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Patents versus patenting: implications of intellectual property protection for biological research

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A new survey shows scientists consider the proliferation of intellectual property protection to have a strongly negative effect on research.

A system of intellectual property (IP) rights can encourage inventions by scientists and help promote the transformation of research achievements into marketed products. But associated restrictions on access can reduce utilization of inventions by other scientists. How is this trade-off working out in practice?

This question has been of particular concern for the biological sciences, where production and exchange of biological 'research tools' are important for ongoing scientific progress. Recent studies addressing this issue in the United States^{1,2}, Germany³, Australia⁴ and Japan⁵ find that "patent thickets"⁶ or an "anticommons"⁷ rarely affect the research of academic scientists. It is well known that biological scientists report increasing difficulties associated with access to research tools but only if the tools are embodied in physical property controlled by others and not easily duplicated. Fear of infringing a prior patent on this material, or the high cost of licensing, is rarely a factor.

Reviewing this evidence, Caulfield *et al.* infer that "[t]he problems that the data do reveal may have less to do with patents than with commercial concerns, scientific competition and frictions in sharing physical materials"⁸. The emerging consensus of the science and policy literature frames the issue as "material versus intellectual property"^{9,10} and considers the latter to be rarely a problem for scientists.

This consensus relies on indirect inference. The literature offers almost no direct evidence

of scientists' own views of the trade-off involved in IP protection of research tools.

Here we report scientists' assessments regarding the overall effects of IP protection, as revealed in a survey of academic agricultural biologists. Scientists believe that, contrary to the current consensus, proliferation of IP protection has a strongly negative effect on research in their disciplines. Our respondents' answers on the details of access problems are highly consistent with those reported in the recent literature, but they ultimately relate these problems to the proliferation of IP protection in academia.

Follow-up interviews, which recorded scientists' extended accounts of selected cases, provide further insights on how bench scientists experience the negative effects of IP protection (**Supplementary Interviews** online). They attribute problems of delayed or blocked access to needed research tools to material transfer agreements (MTAs). Academic administrators mandate use of MTAs to protect the value of the IP rights held by their institutions or to reduce their exposure to lawsuits by third parties. In short, the major impediment to accessing research tools is not patents *per se*, but patenting as an institutional imperative in the post-Bayh-Dole era.

Our respondents do not encounter an anticommons or a patent thicket. Rather, they believe that institutionally mandated MTAs put sand in the wheels of a lively system of interdisciplinary exchanges of research tools. Seeing no countervailing effect on the supply of these tools, they conclude that patenting impedes the progress of research.

These findings challenge the inferences of social scientists that there are no real problems with policies encouraging increased patenting of research tools. They also help explain why agricultural biologists have become leaders in the exploration

of open source biology (BiOS, Biological Innovation for Open Society)¹¹ and in institutional collaborations to facilitate access to crucial enabling technologies (PIPRA, Public Intellectual Property Rights for Agriculture)¹². They support the widespread adoption of the Uniform Biological Material Transfer Agreement (UBMTA) for exchanges among scientists, long advocated by the National Institutes of Health¹³. In concurrence with previous related research, they offer no reason to continue supporting a stronger academic research exemption as urged, for example, by Cukier¹⁴.

The survey

We mailed a questionnaire to all listed faculty in departments related to agricultural biology at four land grant institutions: the University of California (UC) Berkeley, UC Davis, UC Riverside and University of Arizona in 2005. The gross response rate of 25% (93 responses), though modest, is comparable to those reported for the recent studies in the United States (27%), the United Kingdom (16%) and Japan (19%) reported in the American Association for the Advancement of Science (AAAS) study by Hansen¹⁵. Eighty-five of our respondents were able to provide useful responses; the others predominantly reported that their work currently focused on administration or other nonresearch activities. A comparison (**Supplementary Material** online) of PubMed publications and patents of nonrespondents and respondents in a random sample of 80 faculty members in these departments gives no grounds for suspecting nonresponse bias. We conducted follow-up interviews with a subset of respondents (**Supplementary Interviews**) to explore the nature of the access problems they reported.

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Sample characteristics including tool exchange activities

The scientists in our sample are well qualified to report on the relevant issues; many have patented inventions and most are actively involved in exchanges with colleagues in academia and industry, both providing and receiving research tools (defined here to include such research inputs as vectors, markers, cell lines and animal models, antibodies, drugs, transgenic seeds and plants, germplasm, genes and proteins, and databases, but excluding commercial kits and products from vendors). Their responses thus reflect not only their own practices but also those of many more colleagues who are their counterparts in these exchanges.

In the previous five years (the relevant interval for all questions), our respondents launched, on average, seven research projects. Two were directed toward commercial applications, consistent with the 27% average share of funding from industry, including commodity producer associations. Fifty-six percent undertook at least one project directed toward commercial application, and 45% report some funding from industry, a figure identical to that reported for a broader group of land-grant agricultural scientists by Goldberger *et al.*¹⁶. (All percentages refer to fractions of respondents.) By comparison, the studies of biomedical scientists reviewed by Beckelman *et al.*¹⁷ report that 23–28% received some industry funding.

Forty percent have disclosed inventions to their universities in the most recent five years, and one-third of these (13%) had inventions that can be categorized as research tools. Thirty-four percent have obtained or applied for patents over the previous five years, and 9% had patented research tools; in comparison, 56% of US academic scientists in Hansen *et al.*¹⁸ had submitted a patent application in the previous five years. On average, 0.6 patents per researcher have been applied for or granted, greater than the 0.45 reported for land-grant agricultural scientists in general¹⁶. Patentees have the same average 27% share of industry funding as non-patentees.

Active involvement in exchanges of research tools with either other academic researchers and/or industrial scientists is the norm; 66 report 1,224 cases of provision of research tools to others, and 69 report a total of 770 cases of receiving tools, over five years. The types of research tools that are most frequently exchanged between researchers are quite distinct from those that researchers choose to patent. Vectors, plasmids and gene clones are the most commonly exchanged unpatented tools, followed by seeds, germplasm and plant

varieties. Gene and protein sequences feature most frequently in invention disclosures, followed by seeds, germplasm and plant varieties.

Sixty-three respondents sent research tools/materials to academia, with an overall average of 17 each over the five years. Sixty-two received tools from other academics, with an average of 9.5 per respondent. Tools sent to industry averaged 1.2 per respondent, with 23 respondents sending at least one, and tools received averaged 1.6 per respondent, with 31 recipients. Thus, the sample, though of modest size, represents a wealth of experience, on both sides, of exchanging research tools with their peers in academia and industry, forging links to industry and dealing with the patenting process.

For research materials exchanged between academic institutions, it has become standard policy in universities to mandate use of MTAs. However, many researchers willingly ignore such requirements.

For research materials exchanged between academic institutions, it has become standard policy in universities to mandate use of MTAs. However, many researchers willingly ignore such requirements. Formal agreements cover only 21% of cases where respondents provided tools to other academics over the previous five years. Indeed, only one-third of those who provided tools to academic peers use any MTAs at all; just two report using licenses. Even the 22 respondents who sent tools to industry (in a total of 83 instances) often did so without formal agreements; half never used any in the sample period. Licenses cover 16 cases and MTAs only 12.

For tools received from other academics, the average reported share of formal agreements in total exchanges is higher, at 48%. Almost all formal agreements are MTAs, with only eight license agreements. The reason for the difference between respondents' MTA shares as recipients and providers (48% versus 21%) is not clear. The numbers of MTAs involved are more balanced (180 versus 254). It is possible that, for informal transfers, the more active role of provider is easier to recall.

Of the 31 recipients of tools from industry (in a total of 83 cases), 25 report formal agreements, and most transactions were formal. There were 85 MTAs but only 4 licenses. Only one license involved monetary payments.

The impact of IP protection

Respondents tend to be realistically skeptical regarding the existence of any research exemption. Over 80% do not agree with the statement: "Academic researchers have an academic research exemption that allows them to use others' research tools without paying attention to potential infringement."

Nevertheless, researchers' own actions exhibit scant attention to the risk of infringing existing patents. Most (77 of 85) report that, in the past five years, they have never checked whether a tool that they might need in planned research is patented. (Similarly, only 5% of the biomedical scientists surveyed in Walsh, Cho & Cohen² report that they regularly check for patents on research inputs.)

If respondents are generally skeptical regarding a research exemption, why do so few check for prior patent rights? One answer is that many scientists do not believe they would be sued, even if they infringe. Their stance is consistent with the rational toleration of researcher infringement often reported by industry patent holders¹⁹.

One respondent declared in a follow-up interview, "If I do my research and don't make money, even if I broke the law, nothing would happen to me. I am just doing research for the public." Like many others, this respondent contrasts the interest of scientists from those of the university: "What I want is to do my research; what they [firms and universities] want is money. They fought it out and gave me an agreement, and I signed it. That is how it works." This seemingly cynical view of the objectives of university administrators in university-industry negotiations, and the contrast with the objectives of researchers, is confirmed in the survey of land-grant university administrators responsible for research programs and university-industry relationships in the area of agricultural biology by Glenna *et al.*²⁰. They report that administrators rank provision of research funds first in the list of advantages of university-industry relationships, although they acknowledge that their scientists have a very different ranking of priorities for selection of research problems, headed by research enjoyment and curiosity.

Before we asked scientists about their views of the overall effects of IP protection of research tools, we explored a narrower question regarding the possible effects of IP rights on the supply of tools. We asked respondents to evaluate, on the 5-point Likert scale ranging from 1 (disagree strongly) to 5 (agree strongly), the following statement:

Statement I. Intellectual property rights on research tools provide incentives to

invent more tools and/or conduct related research, and advance the research in your area. The mean evaluation is negative, at 2.7 ($P = 0.0003$). Respondents are not strongly impressed by the supply-side effects of IP rights on tools.

Having just been reminded of possible positive effects of IP rights, the researchers nevertheless believe that IP protection hinders their research. We asked them to evaluate, on the 5-point Likert scale, as above, the following statements:

Statement IIA. Overall, the intellectual property protection of research tools is having a positive impact on research in your area. Respondents on average disagree significantly with this statement (mean evaluation 2.3, $P = 0.0001$).

Statement IIB. Overall, the intellectual property protection of research tools is having a negative impact on research in your area. A majority agrees with Statement IIB (mean evaluation 3.7, $P = 0.0001$). Note that Statement IIB is a negative restatement of Statement IIA, and the responses are symmetrical, betraying no bias related to the difference in the form of the question.

How can scientists so unconcerned with infringement see IP rights as an impediment to research? The answer is that they associate problems of IP rights with problems with MTAs. Proliferation of patent protection is a key driver of the increase in university enforcement of the use of MTAs for exchanges of research materials. In particular, after the 1980 Bayh-Dole Act, “When professors sent cell lines or reagents to other scientists, they now had to accompany them with a materials transfer agreement containing complex restrictions against further distribution”²¹.

Walsh *et al.*⁹ find that when the recipient of a request for a research material asked for an MTA, there was less friction in the transfer process, perhaps because the response indicates a willingness to comply with the request. Nevertheless, we find that researchers associate MTAs with the types of transaction costs discussed by Eisenberg²².

The costs of formal agreements

Almost one-half of respondents disagree with the following statement: “*Research tools are easily exchanged through licensing/material transfer agreements.*” (Forty-eight percent and 47% “disagree” or “disagree strongly” for tools from academia and from industry, respectively, whereas only 25% and 17% agree or agree strongly, respectively.)

Less than one-third of respondents disagree with the statement that for tools sourced from academia or industry, “*Getting access to proprietary research tools often involves contractual restrictions on publication that cause significant constraints on academic freedom.*”

Broadly similar results are reported (without comment) in AAAS-supported surveys, focused on exchanges of patented technology.^{18,23–25} Less than one-third of respondents in the United States, the United Kingdom and Germany (and 38% in Japan) agree, on a five-point Likert scale, with the statement: “*Technologies owned by others are easily exchanged through licensing and material transfer agreements.*” More than 40% in all countries but the United Kingdom agree that “*Obtaining access to technologies owned by others often involves contractual restrictions on publications that cause significant constraint[s] on academic freedom.*”

Of course, MTAs are not the only source of access problems for academics seeking research tools. Long before the proliferation of IP protection, scientists were often secretive and uncooperative in their interactions with competitors²⁶. Indeed, scientific competition inhibits tool access for many of our respondents. We asked them to evaluate the likelihood that their rival laboratories, competing with them in the same field, would give them research tools or materials if asked to do so. They anticipate moderate degrees of difficulty in getting tools from rivals, with a mean evaluation of 3.2 on a 5-point Likert scale ranging from 1 (very unlikely) to 5 (very likely).

However, scientific competition cannot explain the increase in access problems experienced by our respondents. More than 50% of our sample agrees that, for tools from either academia or industry, “*for academic researchers, getting access to others’ proprietary research tools has become more difficult over the past five years.*” However, only 6% believe that scientific competition has increased over this time. On the other hand, 45% agree that the use of MTAs in obtaining research tools from academia has increased.

Monetary cost is not an issue, even for research tools sourced from industry (other

than commercial kits, not considered here); only one transaction (for a tool from a private firm) involved a financial payment. Nor do researchers find the MTA transaction process particularly difficult; they rated the difficulty of the MTA transaction process for accessing tools from their academic peers as averaging between 2.5 and 3.0 on a 5-point Likert scale ranging from 1 (very easy) to 5 (very difficult). Obtaining tools from industry using MTAs was moderately more difficult, with a mean of 3.6. Note, however, that researchers often bear only a fraction of the costs of MTA negotiations; follow-up interviews reveal that university administrators often handle MTA negotiations, after the initial inter-scientist contacts.”

The scientists distinguish their cost of negotiation from the delay imposed by the entire MTA process, and identify the latter as the dominant transaction cost. A typical transfer from an academic provider, covered by MTA, takes four months, compared to six months if the transfer is from industry.

It is perhaps understandable that, as providers, researchers report shorter average lags of 2.5 to 2.8 months for MTAs they have sent to academia and industry because they might not always perceive the lag in handling the MTA at the receiving end. Licensing to industry has a longer average lag, 9.8 months, skewed by a few cases with very long lags. Our results show longer delays due to MTAs than found by Walsh, Cho & Cohen². One reason might be truncation bias induced by their shorter two-year window. When scientists are asked to report lags in their most recent completed transaction in a two-year period, it is likely that cases with long lags will be underrepresented in the data, some being misinterpreted as instances of refusal to send requested tools.

Difficulties in obtaining needed tools in turn cause delays in research projects. Thirty-four respondents (42%) report a total of 97 such delays, ending when the tool arrived. Durations range from 1 month to 42 months, with a mean of 8.7 months. Eight report delays related to access to information about genes or protein sequences, and 31 report delays related to access to tangible materials such as vectors, seeds,

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Table 1 OLS regressions of attitude towards IP protection of research tools

Independent variables	Evaluation of Statement IIA	Evaluation of Statement IIB	Evaluation of Statement I
Intercept	2.60 ± 0.14 ^a	3.46 ± 0.13 ^a	2.59 ± 0.14 ^a
Number of delays	-0.2 ± 0.04 ^a	0.17 ± 0.04 ^a	-0.05 ± 0.06
Number of other negative effects	0.04 ± 0.07	0.02 ± 0.08	0.01 ± 0.02
Dummy variable for being tool patentee	-0.04 ± 0.42	-0.34 ± 0.44	0.46 ± 0.58

Coefficient estimates ± s.e.m.
^a $P < 0.01$. (Other negative effects include substitution of equivalent or less effective tools, prevention of initiation of a line of research and abandonment of a line of research.)

germplasm, cell lines and microbial strains. The consequences of these delays were ranked at a moderate average value of three on a 5-point Likert scale ranging from 1 (not bad at all) to 5 (extremely bad).

In addition, 22 respondents (27%) report a total of 53 instances in which difficulties in obtaining research tools affected their research projects in ways other than causing delays. In 14 such cases, an equivalent accessible tool was substituted, but in 20 others, the researchers used less effective tools; in 14, access problems prevented initiation of a line of research. Another 5 research projects were reportedly abandoned. Our follow-up interviews indicate that cases of blocked research have not been catastrophic for the researchers or for their institution, though they affected the direction of some respondents' research programs.

Supplementary Interviews online report on 11 follow-up interviews of some of the scientists who encountered one or more problems of access to needed tools in the past five years. In five cases, researchers identified university-imposed MTA requirements (with no corporate involvement) as the problem, and four more involved conflicts between corporate and university objectives for protecting their respective financial interests. In two more, corporate data confidentiality goals conflicted with freedom to publish. There were two cases of embargoes of material transfers by foreign governments to protect the value of their countries' intellectual property. In at least 10 of the 17 cases, it appears that there would have been no problem of access for research to given innovations, had universities and governments not been trying to protect institutional financial interests in IP claims on research tools. Of the 17 cases investigated in detail, only one involved competitive withholding by an academic peer.

The influence of patent ownership

One might well expect those scientists who are personally involved in patenting to hold more positive opinions regarding IP protection. Our data do show that, for patentees, acquisition of tools from industry is significantly less difficult than for nonpatentees (mean 2.7 versus 3.8, t value = 2.6, $P = 0.02$). Those with patents likewise find it significantly less difficult to provide tools to their academic colleagues (mean 2.0 versus 2.9, $P = 0.003$). Patentee providers report a significantly higher share of formal agreements (34% versus 12%, $P = 0.016$).

Nevertheless, patentees do not significantly differ from the rest of the sample in their evaluations of Statements IIA and IIB. Furthermore, we found no evidence that the share of financial support from industry significantly influences attitudes on IP protection.

The influence of research delays

Personal experience with research tool exchanges affects researchers' attitudes toward IP rights. In particular, researchers who report at least one research delay associated with IP protection are significantly more negative regarding the effects of IP rights in their responses to Statements IIA and IIB.

The number of delays experienced also influences attitudes. Simple Ordinary Least Square (OLS) regressions show that the more delays respondents have experienced, the more they tend to report negative evaluations of the effects of IP protection in responses to Statements IIA and IIB. On the other hand, the number of delays does not significantly affect responses to Statement I; delays do not sour researchers' views on this issue (**Table 1**).

The agricultural biologists we surveyed report that the IP protection of research tools is, on balance, having a negative impact on their research areas.

Conclusions

The agricultural biologists we surveyed report that the IP protection of research tools is, on balance, having a negative impact on their research areas. These scientists, actively involved on both sides of exchanges of research materials, associate the spread of IP protection with the proliferation of MTAs, which in turn has increased the frequency of cases of delayed or blocked access to needed research tools.

These responses are grounded in experience; the IP rights-related research delays the biologists report are strongly and negatively correlated with their attitudes to IP protection. Although they believe problems of timely access to be increasing, few perceive any evidence of increased competitive withholding of cooperation by their peers.

At first glance, our sample's views regarding IP protection might appear to be at odds with previous surveys attributing the research tool access problem to scientists' reluctance to share materials they control, motivated by increasing competitive pressures, cost of sharing or commercial concerns^{2,8}. However, none of those surveys asked scientists for their own assessment of the effects of IP protection on research in their fields. Our general conclusions are consistent with the fact that each of the AAAS' Project on Science and Intellectual Property in the Public Interest four-country studies

reports (without comment) that more than half of respondents believe that IP rights impair the free and open exchange of materials and/or research results^{18,23–25}.

As noted above, several recent studies focus exclusively on patented technologies. Murray and Stern indicate that at least half of the citations to papers reporting research that results in a patent are made before the patent issues, and around half are made before the patent application is published²⁷. Because infringement is impossible before a patent issues, it is not surprising that much use of research tools is not directly restricted by a prior patent. Any methods revealed in publications or presentations can be copied without fear of infringement, until a patent issues. In this environment, it is not surprising that university administrators, focused on protecting prospective IP rights, want their scientists to protect their materials with MTAs as soon as they can.

More generally, the patent-MTA dichotomy, discussed in recent papers, is false. The recent survey of US scientists reports that more scientists (36%) acquired their last patented technology through the use of a MTA than through a nonexclusive or exclusive license (12% and 8%, respectively)¹⁸.

Our findings, consistent with previous surveys, support Eisenberg's conjecture that "patents in and of themselves might only rarely pose an obstacle to the research plans of academic scientists"¹⁹. Scientists by and large pay no attention to the patent status of their research tools because they rightly view themselves as judgment-proof due to their lack of personal resources. Patenting of research tools complicates tool exchanges because it induces institutional administrators, whose financial priorities scientists do not generally share, to encourage or mandate the use of MTAs in exchanges of such tools. Our biologists' accounts of recent instances of delayed or blocked access to research tools recognize this negative net effect of the proliferation of university IP protection after the Bayh-Dole Act of 1980.

An academic research exemption will not discourage universities from insisting on negotiating MTAs to protect their financial interests in prospective commercialization of research discoveries. But agreements between universities and other nonprofit institutions to discourage patenting of research tools used mainly by scientists, or to foster sharing of proprietary technology, could improve access to needed research tools and increase research productivity. The PIPRA and BiOS initiatives are examples designed to facilitate such sharing in the new, IP-dominated research environment.

Note: Supplementary information is available on the Nature Biotechnology website.

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