanying text.

56. *H.S. Crocker Co. v. McFaddin*, 148 Cal. App. 2d 639, 307 P.2d 429 (1957); *Stuart v. D.N. Kelly & Sons*, 331 Mass. 76, 78, 117 N.E.2d 160, 162 (1954).

57. *Gordon H. Ball, Inc. v. Parreira*, 214 Cal. App. 2d 697, 29 Cal. Rptr. 679 (1963); *Barnett*, 19 S.E.2d at 623; *Continental Ins. Co. v. Harrison County*, 153 F.2d 671, 676 (5th Cir. 1946).

58. For example, a bailment is implied where there is an involuntary deposit, or upon the finding of lost property. See *Foster v. Fidelity Safe Deposit Co.*, 264 Mo. 89, 174 S.W. 376 (1915) (lost property found in bank imposes duty of bailee on bank, not finder); *Foulke v. New York Consol. Ry. Co.*, 228 N.Y. 269, 127 N.E. 237 (1920) (leaving package in bailed car does not amount to losing the package, but does amount to an involuntary deposit for care of bailee); *Copelin v. Berlin Dye Works & Laundry Co.*, 168 Cal. 715, 721, 144 P. 961, 963 (1914) (involuntary deposit defined as accidental placing or leaving of personal property in the possession of any person, without negligence on the part of the owner of the property).

59. *H.S. Crocker Co.*, 148 Cal. App. 2d at 644; *Woodbarn Bros. v. Erickson*, 230 F.2d 240, 243 (10th Cir. 1956); *Perkins v. Meeker Sugar Ref. Co.*, 163 La. 227, 230, 111 So. 686, 689 (1927).

60. See, e.g., *Irvine v. Wilson*, 137 Cal. App. 2d Supp. 843, 289 P.2d 895 (1955); *Good v. Harris*, 207 Ala. 357, 92 So. 546 (1922); *Monarch Buick Co. v. Kennedy*, 183 Ind. App. 1, 3, 209 N.E.2d 922, 924 (1965); *Raynor v. Sheffler*, 79 N.J.L. 340, 75 A. 748 (1910).

61. See, e.g., *Hollywood Motion Picture Equip. Co. v. Furer*, 16 Cal. 2d 184, 105 P.2d 299 (1940) (bailee of wooden patterns to be used to make castings for the plaintiff only, made castings from them for third parties); *Hillhouse v. Wolf*, 16 Cal. App. 2d Supp. 833, 834, 333 P.2d 454, 455 (1958) (bailee of farming equipment used it on own farm); *Knight v. Seney*, 290 Ill. 11, 124 N.E. 813 (1919) (bailee to sell securities on instructions from bailor, instead sold some and used others to secure own transactions without delivering proceeds to bailor).

license intends to create a bailment because the license does not expressly create a bailment contract, though it easily could do so. The terms of the license do not mention bailment; they only purport to restrict the recipient to research uses of the biological. Although a loan for use is a bailment,<sup>62</sup> there is no indication in the letter license that the university is making a loan. The university does not expect the transferee to return either the original biological material, or, more importantly, the product produced from it.

Of course, it is unlikely that the university wants the original biological material returned. It already has the original material (and can easily replicate it *ad infinitum*), but that material is generally of limited value in the marketplace.<sup>63</sup> The only property the university would possibly want returned is the changed biological material, which it could then transfer at a profit to enterprises in competition with the original transferee.

Thus, under a bailment theory, the court must deal with the problems which result from changes in the material after the transfer. The biological which was originally bailed need not necessarily be the biological which was used for commercial purposes. Rather, the commercial material could be the progeny or a replication of the original biological, or, more likely, a derivative of the original material created by the efforts of the recipient. If so, the commercial product may not be subject to the bailment at all.

In some jurisdictions, however, statutes provide that the bailor retains title in all increases to the bailed material.<sup>64</sup> In other jurisdictions, the case law pertaining to domesticated animals provides that the owner of the mother is the owner of the progeny.<sup>65</sup> Further, the increase of the increase *ad infinitum* comes under the rule.<sup>66</sup>

The problem is how far this statutory and common law rule of increases or progeny should be carried in the context of biologicals. The rule could easily apply to the replication of the original material,<sup>67</sup> but this material usually has no commercial value to the university. It is less

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62. A loan for use is a contract by which one gives to another temporary possession and use of personal property and the latter agrees to return the same thing at a future time without reward for its use. *People v. Cannon*, 77 Cal. App. 2d 678, 176 P.2d 409 (1947); CAL. CIV. CODE § 1884 (West 1985).

63. *See supra* note 33.

64. This might include growing timber or crops that are bailed. *See, e.g.*, CAL. CIV. CODE § 1885 (West 1985).

65. *Arkansas Valley Land and Cattle Co. v. Mann*, 130 U.S. 67, 78 (1889). *See also* 2 W. BLACKSTONE, COMMENTARIES 390 (1758).

66. *Carruth v. Easterling*, 247 Miss. 364, 367, 150 So. 2d 852, 855 (1963).

67. Replication could be accomplished in culture or by cloning.

easy to apply the rule to derivative materials where they have been changed considerably by the researcher.

Bailment law contemplates such a change. One can bail grapes in expectation of the return of wine,<sup>68</sup> or wheat in expectation of flour.<sup>69</sup> In such cases, however, the bailee is paid for his labor in the transformation.<sup>70</sup> Here, the university has paid nothing for the transformation of its biological into a commercial product, apart from the original grant of the material. This hardly seems to be a situation contemplated by the law governing bailments of changed materials. Given these strained analogies, and given that neither party appears to have intended a bailment, any bailment analogy in the context of a transfer under a letter license should be limited to a return of the actual transferred material, or better, yet not used at all.

## B. Accession

The doctrine of accession provides that if materials owned by A and B are united by the labor of B, who also furnished the principal materials, title to the newly created property vests with B by accession.<sup>71</sup> To obtain title by accession, B must have acted in good faith and have exercised due care in ascertaining who had title to the other part.<sup>72</sup>

The doctrine of accession would apply to biologicals only when the newly-created product cannot be separated from the original biological without destroying the value of each. For example, when the original material has been substantially changed, as where a hybridoma cell line is created using the myeloma cell line of the transferor and the lymphocytes of the recipient, it would be difficult to separate the two different cells again.<sup>73</sup> The opposite situation would occur, for instance, when a promoter sequence obtained from the transferor is linked to a structural gene of the recipient using a conventional restriction-ligation procedure. Since the two sequences could be separated by the same restriction enzyme used to create the material, the doctrine of accession would seem not to apply.<sup>74</sup> Where the newly created material cannot be separated into its component parts, the difficult problem is deciding which is the principal contribution to the commercial product: the original biological

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68. *Powder Co. v. Burkhardt*, 97 U.S. 110, 116 (1878).

69. *Foster v. Pettibon*, 7 N.Y. 433, 11 A. 893 (1852).

70. *Capitol Chevrolet Co. v. Earhart*, 627 S.W.2d 369, 371 (Tenn. App. 1981) (citing *Dunn v. O'Neal*, 33 Tenn. 106, 110 (1853)).

71. *Id.*

72. *Id.* at 372.

73. I. COOPER, *supra* note 22, § 11.03 at 11-43.

74. *Id.* at 11-48.

material supplied by the university, or the money and labor expended, and other biological materials added, by the recipient.<sup>75</sup>

Courts have indicated that labor may be the overriding factor in determining which is the principal contribution to the finished product.<sup>76</sup> However, this analysis can be problematic for the transfer of biologicals because even a minimal contribution of labor may actually account for most of the commercial value of the end product. For example, where, as with the KG-1 cell line, the commercial value of the biological material is inherent in the transferred material and exists at the time of the transfer, a very small contribution of expertise and labor may reveal the commercially viable aspect of the biological. Similarly, a major investment of labor and time may yield little in terms of a lucrative, saleable product. The time and labor expended in the development of biologicals need not correspond to the value of the resulting contribution to the final product.

Furthermore, there is a valuation problem when trying to compare the parties' contributions directly. The university will usually be transferring the biological at a time when it has no certain market value. It will probably be at an early stage of development which might or might not ultimately lead to a commercial product. The material may be a particular clone of a genomic library, or a vector with valuable markers which permits the selection of cells that receive the vector. In most cases, the marketplace would put little value on the material at the time of transfer because it would have no known application.<sup>77</sup>

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75. Historically, the test for deciding which was the principal element was which element gave its name to the product. Jewels acceded to the ring in which they were set, and thread acceded to the garment into which it was woven. J. THOMAS, *TEXTBOOK OF ROMAN LAW* 170 (1976). See also I. COOPER, *supra* note 22, § 11.03 at 11-54. Of course this is an arbitrary test, and in the context of biological materials not very helpful. It is obviously very unclear which biological material (if any) will give its name to the new product. At least one state has codified this doctrine in an attempt to provide a specific answer to the question of what constitutes the principle part. The California Civil Code defines the principal part as:

[that part] to which the other has been united only for the use, ornament, or completion of the former, unless the latter is the more valuable, and has been united without the knowledge of its owner, who may, in the latter case, require it to be separated and returned to him, although some injury should result to the thing to which it has been united.

CAL. CIV. CODE § 1026 (West 1982).

76. See, e.g., *Sound/City Recording Corp. v. Solberg*, 443 F. Supp. 1374 (W.D. La. 1978) (contributions of musicians and technicians to a recorded vocal performance acceded to the contribution of the singer based on their respective labor contributions); *Hamilton v. Rock*, 121 Mont. 245, 191 P.2d 663 (1948) (one who in good faith converts grass into hay accedes to the hay based on the labor of cutting it); *Smith v. Schneider*, 31 Wis. 420 (1872) (regardless of willful trespass, the cutter of logs who transforms them into lumber retains right to the lumber, and is obligated to pay the original owner only the value of the uncut timber). See also I. COOPER, *supra* note 22, § 11.03 at 11-52.

77. See *supra* note 33.

Hence, the values of the transferor's and transferee's respective contributions are difficult to determine by either a time and labor standard or a market value standard. Usually, however, the biological material as received from the university will be only a small part of the value contributed to the final commercial product. Where the recipient has clearly contributed the most value in either labor, money or other biologicals, the recipient may be confident that title will remain with him under the doctrine of accession.

Where a determination of the principal contribution is unclear, the license should be interpreted against the university as the drafting party.<sup>78</sup> For each product, there are costs associated with the university's development of the biological. The university can reasonably condition the transfer on reimbursement of those costs, or can explicitly state that all future products will be the property of the university. If the university chooses not to do these things, and instead transfers under a restrictive license, the university will have to bear the burden of the ambiguity under the accession doctrine.

### C. Specification

Under the related doctrine of specification, one who innocently creates a wholly new thing out of materials belonging to others acquires title to the finished product.<sup>79</sup> Examples include the conversion of corn into meal, grapes into wine, rock into lime, and rye into whiskey.<sup>80</sup> American case law dealing with specification is unclear. Yet, courts have held under property law doctrine that where timber has been converted into boards<sup>81</sup> or charcoal,<sup>82</sup> grass cut and made into hay,<sup>83</sup> or cucumbers converted into pickles,<sup>84</sup> there has not been enough of a change of identity to cause title to pass.

The distinction as to what amount or kind of change triggers the doctrine of specification is obviously obscure. Perhaps the clearest American opinion on specification is *Lampton's Executors v. Preston's Executors*,<sup>85</sup> in which Lampton had innocently fired Preston's clay into

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78. *North Gate Corp. v. Nat'l Food Stores*, 30 Wis. 2d 317, 140 N.W.2d 744 (1966); E. FARNSWORTH, CONTRACTS § 7.11 (1982).

79. *Lampton's Ex'rs v. Preston's Ex'rs*, 24 Ky. (1 J.J. Marsh.) 454, 19 Am. Dec. 104 (1829); *Bozeman Mortuary Assoc. v. Fairchild*, 253 Ky. 74, 68 S.W.2d 756 (1934).

80. *Lampton's Ex'rs*, 24 Ky. (1 J.J. Marsh.) at 462.

81. *Davis v. Easley*, 13 Ill. 192 (1851); *Brown v. Sax & Kimble*, 7 Cow. 95 (N.Y. 1827).

82. *Riddle v. Driver*, 12 Ala. 590 (1847); *Curtis v. Groat*, 6 Johns. 168, 5 Am. Dec. 204 (N.Y. 1810).

83. *Murphy v. S.C. & P.R. Co.*, 55 Iowa 473, 8 N.W. 320 (1881).

84. *Crosby v. Baker*, 88 Mass. (6 Allen) 295 (1863).

85. 24 Ky. (1 J.J. Marsh.) at 455.

bricks. The court initially followed the Roman Rule of Justinian which states that if, after modification, the product can be returned to its original state, title to the new product remains with the owner of the original material.<sup>86</sup> However, on rehearing, counsel for Lampton disputed the decision and the Rule of Justinian, proposing instead an equitable rule based on the value of the labor involved in creating the product compared to the value of the raw materials.<sup>87</sup> Before this petition could be decided, the members of the court resigned, and the new court of appeal granted the petition.

Judge Robertson, delivering the opinion for the new court, rejected the proposed test of relative values as being too overreaching and not in conformity with existing precedents. Instead, he proposed the following test:

[I]f the material be so essentially changed as to prevent its renovation, by individual agency, the owner has lost his right to it; and . . . if the elements of the material have not been changed, but the specific thing which they constituted cannot be reproduced — identically, by individual operation, the owner of the material does not own the new species.<sup>88</sup>

Judge Robertson attempted in this way to distinguish the conversion of grapes into wine or corn into meal, from the conversion of timber into planks or silver bullion into a cup or spoons.<sup>89</sup> Thus, when the identity of the thing has changed but the material from which it is composed remains the same, title does not pass under the doctrine of specification. It is only when the new thing has none of the inherent qualities of the original material that title will pass by specification.

In the context of biological materials, it appears that title to the commercial product may be retained by the recipient/developer when the characteristics or qualities of the original biological material are substantially changed. Such a situation might occur where mutations, either naturally occurring or induced, cause such a significant change in the characteristics that the original biological can no longer be recovered. A different outcome would occur if the researcher were to discover a property inherent in the original biological material, such as the overproduction of interferon in the KG-1 cell line. In that case, there would seem

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86. *Id.*; T. COOPER, THE INSTITUTES OF JUSTINIAN WITH NOTES, BOOK II, TITLE I, § 25 at 75-76 (1812).

87. *Lampton's Ex'rs*, 24 Ky. (1 J.J. Marsh.) at 457.

88. *Id.* at 464 (emphasis in original).

89. In the case of meal or wine, they have been "converted . . . into something specifically different in the inherent and characteristic qualities, which identify it." *Id.* at 462. By contrast, in the case of planks or silver cups, there has been "a modification of a material of one man, by the operations of another, as to change its name and its specific identity, or individuality, without a mutation of its original qualities and ingredients." *Id.* at 463.

to be no change in the characteristics of the original biological material. Indeed, the very characteristic that gave the biological material its commercial potential had always been present, and the recipient did nothing to change the material to produce this characteristic. Given these facts the doctrine of specification will not transfer title to the recipient.

#### D. Willful Trespass

To qualify under the doctrines of accession and specification, the recipient must meet one further criterion: there must not have been a willful trespass when the recipient acquired the original biological.<sup>90</sup> A willful trespasser cannot claim any right in the property no matter how great the labor invested.<sup>91</sup> The trespass is considered willful only when the trespasser has committed an intentional taking or a taking committed under such circumstances as to impute malice.<sup>92</sup>

Thus, when a commercial recipient utilizes a transferred biological in the development of a commercial product, title will only pass if the trespass was not willful. As noted above,<sup>93</sup> regardless of the restriction in the letter that the material be used for "research purposes only," both parties impliedly intend that a commercial product be the outcome of the research. Therefore, the commercial entity cannot be held responsible as a willful trespasser when it creates such a product, as both parties intended that result.

In addition, public policy would argue in favor of granting the commercial recipient greater access to the transferred biological. As part of its investigation, the commercial entity may have uncovered new insights and developed useful new technology. In many instances, the commercial entity will publish the work, making these insights available to the research community at large. The commercial entity will have furthered the purpose of the university by expanding the knowledge about the biological material. From the standpoint of the public, there is a clear interest in encouraging a commercial entity to utilize university-developed biological materials for further development and in disclosing such developments.

Thus, where the restriction is ambiguous, there is a reasonable basis for arguing that there was no willful trespass. The sole exception would be where the commercial entity directly sells the original biological

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90. *Union Naval Stores Co. v. United States*, 240 U.S. 284 (1916).

91. *Burroughs v. Garrett*, 67 N.M. 66, 352 P.2d 644 (1960); *Kirby Lumber Co. v. Temple Lumber Co.*, 125 Tex. 284, 83 S.W.2d 638 (1935).

92. *E.E. Bolles Wooden Ware Co. v. United States*, 106 U.S. 432, 433 (1882); *Kirby Lumber Co.*, 83 S.W.2d at 646.

93. See *supra* text accompanying notes 39-40.

material to a third party. In that case, it might be reasonable to consider such a blatant violation of the terms of the letter license tantamount to a willful trespass, because there would be no ambiguity about what material the license applied to, and no doubt that the original biological material was used for something other than research.

#### IV. BIOLOGICALS AS INTELLECTUAL PROPERTY

Biologicals, although they are tangible property, have many of the qualities of intellectual property. They are usually produced only with the help of a substantial amount of time, expense and ingenuity; once produced, they can be readily reproduced at a substantially lower cost; and, each possessor can enjoy the benefits of the biological without interfering in the enjoyment of other possessors. It is therefore likely that a university will try to rely on the various intellectual property doctrines for protection of their rights in transferred biologicals. The doctrines most likely to be used in this context are those of patent and trade secrets.<sup>94</sup>

##### A. Patent Protection for Biologicals

Recent developments in patent law indicate that biological materials are patentable. The Supreme Court, in *Diamond v. Chakrabarty*,<sup>95</sup> held that a man-made, genetically engineered bacterium constitutes a "manufacture" or "composition of matter" within the meaning of the utility patent statute.<sup>96</sup> However, *Chakrabarty* dealt with a microorganism. The Patent and Trademark Office has said that it will now accept and examine applications covering plants under 35 U.S.C. § 101.<sup>97</sup> Extension of patent protection beyond microorganisms to include any genetically engineered organisms appears to be a logical step.<sup>98</sup>

Even though biologicals are patentable and thus any license restrictions associated with the patent are enforceable, this does not provide an

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94. At one time it was suggested that DNA sequences might be the proper subject of copyright. See Kiley, *Learning to Live With the Living Invention*, 7 A.P.L.A.Q.J. 220, 233-34 (1979); Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH L. REV. 191 (1982). However, there is a lack of current support from commentators. See I. COOPER, *supra*, note 22, § 11.02; Goldstein, *Copyrightability of Genetic Works*, 2 BIO/TECHNOLOGY 138 (1984). This lack of support, together with the absence of litigation on the subject, suggests that copyright would not be a viable alternative to the other forms of intellectual property protection available for biologicals.

95. 447 U.S. 303, 318 (1980).

96. 35 U.S.C. § 101 (1982).

97. Hamburg, *Patentability of Living Multicellular Life Forms*, 81 PAT. & T.M. REV. 28, 29 (1983).

98. See Ihnen, *Patenting Biotechnology: A Practical Approach*, 11 RUTGERS COMPUTER & TECH. L.J. 407 (1985); I. COOPER, *supra* note 22, at § 2.07.

adequate solution to the university's problem of protecting its interests in the many biologicals it transfers to private researchers. Obtaining a patent is an expensive and time-consuming process. Because, in most cases, the biological that is transferred under a letter license has no known market value, it is very unlikely that the university will attempt to patent such a material.

In addition, the biological can be replicated and transferred numerous times while approval of the patent is pending. A product developed from such a material can be sold on the market and profits reaped long before the original biological is granted patent status. Moreover, the patent claims may not extend to the commercial product or process.<sup>99</sup>

In summary, because of the expense and delay involved in obtaining a patent, the use of patent protection would seem to be of little practical use to the university in trying to protect any rights they might have in transferred biologicals.

## B. Biologicals as Trade Secrets

As an alternative to intellectual property protection under patent law, it might be possible for the university to protect transferred biologicals under the law governing trade secrets.<sup>100</sup> For a cause of action based on this doctrine to be successful, the trade secret must, at a minimum: (1) be secret,<sup>101</sup> and (2) be valuable<sup>102</sup> or provide a competitive advantage.<sup>103</sup>

While biologicals are tangible property, they do have some of the attributes of trade secrets. Biologicals can be enjoyed by an infinite number of people without interfering with the enjoyment by others. Although no one may have exclusive use of a biological once it is widely disseminated, each recipient may still enjoy use of the material independently from any other recipient's use.

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99. See Inhen, *supra* note 98, at 421.

100. "Trade secret means information, including a formula, pattern, compilation, program, device, method, technique, or process that: (1) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." UNIF. TRADE SECRETS ACT, 14 U.L.A. § 1(4) (1980).

101. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 475 (1973).

102. While the Restatement requires that value be established by continuous use in the business, RESTATEMENT (FIRST) OF TORTS § 757 comment b (1939), some courts have rejected this analysis and have required only that the trade secret be of value to the company. See, e.g., *Syntex Ophthalmics, Inc. v. Tsuetaki*, 701 F.2d 677, 219 U.S.P.Q. 962 (7th Cir. 1983). See generally M. JAGER, TRADE SECRETS LAW (1985).

103. UNIF. TRADE SECRETS ACT, *supra* note 100, at § 1(4).

Trade secret protection is not limited to ideas.<sup>104</sup> Microbiological cultures<sup>105</sup> and corn hybrid lines<sup>106</sup> have been found to be trade secrets. Courts have held that a cause of action arises where the manifestation of a trade secret is wrongfully acquired.<sup>107</sup> As in the *Golde* case, the university might claim a right in any products developed from the transferred biological material, under a theory of conversion of trade secrets.

### 1. *Secrecy*

The initial and most difficult hurdle facing the university under trade secret doctrine is secrecy itself. Although a trade secret may be considered secret even though it has been transmitted to a large number of people,<sup>108</sup> it appears that universities do not act in a manner consistent with a claim of secrecy.

It is the custom in academia for recipients to give to colleagues, particularly those in the same institution, biologicals which have been received from other investigators, even when the recipients have been requested not to do so without the approval of the original transferor. Such customs are not easily dispensed with among academicians, where acceptance by the scientific community is all-important. Therefore, once a biological is made available to academicians and commercial entities, there will, within a relatively short time, no longer be an accurate list of the possessors of the biological. This would be an adequate defense to a cause of action for conversion of trade secrets.<sup>109</sup>

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104. 12 R. MILGRIM, BUSINESS ORGANIZATIONS, MILGRIM ON TRADE SECRETS § 2.01 (1985).

105. *American Cyanamid Co. v. Fox*, 140 U.S.P.Q. (BNA) 199 (N.Y. App. Div. 1964).

106. *See Pioneer Hi-Bred Int'l v. Halden's Found. Seeds, Inc.* 105 F.R.D. 76 (N.D. Ind. 1985). Although this is a decision denying a motion to compel discovery against a non-party, the underlying cause of action is for misappropriation of inbred seed representing the plaintiff's trade secret. Many seed companies customarily use trade secret doctrine to protect inbred lines because first generation hybrids are not protectable under the plant patent statute.

107. *Hancock v. Decker*, 379 F.2d 552 (5th Cir. 1967) (photocopy of computer program stolen); *U.S. v. Bottone*, 365 F.2d 389 (2d Cir. 1966), *cert. denied*, 385 U.S. 974 (1966) (photocopy made of notes of documents containing a secret drug manufacturing process).

108. For example, a plurality of licensees may agree to keep the trade secret in confidence without divulging the secret nature of the subject matter. *See Data General Corp. v. Digital Computer Controls, Inc.*, 297 A.2d 433 (Del. Ch. 1971), *aff'd*, 297 A.2d 437 (Del. 1972) (distribution of 6000 computer maintenance manuals with a suitable "confidential" legend did not bar trade secret protection for the computer); *Management Science of Am., Inc. v. Cyborg Sys., Inc.*, 1977-1 Trade Cas. (CCH) ¶ 61,472 (N.D. Ill. June 10, 1977) (distribution of software to six hundred licensees under confidential restraints did not, as a matter of law, constitute widespread public knowledge of the software sufficient to terminate trade secret protection).

109. *See Packard Instruments, Inc. v. Reich*, 89 Ill. App. 3d 908, 41 N.E.2d 617 (1980).

In addition, the university and its faculty members often publish information about newly-created biologicals, including instructions on how to create such materials and descriptions of the materials' unique characteristics. Indeed, the pressure to publish is so strong that most academic researchers try to publish at the earliest opportunity.<sup>110</sup> General publication of information regarding the traits of biologicals would also be a defense to any action for conversion of trade secrets.<sup>111</sup> Even if the university were to prevail on the secrecy point, it would face difficulty with the remaining elements of the trade secret doctrine.

## 2. Value or Competitive Advantage

There are two basic doctrines regarding the usefulness which a trade secret must have in order for its owner to get protection. In some jurisdictions, the owner must simply derive a value from owning the secret.<sup>112</sup> In most jurisdictions, however, the owner must gain a competitive advantage from the secret.<sup>113</sup>

The university might meet the value requirement of trade secret law if it knew at the time of the transfer that the biological had certain unique and valuable characteristics.<sup>114</sup> However, most of the biologicals that the university transfers have no known value at the time of transfer. If they did, the university would either sell or license them for a specified amount representing the value at the time of the initial transfer. By transferring the biological without any payment, the university is implicitly admitting that the biological has no discernible value at that time.

Fulfilling the requirement of competitive advantage is still more difficult for a university operating within an academic context. In the business of creating and selling products, the commercial recipient in most cases and not the university enjoys any competitive advantage from the trade secret. It is possible that a court might find that the university has a competitive advantage in the technology licensing market by providing biologicals. However, this would require an unreasonable extension of the concept of competitive advantage in order to bring the university within the doctrine.

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110. See *supra* text accompanying notes 22-28.

111. See, e.g., *Timely Prod. Corp. v. Arron*, 523 F.2d 288, 304 (2d Cir. 1975); *Gallo v. Norris Dispensers, Inc.*, 445 F.2d 649 (8th Cir. 1971).

112. See, e.g., CAL. CIV. CODE § 3426.1(d) (West Supp. 1986).

113. See, e.g., *Data General Corp.*, 297 A.2d at 436.

114. RESTATEMENT OF TORTS § 757 Comment b, (1939) ('Value' means the owner has "an opportunity to obtain an advantage over competitors who do not know or use [the trade secret].").

In summary, trade secret analysis does not seem to offer a reasonable basis upon which to predicate a cause of action for the university. Whereas the requirements of trade secret protection are secrecy and value or competitive advantage, the university rarely keeps the secret and does not use it to create or sell products or services.<sup>115</sup>

## V. REMEDIES

If a university were to prevail on one or more of the previously discussed theories of liability, a court would have to fashion an appropriate remedy. This section of the article addresses various types of available remedies, and points out problems the court will encounter in applying them.

Remedies could be fashioned on the basis of two basic theories of liability: breach of contract and misappropriation or conversion of property. Under a contract theory of recovery, the university could be granted an injunction.<sup>116</sup> Under property law, the measure of damages depends upon which property theory of recovery was used. If the doctrines of bailment, accession or specification formed the basis of recovery, the remedy would be based on an analogy to the more traditional cases under those theories. If trade secret doctrine formed the basis of recovery, two measures of damages might be used: the unjust enrichment to the recipient, measured by the value of the transferred material, or the amount of loss suffered by the university due to the misappropriation.<sup>117</sup>

### A. Injunction to Remedy Breach of Contract

The restriction on use to "research purposes only" can be considered a negative covenant. When a license containing only a negative covenant has been breached, an injunction may be appropriate.<sup>118</sup>

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115. Of course, trade secret analysis can be used even if all the doctrinal elements are not fulfilled, if such analysis provides a reasonable framework in which to consider the transfer of biologicals. Without a "tighter fit", however, between trade secret protection and the unique position of the university, or a lack of other ways for the university to protect its rights in biological material, courts are not likely to consider conversion of a trade secret to be a reasonable basis for liability.

116. A monetary award would seem to be precluded by the fact that the letter license does not provide the university with an expectancy of remuneration for the transfer. Unless a court were to find an enforceable agreement to agree, *see supra* note 40 and accompanying text, the license does not contemplate a payment of money, and therefore the university cannot have an expectancy of a monetary return. If a court were to find that there was a binding agreement to agree, the expectancy remedy would probably be a reasonable royalty. *See infra* note 136 and accompanying text.

117. *See, e.g.,* University Computing Co. v. Lykes-Youngstown Corp., 504 F.2d 518 (5th Cir. 1974).

118. 12 Am. Jur. 2d *Injunctions* § 87 (1969) ("There is no doubt as to the availability

However, an injunction is an equitable remedy and thus is a discretionary one.<sup>119</sup> It would be inappropriate for a court to grant an injunction against the transferee under a letter license.

It is likely that both parties intended or at least hoped that the recipient's research would result in a commercial product, and that this product would be sold for profit. Yet, the university never participated in any of the risks of this venture, except to the extent it provided the valueless biological material. Moreover, the university possibly even took actions, following its mandate to disseminate ideas freely, that were harmful to the transferee's commercial venture by providing the same biological material to potential competitors.<sup>120</sup> Since a party seeking an equitable remedy must himself "do equity,"<sup>121</sup> the attempt to foreclose the commercial entity's work through an injunction is inimical to the very goal the injunction would serve: to preserve the universities bargaining power upon negotiation of a formal license. Because of this "dual position" which the university necessarily would be urging, a court should not grant an injunction.

## B. Damages Under Property Theories

### 1. Conversion

Under a conversion theory in the context of a bailment, the converter is per se liable for the value of the converted property once the bailor has shown use of the property outside of the bailment contract which constitutes a violation of the terms of the bailment. If the bailee is a converter, the normal measure of damages is the value of the property at the time of conversion.<sup>122</sup> Once again there is a valuation problem: what is the original biological material worth?

It would be inappropriate to hold the recipient liable for the full cost of developing the original material for two reasons. First, in some cases the property returned need not be precisely the same property that is bailed. For instance, certificates of stock in a corporation are treated differently than other forms of personal property because each certificate is fungible with the others. If the bailee is at all times willing to transfer

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of [an injunction] to prevent a violation of an express negative covenant in a contract, and the relief is sometimes granted even in the absence of such a covenant.").

119. *Shaver v. Heller & Mertz Co.*, 108 F. 821 (8th Cir. 1901).

120. Letter licenses are seldom licenses for exclusive use. As the biological material usually has no ascertainable value, the university will license it to any qualified researcher.

121. *Carmen v. Fox Film Corp.*, 269 F. 928 (2d Cir. 1920).

122. *Sturges v. Kieth*, 57 Ill. 451, 460 (1870); *Jones v. Morgan*, 90 N.Y. 4, 12 (1882); *Baxter v. Woodward*, 191 Mich. 379, 385, 158 N.W. 137, 139 (1916).

to the bailor an equivalent number of shares in the same company, he is only liable, if at all, for nominal damages.<sup>123</sup> The same result should apply to the return of biologicals. If the recipient gives back the same quantity of the original biological, it should not be liable for any further damages under a conversion theory.

Second, the biological usually has no readily ascertainable market value when transferred. If it becomes valuable, it is due to the recipient's effort and expense. Generally, a bailee is only liable for the value of the bailed property at the time it was bailed, plus legal interest from the date of conversion.<sup>124</sup> Thus, even though both parties may have anticipated commercial development, the most the recipient will be liable for is the value of the biological foreseeable at the time of the bailment. In most cases, that value would be indeterminate.<sup>125</sup>

If a court finds that title to the biological rests with the university under the doctrines of accession and/or specification, the university, as title-holder, would most likely recover one hundred percent of the profits from the biological.<sup>126</sup> Another possible remedy under accession could be the value of the output of the property which was lost by the university.<sup>127</sup> Under this measure of damages, the university would also recover the entire value of the output from the commercial product developed by the transferee.

Even if the recipient were adjudged an innocent trespasser under accession or specification doctrine, the recipient might be required to reimburse the transferor for its labor and materials.<sup>128</sup> Moreover, even where the recipient is found to be a nonmalicious, willful trespasser, there may be reimbursement, since the recipient is denied a right to a windfall.<sup>129</sup>

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123. *Richardson v. Shaw*, 209 U.S. 365, 379 (1908).

124. *Hale v. Barrett*, 26 Ill. 195, 200 (1861); *Schwerin v. McKie*, 51 N.Y. 180, 187 (1872); *Mims v. Hearon*, 248 S.W.2d 754, 758 (Tex. App. 1952).

125. The value is nominal because the material has no known use at the time of the transfer. It merely has the potential (like many other biologicals) to be useful in the development of a new product. Unless and until someone develops a product using the biological, the biological has little market value. See *supra* note 33.

126. See *e.g.*, *E.E. Bolles Wooden Ware Co. v. United States*, 106 U.S. 432, 434 (1882); *Guffey v. Smith*, 237 U.S. 101, 119 (1915); *Lightner Min. Co. v. Lane*, 161 Cal. 689, 704, 120 P. 771, 777 (1912); *Foster v. Weaver*, 118 Pa. 42, 52, 12 A. 313, 314 (1887).

127. *Eitzen v. Hilbert*, 165 Mich. 650, 653, 131 N.W. 449, 451 (1911) (plaintiff allowed to submit evidence on value of eggs and chickens which would be produced by unlawfully detained hens).

128. *Guffey v. Smith*, 237 U.S. 101, 119 (1915); *Herdic v. Young*, 55 Pa. 176, 182 (1867); *Chappell v. Puget Sound Reduction Co.*, 27 Wash. 3, 67, 67 P. 391, 392 (1901).

129. See *Moody v. Whitney*, 38 Me. 174, 177 (1854).

## 2. *Recovery Under Trade Secret Doctrine*

If a trade secret doctrine forms the basis of the remedy, the court would use either unjust enrichment or loss of value to the university to measure the damages.

### a. Unjust Enrichment

The commercial entity may have been unjustly enriched by the transfer of the biological because the commercial entity got the use of the biological without having to incur the cost of developing it. Damages under this theory are measured in terms of the value of the benefit the transferred material conferred upon the recipient.<sup>130</sup> This value can be measured in three ways: (1) by evaluating the benefit to the recipient of the savings obtained through the use of the misappropriated biological material; (2) by estimating the profits gained by the recipient from the use of the biological material; or (3) by calculating a reasonable royalty.<sup>131</sup>

First, the value could simply be the amount it would have cost the recipient to reproduce the biological, or to find a substitute material.<sup>132</sup> Under this measure, the recipient's cost of producing the final product with the use of the misappropriated material would be compared to the cost of producing the final product without the biological material. Evidence on this point could be adduced by comparing the development time of analogous materials, as well as the cost of providing personnel and materials for such development.

In the context of university sponsored research, however, this damage measure is almost impossible to calculate accurately. The actual cost to the university is a difficult measure, since research funds and the ideas and materials of research come from many different sources.<sup>133</sup>

Another consideration which would affect the value of the biological is whether it was given solely to the recipient or to others as well.

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130. *University Computing Co. v. Lykes-Youngstown Corp.*, 504 F.2d 518, 536 (5th Cir. 1974).

131. See generally Annot., 11 A.L.R. 4th 12 (1982) (remedies for misappropriation of trade secrets); Annot., 66 A.L.R. FED. 186 (1984) (remedies for patent infringement). In addition, punitive damages have been awarded in unjust enrichment cases. See, e.g., *Sperry Rand Corp. v. A-T-O, Inc.*, 459 F.2d 19, 21 (4th Cir. 1972).

132. *Servo Corp. of America v. General Electric Co.*, 393 F.2d 551, 557 (4th Cir. 1968); *Telex Corp. v. International Business Machines Corp.*, 510 F.2d 894, 932 (10th Cir. 1975).

133. While in theory there is no reason that the various sources of funds could not be added together to reach a total cost of the research, the practical problems in doing this would be nearly insurmountable. For example, apportioning the cost of plant and equipment which is used for a large number of research projects would be exceedingly difficult, and of dubious accuracy.

The value to the recipient of the biological will be affected by the degree of exclusivity the recipient enjoys with the biological. Yet at the time of the initial receipt, the number of recipients will usually be unknown by the transferee and possibly even by the university. This will add substantial uncertainty to calculating the value to the recipient of the use of the biological.

Second, the notion of benefit could be further extended to include the contribution of the biological to the commercial product.<sup>134</sup> In this instance, the university would enjoy a portion of the profits of the recipient, gaining benefit only when the recipient also gained benefit.

The profit gained by the recipient, however, is an unsatisfactory measure of the university's damages. The biological was transferred by the university with the implied understanding that commercial development was intended by both parties.<sup>135</sup> The commercial entity will have put a significant amount of effort and expense into the development of a product. In addition, the commercial product may bear little resemblance to the biological that was initially transferred. In most instances, it is the commercial entity and not the university that has created nearly all of the value of the product, and thus profits gained by the transferee do not measure the university's damages.

For all the aforementioned reasons, use of the recipient's profits as a measure of damages would be inappropriate. Allowing the university all or a portion of the commercial developer's profits would place a tremendous burden on commercial development. As with an injunction, use of this damage measure will deter commercial exploitation of scientific discoveries made by the university. Society is the ultimate loser when research is foregone or abandoned.

Third, value to the recipient could be measured by reference to a reasonable royalty. This is the more common remedy when the misappropriated property is used to improve the recipient's manufacturing process or is used as a part of a larger manufactured product.<sup>136</sup> An example of a reasonable royalty is the approximate value of the biological material that both parties would have agreed upon had they been willing to negotiate at the time of the initial transfer.

This standard might be reasonable if it were feasible to place a value on the material as of the date of the transfer. However, most of

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134. See *Clark v. Bunker*, 453 F.2d 1006, 1011 (9th Cir. 1972); *University Computing Co.*, 504 F.2d at 536.

135. See *supra* text accompanying note 39.

136. See *Vitro Corp. of America v. Hall Chem. Co.*, 292 F.2d 678, 682 (6th Cir. 1961); *University Computing Co.*, 504 F.2d at 536; 35 U.S.C. § 284 (1982) (reasonable royalty as minimum remedy for patent infringement).

these biological materials are valueless in the marketplace in that they have no known commercial application. If there had been an ascertainable value, the university could have and should have indicated that charge at the time of the transfer. Instead, the university chose to transfer the biological material without a specific charge in the hopes that the recipient would turn the biological material into something of great value.

On this basis the transfer becomes a gamble that only the recipient can lose. If nothing comes of the development, the university receives nothing, but the recipients will have expended substantial resources. If a profitable development results from the recipient's efforts, the university will wish to receive its proportionate share. Imposing such a remedy will prevent commercial entities from accepting biological materials from universities, unless there is a prior understanding as to the maximum liability the recipient may be subject to in the case of a successful product development.

#### b. Detriment to the University

As an alternative to an unjust enrichment theory, a court might award damages based on the detriment to the university from the misappropriation. The detriment to the university could be evaluated in a number of different ways. It could be the cost to the university of developing the biological material.<sup>137</sup> As noted above, however, there may have been little actual cost to the university, or the cost could have been quite large depending upon the particular circumstances of its development. For this reason, it is undesirable that the cost of developing the biological material should be a measure for recovery.

An alternative measure is the university's reasonable expectation if the university and the recipient had negotiated a reasonable royalty at the outset. Again, if it were feasible to return to the time when the recipient first obtained the biological, this standard might be reasonable. However, as noted above, the university did not charge a royalty at the time of the initial transfer although it could have done so. To allow the university to negotiate now that the biological material has a known value created by the recipient would be unfair to the recipient. Like the other measures analyzed here, imposing this measure of damages will prevent commercial entities from accepting biological materials.

Finally, in the typical case involving biological materials there has been no true detriment to the university other than the potential denial

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137. See *Kubik, Inc. v. Hull*, 56 Mich. App. 335, 351, 224 N.W.2d 80, 95 (1974); *Elcor Chem. Corp. v. Agri-Sul, Inc.*, 494 S.W.2d 204, 214 (Tex. 1973).

of royalties from the sale of the product. With biologicals, the value of the material to the university has not been damaged by the recipient. Indeed the contrary is true because the recipient has shown what commercial value the material might have. Further, the recipient can usually return the same, or substantially similar, material to the university. Since no definite harm to the university can be established, a damage measure based on that harm will not provide relief.

### C. Public Policy

Any analysis of the desirability of enforcing letter licenses must include a discussion of the appropriate remedy. A judicial remedy is more than an acknowledgment of the breach of an agreement. The relief specified must be justifiable and appropriate in light of the relationship of the parties. Here, three factors should combine to defeat the university's claim.

First, the university and the commercial researcher probably intended that the research performed on the transferred biological would eventually result in a commercial product. There would be no point in creating such a license if a commercially viable product would never result from the transfer of the biological.

Second, the university's behavior after the transfer is inconsistent with its claim of right. One would assume that the value of the transferred material decreases as the number of recipients increases. Yet it is standard practice for the university to transfer biologicals without regard to the possible detrimental effect on earlier recipients. The university also routinely publishes information about biological discoveries, including how to create the transferred biologicals. This further reduces any value to the recipient which results from the exclusivity of the transfer.<sup>138</sup>

Finally, the public has an interest in the transformation of scientific discoveries into useful products. Enforcement of property rights derived from prior possession of the biological, in a situation where the parties have not chosen to place a value on the material at the time of the transfer, can only have a chilling effect on new product development.

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138. See, e.g., *Instructions to Authors*, 260 J. BIOCHEMISTRY 1 (1985) ("[T]he policy of the American Society of Biological Chemists is based on the principle that published results must be verifiable. Therefore, authors are expected to respect this principle by providing unique materials to qualified investigators.").

## CONCLUSION

In the future, courts will have to wrestle with the legal rights of universities when transferred biologicals form the basis of profitable products. With only vague and incomplete letter licenses, and broad notions of public policy to guide them, courts will have to determine what causes of action, if any, a university may bring against commercial transferees. Remedies for violations will be difficult to determine because monetary damages will generally be hard to evaluate. In addition, such remedies will depend on how broadly the courts interpret such letter licenses.

Treating biologicals as property under the doctrines of bailment, accession and specification will hinge on the equity of doing so, taking into account the intent of the parties at the time of the transfer and the effect of using these doctrines on further research.

Finally, any use of a trade secret analysis will depend on a multitude of factors, primarily how likely it is that the biological is a trade secret, and whether the underlying policies of trade secret protection are served by invoking it in these cases.

Where a nonprofit researcher transfers biologicals to a commercial entity under a letter license, the rights and obligations of both parties are very unclear. Because the interest of the public in the creation of new and valuable products must be weighed against the rights of the parties involved, it will be difficult for the courts to create new law in this area. The ultimate result is that commerce will proceed cautiously in an area of substantial legal uncertainty. If courts make choices that favor the university over the recipient, there could be a significant slowdown in the commercial exploitation of biologicals. Therefore, unless the universities make clear in letter licenses what rights they seek to protect, the public interest in the development of new products and technologies mandates a restrictive reading by the courts of the rights granted to universities under such licenses.

## Appendix A

This appendix contains three examples of letter licenses typically used by universities in transferring biologicals. The first and third examples are from the Author, and the second is from a major research university.

### *Example 1*

#### Agreement for Transfer of Cells and Plasmids

1. The parties to this agreement are: [transferor] and [transferee].
2. The "Material" that is covered by this agreement includes:
  - (a) the following cells and/or plasmids and any related biological material or information, which will be received by [transferee] from [transferor]: [description of material];
  - (b) any cells or DNA molecules that are replicated or derived therefrom by the [transferee] or his/her co-workers.
3. This Material will not be distributed or released to any person other than coworkers working under the [transferee's] direct supervision, and no one will be allowed to take or send this Material to any other location, unless written permission is obtained from [transferor]; such permission will not be withheld unreasonably.
4. This agreement and the resulting transfer of Material constitutes a license to use the materials for research purposes only.
5. [Transferee] will inform [transferor] in confidence of research results related to the Material.
6. If the research which involves the Material results in an invention or substance which may be commercially useful, the [transferee] will promptly disclose the invention or substance to the [transferor's] Patent Administrator, and will provide [transferor] with appropriate recognition of [transferor's] contribution, such as a first option to negotiate a license to use the invention or substance or a reduced royalty if a non-exclusive license is offered.
7. [Transferee] will use the Material in compliance with [all applicable laws and regulations].
8. [Transferee] will indemnify [transferor] and hold [transferor] harmless from any claims or liabilities which might arise as a result of the use of the Material.

/s/ [Transferor]

/s/ [Transferee]

*Example 2*

## Secrecy Agreement for Biological Material for Research Use

THIS AGREEMENT is effective this \_\_\_\_ day of \_\_\_\_, 1985 by and between [transferee], having an address at \_\_\_\_, hereinafter referred to as "RECIPIENT," and [university], having an address at \_\_\_\_, hereinafter referred to as the [transferor]. This agreement shall govern the conditions of disclosure by [transferor] to [transferee] of BIOLOGICAL MATERIAL consisting of [*description of biological(s)*], developed by [scientist/faculty member] of the [transferor]. BIOLOGICAL MATERIAL as used herein also includes any material derived directly from the biological material received from [transferor].

With regard to BIOLOGICAL MATERIAL, [transferee] hereby agrees:

- (1) to use BIOLOGICAL MATERIAL only for experimental research purposes;
- (2) not to use BIOLOGICAL MATERIAL for commercial purposes without first obtaining a license from [transferor];
- (3) not to transfer BIOLOGICAL MATERIAL to others (except to employees, agents and consultants who are bound to it by like obligations conditioning and restricting access, use and continued use of BIOLOGICAL MATERIAL) without the express prior written permission of [transferor], except that [transferee] shall not be prevented from transferring BIOLOGICAL MATERIAL which:
  - (a) becomes publicly available other than through acts or omissions of [transferee]; or
  - (b) is lawfully obtained by [transferee] from sources independent of [transferor];
- (4) To safeguard BIOLOGICAL MATERIAL against disclosure and transmission to others with the same degree of care as it exercises with its own biological materials of a similar nature;
- (5) Not to use the BIOLOGICAL MATERIAL on human subjects; and
- (6) to indemnify [transferor] against any claims, costs or other liabilities which may arise as a result of [transferee's] use of the BIOLOGICAL MATERIAL.

It is understood that the BIOLOGICAL MATERIAL is experimental in nature and, when delivered to the [transferee], is without any warranty either expressed or implied including the warranties of merchantability or fitness for a particular purpose.

It is further agreed by the parties that the furnishing of BIOLOGICAL MATERIAL to [transferee] shall not constitute any grant or license to [transferee] under any legal rights now or hereinafter held by [transferor].

All BIOLOGICAL MATERIAL shall be the property of [transferor], provided however, that property interest in any novel combination or transformation involving BIOLOGICAL MATERIAL shall be governed by the laws of [state].

/s/ [transferor]

/s/ [transferee]

*Example 3*

*[University Letterhead]*

Dear [transferee]:

Enclosed are the [biologicals] you requested. The sequence of the [gene] is published in [Journal]. Upon receipt and use of these [biologicals] you have agreed not to distribute these [biologicals] outside your laboratory or use them for commercial purposes. Furthermore, you agree to follow appropriate guidelines for handling recombinant DNA.

Please keep us up to date on any progress made using the [biologicals].

/s/ [transferor]