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Rebecca S. Eisenberg

*University of Michigan Law School, rse@umich.edu*

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# EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY

INNOVATION POLICY FOR THE  
KNOWLEDGE SOCIETY

Edited by

ROCHELLE COOPER DREYFUSS  
DIANE LEENHEER ZIMMERMAN  
HARRY FIRST

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# BARGAINING OVER THE TRANSFER OF PROPRIETARY RESEARCH TOOLS: IS THIS MARKET FAILING OR EMERGING?

REBECCA S. EISENBERG\*

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As intellectual property claims proliferate in rapidly advancing fields of technology, new research paths often cross the boundaries of many prior patents. Without an exemption from infringement liability,<sup>1</sup> subsequent innovators need licenses from multiple predecessors to pursue such research projects. Whether this state of affairs promotes innovation or retards it is an empirical question of considerable complexity.

Suzanne Scotchmer's work on cumulative innovation highlights an important policy consideration: patent boundaries are a significant determinant of the relative returns to investment at different stages in the course of cumulative innovation.<sup>2</sup> Broad patents on early innovations permit their owners to

\* Robert & Barbara Luciano Professor of Law, University of Michigan Law School. I am grateful to John Barton, Rochelle Cooper Dreyfuss, Ronald Mann, and workshop participants at New York University Law School, Engelberg Center on Innovation Law and Policy, Conference at Villa La Pietra, Florence, Italy (June 1998); the Biotechnology Industry Organization annual meeting, New York (June 1998); the American Type Culture Collection Patent Seminar, Virginia Center for Innovative Technology (September 1998); the Mayo Clinic (October 1998); and the University of California at Berkeley (May 1999) for helpful comments on earlier drafts of this chapter.

<sup>1</sup> The US patent statute does not generally exempt research activities from infringement liability, although it includes a narrow exemption for the use of a patented invention 'solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products': 35 U.S.C. § 271(e)(1).

<sup>2</sup> See Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991); Jerry R. Green & Suzanne Scotchmer, *On the Division of Profit in Sequential Innovation*, 26 RAND J. ECON. 20 (1995).

capture, through license transactions, the value that their innovations contribute to second generation technologies, ensuring that the incentives of early innovators reflect this value. Although the cost of getting licenses from prior innovators diminishes the profitability of second generation innovations,<sup>3</sup> Scotchmer argues that subsequent innovators can still recover an adequate return if they negotiate the terms of licenses before they incur research and development (R&D) costs.

This analysis highlights the importance of transactions between prior and subsequent innovators to permit valuable research to go forward across the boundaries of prior patent claims. In a recent article focusing on biomedical research,<sup>4</sup> Michael Heller and I argue that too many patent rights on 'upstream' discoveries can stifle 'downstream' research and product development by increasing transaction costs and magnifying the risk of bargaining failures. Just as too few property rights leave communally held resources prone to overuse in a 'tragedy of the commons', too many property rights can leave resources prone to underuse in what Heller calls a 'tragedy of the anticommons'.<sup>5</sup> The greater the number of people who need to be brought to agreement in order to permit a research project to proceed, the greater the risk that bargaining will break down or that transaction costs will consume the gains from exchange.

Other commentators have noted that such bargaining failures are not inevitable. In a world of costless transactions, people could avoid commons or anticommons tragedies by trading their rights. Robert Merges has documented the development of numerous institutions that reduce the transaction costs of negotiating through a thicket of intellectual property rights in different industries, including the ASCAP copyright collective and the recent MPEG patent pool.<sup>6</sup> If owners and users manage to negotiate mutually agreeable license terms, then a proliferation of patents can promote equitable distribution of the value of cumulative and interdependent innovations without unduly inhibiting future research.

Is bargaining failure in the market for intellectual property licenses a hypothetical problem that sophisticated institutions and well-functioning markets

<sup>3</sup> Scotchmer worries more about preserving the incentives of early innovators on the assumption that the stand-alone value of their innovations will be small relative to that of the later innovations that they facilitate. On the other hand, it may be that patent incentives are more important in the later stages of cumulative innovation than in the early stages (eg, if early innovations are relatively cheap or are subsidized by the government), whereas subsequent innovations are relatively expensive or more dependent on private sector investment—and if so, it may make more sense to limit the rights of early innovators so that subsequent innovators can capture a larger share of the value of cumulative efforts.

<sup>4</sup> See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

<sup>5</sup> See Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998).

<sup>6</sup> See Robert P. Merges, *Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293 (1996). See also Merges, Chapter 6 above.

are likely to avoid, or is it something to worry about? In biomedical research, there is evidence that the problem is real. In 1997–98, I served as chair of the National Institutes of Health (NIH) Working Group on Research Tools (the Working Group), a group charged with investigating difficulties encountered by researchers in obtaining access to proprietary research tools—materials, information and methods—for use in biomedical research.<sup>7</sup> The Working Group gathered information from scientists, university technology transfer professionals, and private firms in the pharmaceutical and biotechnology industries.<sup>8</sup> Within these communities, there seems to be a widely-shared perception that negotiations over the transfer of proprietary research tools present a considerable and growing obstacle to progress in biomedical research and product development. Scientists report having to wait months or even years to carry out experiments while their institutions attempt to renegotiate the terms of ‘Material Transfer Agreements’ (MTAs), database access agreements, and patent license agreements. University technology transfer professionals report that agreements presented for the transfer of research tools impose increasingly onerous terms. They say that the burden of reviewing and renegotiating each of a rapidly growing number of agreements for what used to be routine exchanges among scientists is overwhelming their limited resources. Private firms—both large, established pharmaceutical firms and small, young biotechnology companies—also report growing frustration with the administrative burden of renegotiating the terms of agreements for the transfer of research tools and with attendant delays in research. Some even

<sup>7</sup> See *Report of the National Institutes of Health (NIH) Working Group on Research Tools, Presented to the Advisory Committee to the Director* (June 4, 1998) <<http://www.nih.gov/news/researchtools/index.htm>>.

<sup>8</sup> Many of the individuals who spoke with members of the Working Group were concerned about maintaining confidentiality. As a result, both the discussion in this chapter and the Report of the Working Group avoid the use of specific examples and citations to conversations with specific individuals. The discussion in text is drawn from communications with representatives of many academic institutions and private firms. I also include quotations from some of these conversations as recorded in my own notes, although without attribution to specific individuals or institutions. The private firms that provided information to the Working Group include: Affymetrix; Amgen; Arena Pharmaceuticals; Ares-Serono; Bristol-Myers Squibb; CEPH; Cephalon; DuPont; Ergoscience; Genentech; Genetics Institute; Guilford Pharmaceuticals; Hoechst Marion Roussel; Hoffmann-La Roche; Human Genome Sciences; Ligand Pharmaceuticals; Megabios; Merck; Millennium; Parke-Davis; Pfizer; Pharmacopeia; Schering-Plough; SmithKline Beecham; Vical. The academic institutions that provided information to the Working Group include: Allegheny Health, Education and Research Foundation; The Bowman Gray School of Medicine, Wake Forest University; University of California; California Institute of Technology; University of Chicago; University of Cincinnati; Columbia University; University of Connecticut; Harvard University; University of Illinois at Urbana-Champaign; Indiana University; University of Iowa; Johns Hopkins University; University of Louisville; Massachusetts General Hospital; Massachusetts Institute of Technology; Miami University; University of Michigan; University of Pennsylvania; Princeton University; University of Rochester; Rutgers University; University of South Carolina; Stanford University; State University of New York; Tulane University Medical Center; University of Washington; Washington University; University of Wisconsin-Madison; Yale University.

confided that in internal discussions they have questioned whether it is worth their while to continue to exchange research tools with university scientists. Although there are many points on which they disagree, most people from each of these quarters seem to agree that the problem is growing rather than diminishing.

Why, in this setting, is it proving so difficult to arrive at mutually agreeable bargains between prior and subsequent innovators? If transaction costs are consuming the gains from exchange, why haven't the communities that confront this problem figured out mechanisms for reducing these costs?<sup>9</sup> Answers to these questions about transactions for the transfer of biomedical research tools may shed some light on broader questions about how far we can rely on bargains among sequential innovators to allocate new technologies to socially valuable uses. If prior and subsequent innovators find it difficult to negotiate the terms of transactions for the transfer of intellectual property, then perhaps initial allocations of intellectual property rights matter, not only because they determine the distribution of returns across various stages of cumulative innovation, but because they either promote or retard the efficient dissemination of prior discoveries to subsequent innovators.

## I. Background

Current problems in the exchange of biomedical research tools arise in the context of dramatic institutional and cultural changes in biomedical research that have not yet come to rest. One important policy shift has come from passage of the 1980 Bayh-Dole Act<sup>10</sup> and subsequent Congressional directives that encourage universities and other recipients of federal research funds to patent the results of federally-sponsored research.<sup>11</sup> The result has been a dramatic increase in patent filings from institutions that, in an earlier era, were more likely to make their discoveries freely available.<sup>12</sup> Two dimensions of this change are particularly relevant to current problems surrounding the exchange of research tools. First, it has expanded and diversified the types of *institutions* claiming proprietary rights in their discoveries, as academic and nonprofit institutions have established technology transfer offices to patent

<sup>9</sup> The Association of University Technology Managers has attempted to streamline transactions for the transfer of biomedical research tools by creating a Uniform Biological Materials Transfer Agreement (UBMTA). See 60 Fed. Reg. 12771 (1995). Many universities have approved the use of the UBMTA in principle, but few seem actually to use it. More recently, in response to the Report of the Working Group, NIH has created guidelines on research tools that include a proposed form agreement. See 64 Fed. Reg. 72090 (1999).

<sup>10</sup> 35 U.S.C. §§ 200–211.

<sup>11</sup> See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996).

<sup>12</sup> See Rebecca Henderson et al., *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting 1965–1988*, 80 REV. ECON. & STAT. 119 (1998).

faculty inventions and to market them to commercial firms. Secondly is a corresponding expansion and diversification in the types of *discoveries* that are the subject of proprietary claims to include the early-stage discoveries, considerably removed from product development, that typically emerge from government-sponsored biomedical research. The domain of proprietary exchange has thus become more diverse in terms of both the participants and the objects of exchange.

A related, contemporaneous change has been the emergence of commercial biotechnology firms in market niches that lie somewhere between fundamental academic research and end product development. These biotechnology firms differ from established pharmaceutical firms in important ways. Many of these firms have academic scientists as founders, retain strong scientific and financial ties to academic institutions, and rely on government grants for research funding. Lacking end products for sale to non-research consumers, some of these firms survive in the private sector by selling research tools and the research capabilities of their scientific personnel to other institutions, especially to major pharmaceutical firms. The evolving profit strategies of biotechnology firms often depend heavily on intellectual property rights in discoveries that are primarily inputs into further research. These firms are motivated to exchange research tools with other institutions, but they also need to preserve the competitive and financial value of their research tools.

The shifting balance of public and private funding for biomedical research is another factor with an important bearing on exchanges of research tools.<sup>13</sup> In the past decade, despite steady increases in federal funding for health-related research,<sup>14</sup> private funding overtook public funding as the principal source of support for biomedical research in the United States.<sup>15</sup> Although public funding remains the principal source of support for university-based biomedical research, public-private boundaries are blurring as relationships between academic institutions and private firms proliferate in the life sciences.<sup>16</sup> Collaborative research that pools research capabilities and funds from different institutions in the public and private sectors is increasingly

<sup>13</sup> See National Science Board, *Science & Engineering Indicators—1998* (1998) (hereinafter 1998 Indicators) <<http://www.nsf.gov/sbe/srs/seind98/start.htm>>.

<sup>14</sup> See *ibid.* ch. 4, at 3.

<sup>15</sup> See *National Institutes of Health: Source of Funds, Medical and Health Related R&D: Fiscal Years 1986–1995* (visited September 1, 1999) <<http://www4.od.nih.gov/ofm/PRIMER97/page6.stm>>. According to these data, from 1986–1995, government funding for medical and health-related R&D doubled, from \$7,924 million to \$15,846 million, while industry funding for medical and health-related R&D more than tripled, from \$6,192 million to \$18,645 million. These data indicate that industry funding first exceeded government funding in 1992.

<sup>16</sup> See David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Survey*, 334 N. ENG. J. MED. 368 (1996) (finding that 90 percent of companies conducting life science research in the United States had relationships involving the life sciences with academic institutions).

common, not only in the life sciences<sup>17</sup> but across all fields of research.<sup>18</sup> Mature pharmaceutical firms, biotechnology start-ups, and academic institutions find themselves sometimes collaborating and sometimes competing to achieve overlapping research goals. As a result, it is often difficult to tell when an academic researcher is a commercial competitor.

In this environment, many institutions that develop new materials, methods, and information for use in research regard these tools as valuable intellectual property. By restricting access to new research tools, some institutions seek to capture their value through sales and licenses to researchers in other institutions, and some seek to preserve a competitive advantage in subsequent stages of research by withholding these resources from their rivals entirely. At the same time, many scientists and institutions at least purport to embrace traditional scientific norms calling for widespread sharing of research tools to promote scientific progress, especially when they seek access to tools that have been created by others.

Some of these scientists and institutions resolve the dissonance between the norms they would apply to the tools created by others and the norms they abide by in disseminating their own tools through the use of carefully crafted definitions of the term 'research tool'. The term 'research tool' would seem to connote a user perspective, indicating something that is not yet an end product and has its primary value as an input into further research. Yet a user's research tool may be a provider's end product. Some products that are currently used in research might also have markets, actual or potential, among nonresearch consumers. A pharmaceutical compound might be used in academic research, and a DNA sequence that is associated with disease might be marketed as a diagnostic product at the same time that it is used in further research to understand its role in a disease pathway. Some biotechnology firms make a business out of developing and supplying proprietary materials, information and methods that are useful primarily, if not only, in further research; to these firms research tools *are* end products.

Some major pharmaceutical firms that earn profits by selling proprietary drugs to nonresearch consumers have been outspoken supporters of improving access to research tools throughout the research community.<sup>19</sup> But what these firms mean by 'research tools' is the biological materials that they use in

<sup>17</sup> See Walter W. Powell et al., *Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology*, 41 ADMIN. SCI. Q. 116 (1996). See also Powell, Chapter 10 below.

<sup>18</sup> See 1998 Indicators, n. 13 above, at 4–28 to 4–32.

<sup>19</sup> A research director of a major pharmaceutical firm said that 'we consider this a matter of enlightened self-interest—no one can own them all, so we really should figure out ways to make them accessible'. He conceded that his firm will not supply materials to a competitor, noting that it is important to 'distinguish enlightened self-interest from stupidity', but said that if a competitor were willing to make the materials itself and simply needed a license to avoid patent infringement, the firm would provide an 'unblocking license' for a nominal fee.



the course of drug discovery, not the end products that they sell (or hope to sell) to consumers.<sup>20</sup> The same firms are quite restrictive about disseminating their own proprietary therapeutic products to researchers. A scientific liaison for a biotechnology firm that makes transgenic animals, noting that there are different levels of security for different types of materials, states that 'any type of proprietary material is not a research tool' and 'our transgenics are proprietary'. A representative of a biotechnology firm that sells therapeutic proteins has two different form agreements—a simple form with few restrictions that it uses for 'things that aren't proprietary products in development', and a more restrictive form that it uses for materials that the firm has identified as potential products.

Institutions tend to be high-minded about the importance of unfettered access to the research tools that they want to acquire from others, but no institution is willing to share freely the materials and discoveries from which they derive significant competitive advantage. Thus many of the people that spoke with the Working Group were eager to establish that the term 'research tool' means something other than their own institution's crown jewels. Those firms whose crown jewels could only be characterized as 'research tools' insisted that they were different in kind from ordinary research tools and therefore called for different terms of exchange.<sup>21</sup> When one institution's research tool is another firm's end product, it is difficult to agree upon a universe of materials that should be exchanged on standardized terms.

Some proprietary research tools have been widely distributed under license agreements that permit subsequent research to go forward while preserving a return for the patent owner. Two outstanding examples of fundamental importance to biomedical research are the recently-expired Cohen-Boyer patents on recombinant DNA technologies, jointly owned by Stanford University and the University of California,<sup>22</sup> and the patents on the polymerase chain reaction (PCR) owned by Hoffmann-La Roche.<sup>23</sup> Both are

<sup>20</sup> A representative of a major pharmaceutical firm defined 'research tool' as 'something that gets you on the path of doing drug discovery, not a chemical entity or product, but an assay, or a target, or genetic information encoding a target, cell line, or other materials used in the research process'. A senior executive from another major pharmaceutical firm acknowledged that such a broad definition of 'research tool' would extend to materials that 'may be a quite meaningful competitive differentiation, particularly to a small company that makes a living through the identification of [drug] targets'. He added that even for large companies, 'if you have a series of molecular species that have given you the ability to resolve a disease pathway ahead of your competitors, that has competitive value, and you don't want others to use the tools after you've invested time and money to get there'.

<sup>21</sup> A lawyer for a biotechnology firm that earns most of its revenue from selling tools used in the analysis of gene expression stated that 'while on the surface it might look like what we have is a simple research tool, the value [of the product] is orders of magnitude more than what any other research tool might have'.

<sup>22</sup> See Intellectual Property Rights and the Dissemination of Research Tools in Molecular Biology: Summary of a Workshop Held at the National Academy of Sciences, February 15–16, 1996, 40–42 (1997).

<sup>23</sup> See *ibid.*, 43–46.

fundamental enabling technologies that have had considerable value in research on a wide range of problems, and both have been licensed on terms that have permitted widespread dissemination and use.

One might expect these early success stories to lead the way toward the licensing of other research tools on increasingly routine and uncontroversial terms. Yet recent experience reveals precisely the opposite trend. Exchanges between universities and private firms are particularly likely to be problematic, but bargaining difficulties extend to purely academic and purely commercial exchanges as well. Although there is significant variation in the terms of agreements for the transfer of research tools, most of the conflict between providers and users of research tools focuses on the same handful of provisions over and over again.<sup>24</sup>

Some, but not all, of these conflicts have been relatively easy to resolve through negotiations. For example, tool providers will often modify restrictive prepublication review provisions in response to objections from the user.<sup>25</sup> What is surprising about these routinely renegotiated provisions is that tool providers continue to propose the more aggressive terms initially, rather than modifying the language of their draft agreements to avoid the costs of repeated renegotiations.<sup>26</sup>

More intractable disagreements arise over so-called 'reach-through' and 'grantback' provisions governing rights to potential future inventions made by the user of the research tool. For example, providers of research tools may seek royalties on future product sales, options to acquire exclusive or nonexclusive licenses under future patents, or even outright ownership of future inventions as a condition for making the tools available. Through such provisions, owners of research tools may seek to leverage their proprietary rights in early innovations into a share of the profits from future innovations that may be more lucrative. Or, by asking for automatic license rights to discoveries made while using their tools, they may seek to protect themselves from intellectual property claims that users might assert against them in the future. But these precommitments to extend future licenses create a problem for users of multiple research tools faced with similar reach-through demands from multiple owners. A user cannot promise an exclusive license to future discoveries more than once in the course of a research project before creating

<sup>24</sup> See Rebecca S. Eisenberg, *Streamlining the Transfer of Research Tools*, 74 ACADEMIC MEDICINE 683 (1999).

<sup>25</sup> For example, the provider's initial draft might require the user to submit manuscripts for pre-publication review 180 days prior to submission for publication, a period that is reduced to 60 days in the course of negotiations.

<sup>26</sup> One inhouse lawyer for a biotechnology firm suggested that a possible explanation for repeated use of forms that consistently need to be renegotiated may be that these forms are drafted by retained counsel that profit from the time spent in renegotiating the terms of the agreement. Another possibility is that sometimes the forms are signed in the form presented, encouraging owners to try for the same terms again.

conflicting obligations. Even past promises of nonexclusive licenses would conflict with future promises of exclusive licenses to the same discoveries. Concerned about incurring overlapping and inconsistent obligations to providers of different research tools, and reluctant to enter into agreements that disable them from licensing potential future discoveries as they see fit before they even know what the discoveries are, users balk at signing the proffered terms of access, and negotiations stall.

Although the terms of access to some high value research tools have provoked controversy,<sup>27</sup> the more serious bottleneck to research is the growing burden of negotiating numerous agreements for routine use of methods, materials and data in experiments. Taken individually, none of these agreements is likely to yield commercially valuable results. Nonetheless, in the aggregate, they create significant administrative delays that slow the pace of research.

## II. Analysis

The investigation of the Working Group on Research Tools provides a rare opportunity to examine, from multiple perspectives, difficulties encountered in negotiating for the transfer of intellectual property. What accounts for apparently growing difficulties in establishing a market for the exchange of biomedical research tools? Four themes emerge from interviews with participants in this market, each of which I elaborate below. First, transaction costs are a greater obstacle to low-value exchanges than to high-value exchanges. Transaction costs are thus more likely to impede the transfer of research tools for use in experiments that are unlikely to yield commercially valuable results than they are to impede major research collaborations, even among the same people and institutions. Secondly, heterogeneities among institutions within the biomedical research community seem to be complicating the search for mutually agreeable terms of exchange. Universities, pharmaceutical firms, and biotechnology firms each find it relatively easy to deal with their own kind, but each finds institutions of the other kinds to be unreasonable and unrealistic in their demands and expectations. Thirdly, even within a single institution, the interests of scientists who make and use research tools and the interests of the lawyers and business people who negotiate the terms of these exchanges on behalf of the institutions that employ the scientists are not necessarily the same, and these different 'agents' do not always present a united front in negotiations. These internal conflicts complicate the bargaining process and frustrate the emergence of agreement about fair terms of

<sup>27</sup> See, eg, Eliot Marshall, *The Mouse That Prompted a Roar*, 277 SCI. 24 (1997); Jon Cohen, *Exclusive License Rankles Genome Researchers*, 276 SCI. 1489 (1997).

exchange within the biomedical research community. Fourthly, evaluation of research tools, and estimation of the contribution that they might make to potential future discoveries, is highly speculative and subjective and does not lend itself to dispassionate negotiations from agreed-upon benchmarks.

### A. Transaction costs

A striking feature of the market for biomedical research tools is the sophistication of the institutions involved and the frequency with which the same parties conclude other, higher value deals.<sup>28</sup> How can it be that institutions with the resources and skills to establish major collaborative research agreements nonetheless stumble over mundane exchanges of research materials and techniques?

A simple explanation is that transaction costs are worth incurring for high value transactions, but not for low value transactions. Collaborative research agreements generally involve more substantial commitments of resources, and hopes for future value, on all sides of the deal than MTAs.<sup>29</sup> Not surprisingly, institutions involved in biomedical research give priority in the allocation of their negotiating resources to higher value transactions, while lower value transactions get deferred. As a result, the transaction cost bottleneck presents more of a problem for low value exchanges than for major collaborations.

This generalization was repeatedly confirmed by people who negotiate agreements on behalf of institutions in the private sector. Representatives of biotechnology firms and pharmaceutical firms indicated that, although routine exchanges are increasingly likely to be delayed to the point that the transaction loses its value, the exchanges of research tools that matter most to the firms' scientists generally go forward.<sup>30</sup> Representatives of universities, on the

<sup>28</sup> Walter Powell describes elaborate networks for pooling the resources of pharmaceutical firms, biotechnology firms, and universities to perform collaborative biomedical research. See, eg, Walter W. Powell & Jason Owen-Smith, *Commercialism in Universities: Life Sciences Research and its Linkage with Industry*, 17 J. POL'Y ANALYSIS & MGMT. 253 (1998); Powell et al., n. 17 above.

<sup>29</sup> As noted earlier in text, MTA is a standard abbreviation for a 'material transfer agreement' that sets forth the terms of access to a (typically unpatented) biological material. Several representatives of private companies said that they would only use an MTA if the company has little or no interest in the research of the scientist to whom it is sending a research tool. If the company anticipates that the scientist's research will yield valuable results, it would propose a more substantial relationship, perhaps involving research sponsorship or collaboration. Exchanges for which an MTA is used are thus typically of low value to the provider of the material.

<sup>30</sup> For example, a Vice President and General Counsel of a biotechnology company stated that 'there isn't anything that people can't get access to if they really need it', although sometimes it is cheaper and easier to design around a proprietary research tool. A representative of a different biotechnology company reported that her firm only cares about approximately 100 MTAs out of 2,000 that she processes annually, and those agreements always get done. The research director of a major pharmaceutical firm claims that his firm has never had to shut down a research project for failure to gain access to a proprietary research tool, although they sometimes

other hand, appear to be frustrated not only by the large volume of low value agreements demanding their attention, but also by the terms of access to certain high value research tools that have led to bargaining impasses.<sup>31</sup>

Even from the perspective of large, private firms, the value of foregone exchanges due to failed bargains over the transfer of research tools is often more than trivial. For example, a former scientist who now represents a major pharmaceutical firm in research tool negotiations indicated that, even when her firm would be willing to pay \$20,000 for a license to a research tool, negotiations over contract language can take months or years, during which time the scientists often give up and turn their attention to something else.<sup>32</sup> The same representative indicated that when her firm receives an unsolicited request to provide a research tool, the firm is unwilling to invest any resources at all in renegotiating the terms of exchange; would-be users can take the firm's form agreement or leave it.<sup>33</sup> Paradoxically, such cost-driven intransigence in renegotiating the terms of agreements may slow the emergence of a consensus on what counts as fair terms of exchange. A representative of another pharmaceutical firm explained that 'the deal breaker [in negotiations over the transfer of research tools] typically isn't cost, but terms and conditions'.

The terms and conditions that are so difficult to agree upon generally involve the allocation of speculative future value and risks. If most transfers of research tools will not produce discoveries of any value, the ratio of value to transaction costs could be improved, and aggregate transaction costs reduced, by deferring the most difficult negotiations until after it becomes apparent that there is significant value at stake. Some firms try to do this—or at least suspect that other firms try to do this—by using patented research tools without a license, assuming that they can settle the matter later in the

have spent considerable resources inventing around patents, and sometimes have performed experiments offshore when a US license has not been available on reasonable terms.

<sup>31</sup> See, eg, Marshall, n. 27 above; Cohen, n. 27 above.

<sup>32</sup> 'We wouldn't mind paying \$20,000 for a license if we thought it were something we could build a research program on . . . The biggest barrier in that price range is disagreements over legal language and the turnaround time to get that accomplished. Most university offices have long backlogs of these projects on their desks, and they have to prioritize. Rarely does it seem like our small research tool contracts make it to the top of their piles. It takes a long time for them to get back to us . . . We also have limited staff that can work on these agreements . . . If each round takes a couple of months, even though it might take only an hour or so, it ends up taking several months. I'm working on something that's taken over a year for a \$20,000 research tool. We're stuck on the issue of indemnification . . . Eventually, the scientists shrug their shoulders and pick something else to work on rather than trying to work out an agreement with the university . . . It's the time delay, rather than the cost, that discourages us from going forward most of the time.'

<sup>33</sup> 'We have a policy that people find pretty hard. If we get an unsolicited MTA, we basically ask them to accept our MTA word for word. But if our scientist says that this is a valuable proposal and the data would be important for us, then we'll try to work it out. It's a two-tiered system. We are constrained in terms of the legal staff that we have available. Otherwise, we couldn't get any work done.'

unlikely event that they discover something significant.<sup>34</sup> Other firms try to achieve a similar result through the use of agreements that do not resolve difficult issues, such as the division of future intellectual property, up front. Instead, they preserve the parties' bargaining positions and obligate each side to return to the table for further negotiations in the event that a valuable discovery emerges. Although this is not always possible, a lawyer for a biotechnology company reported some success with such a strategy in negotiations over transfers of his company's libraries of combinatorial chemistry compounds to other firms planning to screen the compounds against their own proprietary biological targets. Frustrated with up-front negotiations that could take a year or longer, he began proposing simple agreements under which his firm would make its compounds available to firms that would promise to return to negotiate over any 'hits' between compounds and targets prior to filing any patent applications. He proposed such contracts to 15 firms over the course of a year and concluded seven deals on those terms. The subsequent license negotiations over rights to the 'hits' take time, 'but at least you're arguing over something that has value'.

Not all transfers of research tools can follow a strategy of deferring negotiation over the tough issues until it is known whether the results justify the transaction costs. The reason this strategy is viable for the screening transactions is that each side is in a position to withhold value after the screening is complete, and thus each side retains bargaining leverage for use in subsequent negotiations. The owner of the combinatorial chemistry libraries has intellectual property rights in the compounds that can still be enforced after the screening is complete, and the owner of the targets can disclose the existence of a hit while withholding information about which compound has hit which target. Each side thus has good reason to return to the bargaining table after a successful screening. Often, however, the owner of a research tool retains no leverage after the fact if use of the tool facilitates a valuable discovery. Tool owners are thus forced to negotiate before the research takes place if they wish to stake a claim to future value, even though at that point the value is entirely speculative.

When progress in research depends on the relatively unfettered flow of low value exchanges of information and materials among scientists, a proliferation of intellectual property claims to the objects of these exchanges may impose transaction costs that consume the gains from exchange. If owners and users are unable to reduce these transaction costs, exchanges that could have considerable value in the aggregate might not occur.

<sup>34</sup> One representative of a major pharmaceutical firm, while insisting that his own firm has a strict policy of not infringing patents, said that 'other companies just go ahead and work on the project without a license. The likelihood of success is so low, you end up buying 100,000 licenses for everything that succeeds. You spend a lot of money churning. People on the outside don't know if companies are using things on the inside. Maybe they think they can litigate it after, or get licenses retrospectively'.

## B. Institutional heterogeneity

Biomedical research occurs in universities, nonprofit institutions, government agencies, small biotechnology firms and major pharmaceutical firms. Research in each of these settings both draws on and contributes to research in the other settings, yet these institutions have different missions and objectives and face different constraints. Elinor Ostrom and others have observed that heterogeneous groups have greater difficulties than homogeneous groups in reaching agreement on how to manage natural resources so as to avoid a tragedy of the commons.<sup>35</sup> The investigation of the Working Group on Research Tools suggests a parallel phenomenon in efforts of the heterogeneous biomedical research community to manage intellectual property rights so as to avoid a tragedy of the anticommons.<sup>36</sup>

Across the spectrum of institutions involved in biomedical research, people report that although they sometimes have difficulty reaching agreements within their own sector, the really serious problems arise in dealing with the other sectors. More specifically, with a few exceptions, the primary focus of complaints is difficulty negotiating the terms of access to *incoming* research tools from institutions in other sectors rather than difficulty negotiating the terms of access to *outgoing* research tools. Whether the research tool originates in a university, a biotechnology firm, or a pharmaceutical firm, it is generally the would-be user who is frustrated by the provider's terms of exchange.

Representatives of universities say that they are generally successful in negotiating with other universities, but that they find private firms unreasonable and unrealistic in their expectations of what academic institutions can promise in exchange for access to research tools. In the private sector, one hears exactly the opposite generalization—that private firms know how to do deals, but that universities are unreasonable and unrealistic in their demands. Even within the private sector, representatives of pharmaceutical firms find it relatively easy to deal with other pharmaceutical firms, but find many biotechnology firms to be unreasonable and unrealistic in their demands.

Although all sides recognize that differences in institutional resources and missions might justify asymmetrical terms of exchange, each side seems to think that the asymmetries should work in its favor. For example, universities often expect private firms to make research tools freely available to university scientists, although the same universities routinely charge private firms for access to research tools created in academic laboratories.<sup>37</sup> Universities feel

<sup>35</sup> See ELINOR OSTROM, *GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS FOR COLLECTIVE ACTION* (1990).

<sup>36</sup> See Heller & Eisenberg, n. 4 above.

<sup>37</sup> In the words of the general counsel for a biotechnology firm, 'When [they seek access to a research tool from a company], universities wear the mortarboard, they want the company to pay

justified in making this distinction because their own research is for academic purposes, whereas the research done in private firms is for profit.<sup>38</sup> In the ethos of many university technology transfer professionals, the financial interests of their institutions converge with the public interest in scientific progress.<sup>39</sup> But private firms resent this claim to the moral high ground and see it as hypocritical. Some representatives of private firms challenge the claim that university research is not for profit, noting that many university scientists collaborate with private firms, and that proprietary research tools supplied to university scientists sometimes find their way into the hands of commercial competitors.<sup>40</sup> Others take exception to the claim that it is more fair for universities to restrict access to their research tools by commercial scientists than it is for commercial firms to restrict access to their research tools by academic scientists. Instead, they argue that university research is publicly-subsidized and should therefore benefit the taxpaying public, including private firms, while companies that pay for research with shareholder dollars have a corresponding obligation to return value to their shareholders and therefore cannot give intellectual property away.<sup>41</sup>

The Working Group also heard numerous complaints from representatives of all sectors of the biomedical research community that their counterparts in the other sectors are unrealistic in their demands and fail to appreciate the difficulties that they face in complying with contract terms. For example, recurring complaints among university technology transfer professionals focus on prepublication review provisions and limitations on who can work with the

all the money and take all the risk. But when they [seek to license a research tool out to a company], they scream about how they don't have any money, they're constantly ripped off by private firms . . . Universities want it both ways. They want to be commercial institutes when it comes to licensing their technology, but to be academic environments when it comes to accessing technology that others have developed. Sit down with a university and they will insist that they have discovered the holy grail and it's worth all the tea in China. But if they need something, they are academic institutions who are being impeded. They throw the same things in the way of small companies'.

<sup>38</sup> This attitude was particularly apparent in discussions among university technology transfer professionals at a meeting of the Association of University Technology Managers attended by members of the Working Group.

<sup>39</sup> A representative of a nonprofit institution told me that when, in the course of negotiations over terms of access to a research tool, a private firm tells her that they have a duty to their shareholders, she responds that she has a duty to the public.

<sup>40</sup> The research director of a major pharmaceutical firm claimed that academic scientists whose names would be recognizable to the firm as collaborators of its competitors sometimes use graduate students and post-doctoral fellows to get access to materials without revealing their identities. The general counsel of a biotechnology firm similarly reported that 'many companies will tell you they've been burned by professors who've made deals with multiple companies'.

<sup>41</sup> The words of a representative of a major pharmaceutical firm are typical of many comments from the private sector: 'It's hard to expect companies to forbear from seeking the same terms that universities are seeking. The universities don't have any moral imperative working in their favor—they aren't even accountable to shareholders'.



materials and what they can do with them.<sup>42</sup> They cite these provisions as evidence of a lack of appreciation for the open culture of academic research and the absence of control mechanisms within universities for ensuring compliance.<sup>43</sup>

University representatives also complain about prohibitions on the use of materials in research that is subject to a licensing obligation to another entity, and grantback provisions that give the provider automatic licenses under future patents. Such provisions, in their view, create conflicting obligations when multiple firms provide different research tools for use in the same project. They worry that contractual obligations to extend even nonexclusive licenses to past providers of research tools will compromise universities' stewardship over future discoveries. They point out that when these discoveries result from government-sponsored research, the Bayh-Dole Act imposes technology transfer obligations on the university.<sup>44</sup> In this view, the ownership rights that universities retain over discoveries made with public funds come with a corresponding trust that obligates universities to license those discoveries so as to promote transfer of technology to the private sector. Often, the best way to promote commercial development of an invention is to grant an exclusive license to a firm that promises to pursue development with diligence. But universities are unable to grant such exclusive licenses if they have previously promised nonexclusive licenses to past providers of research tools under the terms of MTAs. Precommitted licenses to future discoveries also conflict with opportunities to obtain corporate research funding for university-based research, as corporate research sponsors typically demand preferential license rights to such discoveries. Universities see the exchange of future license rights for access to a research tool as tantamount to 'free research for the company' that provides the tool. This characterization

<sup>42</sup> A representative of a university that many companies singled out for praise as a negotiating partner observed that 'Most of these problems appear to be caused by the material provider's inexperience in dealing with a non-profit institution and its special duties and concerns'.

<sup>43</sup> One university technology transfer professional explained that 'scientists have a tendency to get material for one purpose and use it for something else. Nobody knows about it. It's up to the investigator to comply with reporting requirements [to the provider of a research tool]. We don't have the resources to do it . . . Research projects metamorphose all the time'. In fact, many companies are acutely aware of the risk that scientists will obtain material for one purpose and, without letting the company know what they are doing, use it for another in violation of their agreements. They seek to control this risk through the terms of their MTAs.

<sup>44</sup> As explained by a representative of a major research university, 'Because companies will not typically allow use of their materials in research being funded by another commercial entity, the material provider who successfully negotiates sole rights gets exclusive control of inventions whose discovery was funded by the federal government—simply by providing a sample of material . . . The provider who successfully negotiates an automatic, royalty-free, non-exclusive license has seriously damaged the ability of the research institution to promote the commercial development and marketing of any invention by offering exclusivity as an incentive to investment'.

enrages firms that see themselves as seeking a modest *quid pro quo* for providing free materials to university scientists.<sup>45</sup>

Companies complain that universities do not understand business and suffer from a 'cultural schizophrenia' about whether they are businesses or academic institutions. In the words of a lawyer for a company that was the focus of many complaints from university technology transfer professionals: '[university] tech transfer offices are not close enough to people who do deals. People out here do deals, and do them fast. University tech transfer offices take eight months to get to the point of doing a deal, and then the relevant people quit and you have to start over with someone else . . . They're overly conservative. They would rather pass up ten good deals than make one mistake'.<sup>46</sup> A number of private firms complained that university technology transfer offices are inadequately staffed, use inexperienced people who lack adequate authority to conclude agreements, and place considerable pressure on their staffs to bring in money for the university, giving them little incentive to spend time on smaller agreements for the transfer of research tools.<sup>47</sup>

<sup>45</sup> The 'free research' characterization infuriates corporate providers of research tools to universities because it suggests that the value of the research tool is zero. From another perspective, however, it may not be entirely off the mark. When asked why they provide research tools to university researchers, many representatives of private firms cited the benefit of getting interesting and reliable research results from leading experts in the field. For example, a lawyer for a small biotechnology firm explained that 'small companies can't do everything. Often what you're looking for is an expert in academia who isn't in a competing company, has lots of expertise in the area, and may be the best person in the country to work on it, giving us confidence in the results'. A senior patent counsel for a larger biotechnology firm said 'it's useful to learn as much as possible about our proteins. We'd probably miss things if we did everything internally, because we don't have expertise in all tissue types and organs. In fact, we've learned a lot from academics. We've had a number of developments come back to us, and we've licensed in a new use of a material'. In other words, companies make research tools available to university researchers because that is a cheap way of getting research done that might yield useful results for the firm. Similar motivations account for the interest of firms in receiving incoming research tools that have been developed by university scientists, notwithstanding the difficulties that they describe in negotiating with university technology transfer offices. A representative of a small biotechnology company explains: 'It's just time that we're saving by getting [a tool] from a university. If I were Merck or Pfizer, they may have their own cloning group. They know up-front that it's not worth wasting time dealing with universities. They're so resource-rich, but we're not. We have to go to the academic community'. These comments from the private sector suggest that an important motivation for exchanging materials with academic investigators, whether the firm is providing or receiving the materials, is to obtain research results while conserving the firm's own resources for other research projects.

<sup>46</sup> The same lawyer also expressed contempt for the competence of universities in licensing out their own technology to companies: 'We don't have any faith in the ability of universities to license technology effectively. They don't have the infrastructure, they don't understand, they don't have a clear mission. The scientific collaborators want it both ways—they want to pocket their money but remain in the ivory tower. Quite frankly I have no faith in them to license it and get value out of it, to appreciate what's valuable in it . . . We want to be in a position to control what's done'.

<sup>47</sup> The research director for a major pharmaceutical firm explained: 'Problems we have that are impediments to getting things done quickly are tech transfer offices not having enough people available, combined with the agenda to bring in money for university, means that it's hard to get their attention to these smaller agreements. You need to get the attention of enlightened people on both sides in order to do these low-cost agreements in a more rapid, expedient way. You need enough people with the tools of legal language at their fingertips'.

Another recurring complaint was that universities try to impose unrealistic diligence obligations on firms to achieve rapid commercial development and are unduly suspicious that firms will suppress licensed technology.<sup>48</sup>

Perhaps the most consistent complaint about universities from the private sector is that they overvalue their own discoveries<sup>49</sup> and underestimate the considerable risk and expense involved in commercial research and product development.<sup>50</sup> Pharmaceutical firms voice a similar complaint about biotechnology companies,<sup>51</sup> and biotechnology companies say the same about people who provide them with research tools.<sup>52</sup>

Heterogeneities within the biomedical research community appear to impede the exchange of research tools in a number of ways. Each segment of the community feels misunderstood by the others, and each feels that the differences in institutional cultures and missions should weigh in its favor. Institutions from each of the different segments of the community thus have an easier time negotiating mutually agreeable terms of exchange with their own kind than with representatives of the other segments.

### C. Conflicting agendas of different agents

Quite apart from heterogeneities across the spectrum of institutions involved in biomedical research, each institution itself is a heterogeneous community employing different kinds of people whose agendas may come into conflict in negotiating the terms of transfer for research tools. This was particularly apparent for universities, perhaps because the Working Group separately sought out the views of scientists and technology transfer professionals within universities. The perceptions and concerns of these two groups differ

<sup>48</sup> A vice president and general counsel for a biotechnology company complained that universities 'want to revoke the license if they don't see an NDA [New Drug Application] filed [with the Food and Drug Administration] within three years. They have no idea how long it takes to go from an IND [Investigational New Drug application] to an NDA. Academic institutions are always afraid someone is going to tie up their technology. Why would I want to do that?'

<sup>49</sup> One lawyer for a biotechnology company politely observed that 'the academic community sometimes has less information than the company does about what kind of royalties are typical'. A less diplomatic representative of a major pharmaceutical firm said that 'university tech transfer offices have gone fantastical'.

<sup>50</sup> A licensing professional in a major pharmaceutical firm, citing the tendency of universities to overvalue molecular drug targets that might be used to screen potential products, explained: 'Universities don't understand the drug discovery process. They think screens are like sieves, with drugs coming out the bottom. They don't understand how much attrition there is in the path of product development'.

<sup>51</sup> One representative of a pharmaceutical firm said that many biotechnology companies that seek substantial reach-through royalties on future products are 'dreaming', and that 'greedy biotechs will freeze themselves out'.

<sup>52</sup> For example, a senior executive of a genomics company reported that clinicians who collect DNA samples from families for use in cloning disease genes often seek royalties on future products, without appreciating how much more work remains to be done to clone the genes involved in the disease pathways and identify potential drug targets.

strikingly, setting the stage for intra-institutional conflict and raising obstacles to the emergence of market norms.

Academic scientists are under considerable pressure to generate and publish research results. Their top priority when they seek access to research tools is acquiring the materials they need as quickly as possible. Scientists have limited patience for reading the terms of the agreements accompanying these tools and express considerable irritation with their institutional representatives for taking too long to get the paperwork in order. Rather than seeing these technology transfer professionals as facilitators and guardians of their best interests who enable them to gain access to research tools on reasonable terms, they see them, in the words of one scientist, as 'paper pushers who sit on these documents and try to find errors'.<sup>53</sup>

University technology transfer professionals, on the other hand, are primarily charged with licensing university-owned inventions out to the private sector and bringing in money to the university (whether in the form of grants or license revenues).<sup>54</sup> Their top priorities in reviewing agreements are to protect the university and its scientists from incurring obligations that will limit their freedom to conduct research, to preserve future opportunities to obtain research funding, and to preserve their freedom to license future discoveries on lucrative terms. From their perspective, the terms of incoming MTAs are treacherous land-mines waiting to explode beneath unsuspecting signatories. They see scientists within their institutions as naive, short-sighted, and careless in their readiness to assume legal obligations that they will later regret.<sup>55</sup>

<sup>53</sup> This is more of a problem for some kinds of contract provisions than for others. Technology transfer professionals in universities report that it is relatively easy to explain to scientists why they should resist draconian prepublication review provisions, but that the scientists see little point to renegotiating provisions governing more remote contingencies such as the allocation of intellectual property rights in future discoveries or the allocation of tort liability in the event of injuries. Particular difficulties arise with definitions of terms used in agreements that do not track the ordinary meaning of these terms to scientists. For example, an agreement might define 'the material' that is subject to restrictions in a way that includes modified derivatives, or it might define prohibited use for 'commercial purposes' to include use in research that is subject to a licensing obligation to another firm (including a firm that might have supplied another research tool). On a quick reading, these provisions appear innocuous to scientists, leading them to suspect that it is their own university technology transfer office, rather than the provider of the material, that is being unreasonable.

<sup>54</sup> In some universities, agreements governing incoming research tools are processed by an office that is primarily concerned with negotiating and administering grants for sponsored research, while in other universities they are processed by a technology transfer office that is primarily concerned with negotiating and administering license agreements for university-owned technologies. Either way, incoming research tool agreements represent an additional responsibility that adds to the workload of the professional staff without adding in any visible way to the revenues that they bring in to the university.

<sup>55</sup> Speaking about the university's reluctance to agree to assume tort liability under an MTA, one university technology transfer professional remarked that 'the faculty doesn't understand this issue at all, and it's hard to explain it to them. We have no real horror stories to back up our concern. But universities have endowments [that could be depleted by tort judgments], and some of these materials are actually dangerous'.

At the same time, however, technology transfer professionals must rely on the scientists to alert them to potential problems and to monitor and comply with any obligations imposed by the agreements.<sup>56</sup>

This divergence of perspectives within universities is not lost on those who negotiate the terms of research tool agreements on behalf of private companies. Company representatives see (and encourage university scientists to see) university technology transfer professionals as the true obstacles to the expeditious transfer of research tools, stalling research in the hope of preserving speculative future intellectual property. In the words of a scientific liaison to a biotechnology company, 'the function of the technology transfer office should be to serve the faculty, not to make money, yet they refer to faculty as children'.

But the interests of the faculty are not necessarily the same as the interests of the university. Although faculty members are employees of universities and are typically bound by contract to assign intellectual property rights in their discoveries to their employers, the agency relationship between faculty members and universities is attenuated by traditions of academic freedom that protect faculty from institutional control of their academic work. Faculty members enjoy considerable freedom to select and pursue their own research agendas—typically with external funding—and to publish their results without prior institutional approval. Whereas researchers in the private sector are often bound by confidentiality agreements or non-competition covenants that prohibit their use of information gained from working for a particular employer when they move to a new job, faculty members who move from one academic institution to another typically take their research (and grants) with them. Moves from one academic institution to another rarely lead to litigation over intellectual property rights between universities and former faculty members, although as a purely legal matter universities are generally entitled to claim ownership of the patentable inventions developed by their employees using university facilities.<sup>57</sup> Within the academy, faculty members who resist institutional constraints on their research feel that they are upholding a sacrosanct tradition rather than violating a fiduciary duty.

This strong tradition of faculty autonomy from institutional control of the conduct of research makes universities wary of incurring institutional obligations that rely on faculty members for compliance.<sup>58</sup> Yet providers of

<sup>56</sup> A technology transfer professional for a major research university noted: 'It's not really possible for a bureaucrat to recognize the problems looking at a text. You have to rely on the scientists, whose skill and integrity in these matters vary'.

<sup>57</sup> Litigation is more likely when a departing faculty member brings research to a private firm. See eg, *University Patents v. Kligman*, 762 F.Supp. 1212 (E.D. Pa. 1991).

<sup>58</sup> Some common provisions in research tool agreements, such as prepublication review provisions, prohibitions against transfer to another laboratory or institution, and obligations to disclose data to the provider, impose obligations that call for compliance on the part of the faculty scientist. Others, including payment obligations, reach-through royalties, automatic licenses,

research tools to academic scientists typically seek to bind the universities, and not just the faculty members, to the terms of their agreements. Academic scientists thus need the concurrence of university technology transfer professionals to receive incoming research tools. But if the scientists later violate the terms of the agreements, whether through inadvertence or indifference, the institution will be exposed to liability.

Faculty autonomy also limits the power of university technology transfer professionals over the terms of exchange for outgoing research tools. Although in theory the university owns these tools, as a practical matter faculty members have the power to bypass the technology transfer office when they send out their materials for use in other institutions and universities are unlikely to sue them for doing so.

Private companies typically have considerably more control than universities over the activities of their employed scientists. Nonetheless, some comments from lawyers and business people in these firms suggested there might be similar divergences of interest among the various agents involved in the transfer of research tools in the private sector. The benefits of exchanging research tools with academic counterparts—collegiality, access to data, opportunities for prestigious collaborations and publications, and scientific credibility—are often more palpable to commercial scientists than they are to the lawyers and business people whose approval is necessary to conclude the exchange. Many company representatives reported that their scientists exchange materials with academic counterparts informally without getting the approval of the firm or its lawyers.<sup>59</sup> This practice exceeds the authority that firms typically give scientists to send out materials under the company's form agreement, but not to vary the terms of the agreement without approval.

The practical (if not legal) ability of scientists to bypass the business and legal agents that represent their employers when they exchange research tools appears to be creating a two-tiered market. In the 'free exchange' tier, scientists deal with one another directly and impose minimal obligations and paperwork, while in the 'proprietary' tier, lawyers and technology transfer professionals haggle over terms of exchange with resulting delays in research. The existence of a free exchange tier relieves some of the pressure on the exchange system overall by avoiding the transaction costs of proprietary

options to acquire licenses, and indemnity provisions, call for compliance on the part of the university. Either way, the institution is likely to face liability for noncompliance. Even if the university has a formal right to seek indemnity from the faculty member, this right is unlikely to be exercised and may be of little value.

<sup>59</sup> The director of scientific affairs at a biotechnology company reported: 'The scientists here will often send research reagents without my knowledge . . . We have an R&D driven staff that generally think it's a waste of resources to use agreements for all the research reagents . . . It's a method of gaining good will, developing a rapport with labs that we may later have more substantial relationships with. The legal department frowns upon it. Scientists are under specific instructions not to send out anything proprietary without an MTA'.

exchange in some cases. But these two tiers are not entirely separate. Because the terms of exchange in the proprietary tier typically restrict subsequent free exchange of materials, some of the free exchange transactions may eventually give rise to liability for breach of contract. As a result, lawyers and technology transfer professionals become ever more wary of free exchange and more assiduous about restricting its domain, while scientists become ever more frustrated with proprietary exchange and more motivated to bypass its constraints.

#### **D. Difficulties in valuation**

Virtually everyone who provided information to the Working Group cited difficulties in measuring the value of access to a research tool as an obstacle to negotiating terms of exchange. Pharmaceutical firms, biotechnology firms, and universities framed the problem somewhat differently, but research tool users within each sector share the perception that tool-providers in the other sectors are asking for too much and overvaluing the contribution of particular tools relative to other inputs that contribute to future valuable discoveries.

Representatives of pharmaceutical firms argue that a fair measure of the value of both incoming and outgoing research tools is the cost of creating the tools.<sup>60</sup> They are often willing to pay such a sum for incoming tools up-front, but they are loath to promise to pay royalties on future product sales for access to research tools, believing that in most cases such payment terms would grossly overvalue the contribution of a research tool relative to other investments in the course of drug development.<sup>61</sup> They complain that universities and biotechnology firms have unrealistic expectations of making money from research tools, given that these institutions do not share in the full costs and risks of the complex process of drug discovery.<sup>62</sup>

<sup>60</sup> One representative of a major pharmaceutical firm said that his firm has a philosophy of 'making research tools available at reasonable cost' defined as 'what it would cost in time and money to reproduce [the tool]'. He contrasted this perspective with the 'gold rush mentality' of some universities that have 'inappropriate expectations' that they are 'going to be able to make money for the university' and biotechnology firms that are 'striving to jack up stock prices' with 'business plans that are strictly financial, not drug discovery'.

<sup>61</sup> A research director for a major pharmaceutical firm explained: 'Reach-through royalties are making everyone crazy . . . If someone makes a discovery of substantial value that was the core critical issue that gave us a competitive advantage, that has value, and if we succeed, the person who gave us that should succeed. But [only] for really critical discoveries . . . The way to judge a critical contribution is for the company to say I can't do this without it'. A high-ranking executive in another major pharmaceutical firm sees the overvaluation problem as compounded by the issuance of multiple, overlapping patents on research tools: 'You have a series of different academic labs working with a receptor and you may get lots of different claims coming from different labs. Royalty-mounting can frustrate the economic incentive to develop'.

<sup>62</sup> In the words of a high-ranking representative of a major pharmaceutical firm: 'Individuals in tech transfer offices in universities have had the fire lit under them to go forth and capture this presumed pot of gold. It leads them to take an unrealistic posture in asking for reach-through rights'.

Consistent with the position that they take for incoming research tools, when pharmaceutical firms set the terms of access to outgoing research tools and materials for other institutions, they do not seek promises of future royalties or even large up-front payments. They are typically more concerned about protecting themselves against future obligations than about collecting cash payments or garnering a share of future profits.<sup>63</sup> Their principal worries are (1) that use of the tool will compete with the firm's own work and enhance the position of a competitor who either collaborates with the user or takes a license to the user's discoveries;<sup>64</sup> (2) that the research will yield publications that undermine the firm's patent position<sup>65</sup> or generate patents that constrain the firm's freedom to develop its own products fully;<sup>66</sup> and (3) if the research tool is a pharmaceutical product in development, that the user's data will suggest possible harmful side-effects that create regulatory problems and add to the costs of clinical trials.<sup>67</sup> They therefore ask that the tool not be distributed beyond the laboratory and/or scientist to whom the firm is providing it, that the scientist explain what will be done with the material and report research results, and in some cases that the firm receive an automatic license to use any improvements for internal research purposes and/or an option to obtain an exclusive license to future discoveries. To pharmaceutical firms, these provisions are defensive measures that protect them from losing competitive ground when they make their materials available free of charge to academic scientists.

Universities that are confronted with such provisions for access to incoming research tools take a different view. From their perspective, agreements

<sup>63</sup> A representative of a major pharmaceutical firm explained that 'we don't charge academic labs anything, but we do charge companies nominal payments. We ask [universities] for a non-exclusive license for internal research to improvements that they make, disclosure of improvements, and maybe prepublication review'.

<sup>64</sup> A research director for a major pharmaceutical firm said that when the firm makes research tools available to academic researchers, there is a 'major risk . . . of transfer to another company . . . Scientists with the most strident voices in the debate [about access to research tools] are often those that have conflicts of interest'.

<sup>65</sup> In the words of a research director for a major pharmaceutical firm: 'What matters most is being informed that something has been found using this tool, so we don't just find out about it in a paper. We want the opportunity to file for patents or seek a license'.

<sup>66</sup> This concern is particularly significant in the case of research that might uncover new uses for pharmaceutical compounds. A representative of a major pharmaceutical firm explained: 'with a compound, we'd probably be very sensitive if we saw an experiment description that might lead to a new use. We might use a research collaboration and licensing agreement rather than a simple material transfer agreement. If someone is going out to find a new indication, and we think that we've given the essential material, it makes no sense to exclude us'.

<sup>67</sup> A lawyer for a major pharmaceutical firm said that 'the last thing you want to do is become obligated to do further toxicology studies'. Another pharmaceutical representative downplayed this concern, saying that although 'inadvertent activity that gives rise to concern about the compound can be very difficult to deal with, you don't want to suppress legitimate information about adverse effects'. He rated this concern as 'minor on the scale of things', although conceding that this problem is minimized because firms rarely release products in development for use as research tools.



that condition access to a research tool on license rights to future discoveries overvalue the research tool relative to potential future discoveries. If they agree to give automatic, nonexclusive licenses to providers of research tools, they will not be able to grant more lucrative exclusive licenses to their future discoveries to anyone else, regardless of the value of the discoveries. As for granting options to enter into an exclusive license, this is the compensation that universities give for full research sponsorship, not for the mere contribution of a research tool. They see promises to grant license rights to future discoveries in exchange for research tools as forced bargain sales that undervalue their future intellectual property.<sup>68</sup>

On the other hand, many private firms reported to the Working Group that universities frequently seek reach-through royalties on future products as payment for the outgoing research tools that they provide to the private sector. Although reach-through royalties on future product sales are not the same as grantbacks of license rights to future discoveries, both mechanisms compromise the value of future discoveries made by the user of a research tool. Universities may be more successful in imposing reach-through royalties on biotechnology firms than on pharmaceutical firms.<sup>69</sup>

Biotechnology firms and pharmaceutical firms tend to agree with each other that universities have unrealistic expectations as providers of research tools. They have different concerns, however, when it comes to setting the terms of access to their own outgoing research tools. In contrast to the defensive focus of pharmaceutical firms in licensing their outgoing research tools, biotechnology firms often see their own proprietary research tools as central to their evolving business strategies and as a critical source of value for the firm. Both pharmaceutical firms and universities complain that biotechnology firms overvalue their research tools and have unrealistic expectations about what they can demand for them. Pharmaceutical firms explain the tendency to overvalue research tools on the part of both biotechnology firms and universities as stemming from ignorance of the costs and risks involved in the drug discovery process. One representative of a pharmaceutical firm explained that biotechnology firms typically focus on a small number of

<sup>68</sup> A representative of a biotechnology firm suggested that concern on the part of universities about undermining the marketability of their future discoveries reflects an inflated sense of the commercial value of their own discoveries: 'Universities think they have something commercially viable when they don't. If it were viable we'd be in line for an exclusive license. So I don't think our nonexclusive licenses are really preventing them from selling anything they could otherwise sell'.

<sup>69</sup> In the words of a representative of a major pharmaceutical firm: 'biotechs like reach-throughs, and pharmas hate them'. This may be because biotechnology firms themselves seek reach-through royalties as compensation for providing research tools. One high-ranking officer of a biotechnology firm speculated that another reason may be that biotechnology firms expect to be able to offload reach-through royalty obligations onto a pharmaceutical firm that ultimately develops the product, although the biotechnology firm might thereby reduce its own royalties on the product.

research strategies and overvalue their chances for success. Pharmaceutical firms, on the other hand, understand that 'in this business, you've got to get a lot of shots on goal, because most of them never make it'.

Conflict over the value of research tools seems to be particularly aggravated for exchanges between biotechnology firms and universities, perhaps because both sides of the exchange are typically cash-poor. When biotechnology firms provide outgoing research tools to universities, they often seek not merely to protect themselves from competitive harm, but to profit from future discoveries made through use of their tools. In the words of a lawyer for a biotechnology firm: 'most small companies resolve it this way: If we're going to give a research tool to a company, we'll charge money. If we give it to a university, we need to get some other kind of value out of them' in the form of license rights to future discoveries. A lawyer for another biotechnology firm elaborates that since universities can't afford to pay full price for access to research tools, 'we ask them to pay with the currency they have, which is intellectual property'.<sup>70</sup>

In contrast to some pharmaceutical firms that express a commitment to make research tools available in order to advance science, many representatives of biotechnology firms expressed a need to justify their dissemination of research tools to shareholders and boards of directors in terms of potential profits for the company. One representative of a biotechnology firm explained that 'the promise of a possible exclusive license is how we justify throwing money away by giving out free material'.<sup>71</sup>

Some biotechnology firms seek grantbacks of licenses to any discoveries made through use of their research tools, without restrictions to particular fields of use contemplated by the firm. A senior patent counsel for a biotechnology firm explained that such broad rights are necessary because of the difficulty of drafting agreements that precisely allocate rights in unpredictable research results: 'Whatever they come up with is likely to either be useful with or compete with our molecule. It's hard to draft an option that only catches the things we will want an exclusive license to, so we draft it broadly'. A lawyer for another firm offered a somewhat different, and perhaps more candid, explanation: 'My biggest fear is that an academic institution is going to discover something valuable with my technology, whether I planned on it or it's totally unplanned. I want to have some opportunity to get access to the technology, to use or exploit it, or to work with the institution to jointly control disposition. It's human nature to want that, even though I'm no worse off. It's more emotional than rational'.

<sup>70</sup> This firm asks universities for an option to take an exclusive license to future discoveries at a predetermined royalty rate, a provision that is very unpopular with universities. He explains that 'no one knows how to value this stuff, and everyone's afraid of getting burned. They're worried that they're going to license out a blockbuster cheap'.

<sup>71</sup> A lawyer for another biotechnology firm put the point even more bluntly: 'A business is in business to make money for somebody. You can't have people giving things out for free'.

One senses in the remarks from representatives of all sectors that emotions are playing a large role in negotiations over the transfer of research tools. Perhaps the inherent difficulty of assessing values for research tools relative to the values of potential future discoveries makes it difficult to identify dispassionate points of reference that everyone can agree upon. Research involves investigation of the unknown; its outcome is inherently uncertain. Information that would help estimate the likely value of research using a tool is divided between the owner of the tool (who has typically worked with the tool and may already be pursuing what it considers the most promising uses) and the would-be user (who may have complementary expertise that brings into view a research plan that might or might not have occurred to the owner). If owners and users perceive each other as rivals, they may be reluctant to share information regarding their valuations and skeptical of each other's purported assessments.<sup>72</sup> For research that is remote from end product development, it may be some time before the commercial value of resulting discoveries becomes apparent; and even when research yields an outcome of manifest value, it may be difficult to agree on a formula for assessing how that value should be apportioned between prior and subsequent innovators.

The profitable endpoint of biomedical research is the development of a successful pharmaceutical product. A strong patent position on such a product can be quite lucrative, although such products are outliers in a distribution that includes many costly failures.<sup>73</sup> But many of the institutions involved in the complex enterprise of biomedical research have no expectation of ever bringing a pharmaceutical product to market themselves. Universities and many biotechnology firms specialize in earlier stage discoveries that provide a platform for the discovery of new pharmaceutical products. The challenge for these institutions is to leverage their proprietary rights in premarket discoveries into a place at the feeding trough of a new pharmaceutical product.

Given the vicissitudes of drug discovery, tools used in research that may or may not yield lucrative products typically have a low expected value to the user. The farther upstream from product development the research lies, the less likely the user is to be willing or able to pay a large up-front fee for use of

<sup>72</sup> Recognizing that informational asymmetries exist, owners and users of research tools may draw inferences from each other's bargaining behavior that lead them away from agreement rather than towards it. For example, an owner of a research tool may figure that if a prospective user wants to use it badly enough to invest resources in negotiating the terms of exchange, it must be valuable, and the owner will therefore hold out for favorable terms. The user's resistance to particular terms in the agreement may signal to the owner that those provisions are particularly valuable to retain, eg, if the user is reluctant to promise the owner a license to future discoveries, the user must believe it is on the verge of making an important discovery.

<sup>73</sup> As F.M. Scherer and his co-authors have documented, the value of innovations exhibits a highly skew distribution. See Scherer, Chapter 1 above; F.M. Scherer et al., *Uncertainty and the Size Distribution of Rewards from Technological Innovation* (March 1998) (unpublished manuscript); Dietmar Harhoff et al., *Exploring the Tail of Patented Invention Value Distributions* (1998) (unpublished manuscript).

the tool. Academic researchers may lack the resources to pay more than a trivial sum, and private firms may consider the remote prospect of future commercial gain insufficient to justify a large payment. Contingent payment mechanisms such as reach-through royalties or grantbacks of license rights in future discoveries rest on even less informed speculations about how large a share of the value of potential future discoveries is properly attributed to the use of a research tool. To the extent that these mechanisms diminish the value of future discoveries to their owners, they also undermine incentives to pursue commercial development. Owners of research tools may believe that their materials will be of considerable value in the discovery of commercial products, and manifestations of interest from researchers at other institutions are likely to confirm that belief. The result may be protracted negotiations over value that lead the parties away from, rather than towards, agreement.

### III. Conclusion

The exchange of research tools within the biomedical research community often involves vexing and protracted negotiations over terms and value. Although owners and users of research tools usually manage to work out their differences when the transactions matter greatly to both sides, difficult negotiations often cause delays in research and sometimes lead to the abandonment of research plans. Transaction costs have remained persistently high in this setting as the heterogeneous institutions involved in the exchange of research tools have been unable to agree upon standardized contract language, or even to agree upon a universe of materials, information and techniques that are properly termed 'research tools'. The result has been burdensome and frustrating case by case negotiations over exchanges that in an earlier era might have occurred between scientists without formal legal agreements.

Is this a picture of market failure, or is it simply a market? Surely most markets are characterized by positive transaction costs that render some low value transactions prohibitively expensive. Why should we care if the low value end of this particular market gets bogged down in negotiations, or even fails?

One reason why we might care about this particular market is that, although the value of any particular transfer of a research tool may appear small *ex ante*, some such transfers, if they go forward, may prove to have been highly valuable *ex post*. (Indeed, it is this remote possibility, and the impossibility of distinguishing high value from low value exchanges *ex ante*, that motivates the parties to bargain hard over the terms of each exchange.) However skewed the distribution, the aggregate social value of widespread dissemination of biomedical research tools is likely to be quite large. When

biomedical research is repeatedly stalled pending negotiations over the terms of MTAs, the social cost of foregone or delayed innovations, measured in lives and health, could prove to be substantial.

This close-up picture of what goes on in the market for biomedical research tools serves as a reminder that transaction costs for transfers of intellectual property are indeed positive and not negligible. Bargaining over intellectual property rights in the context of cumulative innovation is problematic. Nonetheless, the limited context investigated by the Working Group cautions against broad generalizations about what might be happening outside that context. Do similar problems arise in other settings, including other fields of technology? The foregoing discussion suggests some features of a market for intellectual property that may impede agreement upon terms of exchange, including high transaction costs relative to likely gains from exchange, participation of heterogeneous institutions with different missions, complex and conflicting agendas of different agents within these institutions, and difficulties in evaluating present and future intellectual property rights when profits are speculative and remote.

In some settings institutions have emerged to bring down transaction costs associated with a proliferation of intellectual property rights, but in some settings they have not. It is important to weigh these costs, and the foregone value of the exchanges that they prevent, in assessing the wisdom of creating new intellectual property rights, rather than simply assuming that bargains between owners and users will bring about efficient reallocation of rights.