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Public vs. Proprietary Science: A Fruitful Tension?

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Public vs. proprietary science: a fruitful tension?

What should be public and what should be private in scientific research?

The competitive sprint of public and private laboratories to complete the sequence of the human genome has brought this question to the fore. The same question frames the developing struggle over terms of access to human embryonic stem cell lines and the conflict between Microsoft and the open-source movement over how best to promote software development.

We expect such conflicts to become more widespread as the role of for-profit research expands in a broader range of scientific fields. Will science progress more swiftly and fruitfully if its findings are in the public domain, or if they may be captured as intellectual property? What kinds of research should be funded publicly and what kinds left for private financing? Is competition between public and private science stimulating and constructive, or is it wasteful and counterproductive?

Our aim in this essay is to bring these issues into clearer view. They have been kept in the analytic shadows until recently by the presumption that science and technology are largely distinct enterprises. In fact, the problems arise in areas where science and technology overlap.

We thus begin our discussion by reviewing the conventional distinction between science and technology. We then consider different perspectives on the appropriate public and private spheres in fields where science and technology are intertwined, first in general, and then in the context of the Human Genome Project. We conclude with a brief analysis of policy options.

It is often assumed that science and technology are – or ought to be – inde-

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pendent enterprises. In a classic series of essays, collected in his 1973 book *The Sociology of Science*, Robert Merton described science as a public enterprise generating public knowledge. This has become the standard view, accepted by many working scientists.

According to this theory, the goal of scientific research is to advance fundamental knowledge about the world. This effort need not be directly useful, much less profitable, at least in the near term, although sponsors and practitioners of science generally expect that advances in scientific understanding will foster later useful advances in applied technology. The principal venues for science are universities and government laboratories, and the principal reward for success is recognition and acclaim from the scientific community. Open disclosure of research results, through timely publication and other mechanisms permitting free access, is the norm. Since researchers do not earn financial returns from this work, they rely on philanthropic or public funding.

Most social theorists, including Merton, have drawn a sharp contrast between basic science and applied technology. While basic science is a public enterprise pursuing fundamental knowledge, applied technology is a private enterprise pursuing proprietary solutions to practical problems. The goal of the individuals and firms doing such applied research is to solve practical problems in the hope of earning profits. Such research draws freely on the pool of public scientific knowledge, but does not contribute to that pool. Intellectual property rights protect the profits of those who invest in successful technology research, preserving incentives to provide additional funding.

There is considerable truth in this conventional account and the distinction between science and technology on which it rests. Basic science and applied technology often differ in important ways and flourish under different institutional regimes. Horace Freeland Judson's fine history of molecular biology, *The Eighth Day of Creation*, illustrates the power of a research regime in which all scientists can draw freely upon the prior work of others, each pursuing their particular interests and bets regarding the most promising lines of inquiry, checking, correcting, and building upon each other's results. At the same time, the history of technological progress in such fields as pharmaceuticals shows the power of profit incentives to promote the development of products that meet human needs.

What the conventional account leaves out, however, is the often complex ways in which basic science and applied technology frequently overlap. Such cases of overlap raise difficult questions about where, and how, to draw lines between the public and private spheres. Moreover, in cases where science and technology do overlap, public and private interests may conflict – which only makes more pressing the question of where, and how, to distinguish between what ought to be public and what ought to be private.

From the start of modern science, many scientists have been interested in practical problems, and the challenge of solving those problems has driven their search for fundamental knowledge. Universities long have dedicated a considerable portion of their research efforts to understanding and solving practical problems, particularly in the United States, where, until World War II, agriculture occupied a large share of academic research. In the postwar era, medical schools have accounted for a large and growing share of research at U.S.

universities, currently amounting to roughly half of the total. Much of this work is motivated by the practical goal of improving human health.

More generally, much academic science lies in what the late Donald Stokes called "Pasteur's Quadrant."[1] Standard taxonomies place the pursuit of fundamental knowledge and the solution of practical problems at opposite ends of a one-dimensional spectrum from "basic" to "applied" research; Stokes's taxonomy recognizes that the work of many scientists combines both objectives simultaneously. Like Niels Bohr, Louis Pasteur sought fundamental understanding, and like Thomas Edison, he sought solutions to practical problems. For scientists conducting research within "Pasteur's Quadrant," the objective is to achieve the fundamental understanding necessary to solve practical problems.

This hybrid motivation characterizes most research in the biomedical sciences as well as in material science, computer science, and theoretical work in engineering. These fields are not exceptional: they are in the mainstream of contemporary academic research, posing a serious challenge to a taxonomy that draws a sharp distinction between basic science and applied technology. In recent years private industry has been a growing source of funds for academic research in these areas, and universities have been increasingly inclined to patent their discoveries.

The other side of the coin is that corporate research and development (R&D) often involves the pursuit of fundamental knowledge. Many technologies depend on scientific knowledge, and focused scientific research is often essential in order to advance these technologies. Some private firms perform basic research, and many of their researchers publish scientific papers, although for-profit firms are less inclined than universities to place their findings in the public domain without restrictions.

Public vs. proprietary science

In fields where scientific advances have conspicuous commercial potential (such as pharmaceutical research), the pursuit of profit and the pursuit of knowledge often converge, creating substantial overlap in research pursued in academic and industrial settings. Research results are at once part of a growing corpus of scientific knowledge for use in further research and an important step toward a promising commercial product. Within this zone of overlap, Mertonian public science and market-driven proprietary research coexist, setting the stage for conflict over what should be public and what should be private. The challenge for public policy is to devise arrangements that preserve the great advantages of an open system for basic science while still preserving profit incentives for the creation of valuable new products.

In our view, a common way of thinking about how to draw the line between public and private science is seriously misleading. It is often said that public science ought to focus only on research that private firms will not conduct. If certain areas of research appear to have high social value yet promise relatively low returns, then public financing may be necessary to correct for the failure of markets to get the job done. Private sponsors might not expect to capture enough value to justify R&D costs if anticipated research results are far removed from practical applications, if they are unlikely to be patentable, or,

1 Donald E. Stokes, *Pasteur's Quadrant: Basic Science and Technological Innovation* (Washington, D.C.: Brookings, 1997).

more generally, if profits are highly uncertain. On the other hand, if the research offers a reasonable prospect of yielding practical benefits, if intellectual property law permits the sponsor to appropriate a sufficient share of the value of those benefits, and if private firms are therefore willing to undertake the research, so much the better. In this case, it is commonly argued, public funds are not needed and should be spent for other purposes (or left in the pockets of taxpayers).

This analysis assumes that the only argument for public support of science is that important research would not occur without it. Although this is an excellent reason for public support of research, it is not the only reason. Even if expected practical benefits make patentable outcomes likely and motivate private firms to pay for the research, public funding might still be justified in order to increase the open domain of commonly owned knowledge upon which scientists may draw freely in future research.

From an economic standpoint, patents are not an unmixed blessing. Patent rights motivate private firms to invest in research, but they also introduce significant inefficiencies that may inhibit future research. Patents permit innovators to restrict access to, and thus raise prices for, their inventions. Although sometimes necessary to allow firms to recover R&D costs and thus profit from innovation, such pricing is inefficient, because it excludes users who would be willing to pay enough to cover marginal production costs but not the additional patent premium. The resulting losses could be considerable if the excluded users are not merely private consumers, but publicly funded researchers performing a socially valuable activity.

While the effect of patents on prices has been a central concern of economists, we think another inefficient aspect of patents is especially important in the context of scientific research: patents on essential materials and processes may require researchers to seek licenses before they proceed, which can impose significant transaction costs. In biomedical research today, exchanges of proprietary research materials, techniques, and data are increasingly governed by material transfer agreements, patent license agreements, and database access agreements.

At a minimum these agreements need to be reviewed and approved before research proceeds; often they must be renegotiated, leading to further delays and sometimes to bargaining breakdown with the potential for future litigation.[2] Having the relevant knowledge and materials freely available in the public domain minimizes transaction costs by relieving users of the need to identify and bargain with intellectual property owners.

A third problem patents present for research activity is that they may give patent holders broad control over future research paths, allowing them to block research by rivals. Patents on fundamental discoveries that open up new research areas are typically broader than patents on incremental technological advances in established fields, because the principal constraint on the scope of

2 Rebecca S. Eisenberg, "Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?" in *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society,* ed. Rochelle Cooper Dreyfuss, Diane Leenheer Zimmerman, and Harry First (New York: Oxford University Press, 2001), 209–249; Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280 (1998): 698–701.

patent claims is the prior state of knowledge in the relevant field.[3] Broad claims on early discoveries that are fundamental to emerging fields of knowledge are particularly worrisome in light of the great value, demonstrated time and again in the history of science and technology, of having many independent minds at work trying to advance a field. Public science has flourished by permitting scientists to challenge and build upon the work of rivals. Intellectual property rights to fundamental discoveries threaten to limit the number of players in the system at an early stage, thereby diminishing its power.

On the other hand, private enterprise has been an extraordinarily powerful engine for the generation of new products and processes, and in some fields (notably pharmaceuticals) strong patent protection has been a vital part of the system. Businesses, driven by the hope of profit and the fear of competition, have a far better feel than government agencies for the kinds of new products the market wants and can respond more quickly to emerging demand and technological opportunities.

For the most part, the inefficiencies associated with patents do not generate strong pressures to substitute public R&D for proprietary R&D, even for products such as pharmaceuticals that meet important public needs. Although we might lament the high cost of patented drugs, the advantages of promoting private investment in new product development generally outweigh the inefficiencies of patents. Rather than displacing private R&D, the government can subsidize access to patented inventions for needy users (such as AIDS patients in sub-Saharan Africa or Medicare patients in the United States).

Public vs. proprietary science

The problem that concerns us arises when the domain of public science becomes entangled with the domain of proprietary product development. This zone of overlap has been growing steadily since the late 1970s. An important factor has been the development of molecular biology, a science squarely in Pasteur's Quadrant, as a field of both public and private research. Partly because of a series of laws often referred to collectively as "the Bayh-Dole Act," by which businesses and universities can claim property rights to technology created under publicly funded programs, universities have become active participants in the patent system.[4] A large share of university patents are in molecular biology. Many of these patents cover basic discoveries:[5] as the Patent and Trademark Office (PTO) and courts have allowed such "upstream" patents, a significant private industry has grown up around pre-product development research in molecular biology, seeking to profit by patenting and licensing discoveries to other firms that use them to develop commercial products. The result has been a considerable blurring of the public-private divide, with universities and other one-time champions of open science claiming their own intellectual property, while private firms extend proprietary research further upstream, sometimes in collaboration with aca-

3 See 35 US Code §§ 102, 103; Robert P. Merges and Richard R. Nelson, "On the Complex Economics of Patent Scope," *Columbia Law Review* 90 (1990): 839–916.

4 Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," *Virginia Law Review* 82 (1996): 1663–1727.

5 David C. Mowery, Richard R. Nelson, Bhaven N. Sampat, and Arvids A. Ziedonis, "The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole Act of 1980," *Research Policy* 1 (30) (2001): 99–119.

demic scientists and sometimes in competition with them.

Although the convergence of public and private resources for biomedical research has accelerated progress, we believe that current policy and practice may have gone too far in promoting patenting of fundamental research discoveries.

Patents on inventions with clear practical applications may well facilitate product development, but patents on discoveries that may spur future basic research impose serious costs on the scientific enterprise and are much harder to justify. The Bayh-Dole Act ignores this distinction, although it is becoming increasingly important to federal agencies that support fundamental research and to private firms that draw on emerging knowledge to develop new products. The Human Genome Project provides a useful focus for exploring these issues.

Public and private efforts to complete the DNA sequence of the human genome vividly illustrate the interests at stake in mediating the public-private divide in Pasteur's Quadrant. Although the Human Genome Project began in the late 1980s as a government funded "Big Science" project, from the outset it promised both new fundamental knowledge and practical payoffs with the potential for commercial profit.[6]

By the late 1980s private firms already had a substantial presence in genetics and molecular biology and had developed proprietary tools that would greatly accelerate the Human Genome Project, including automated DNA-sequencing machines and the polymerase chain reaction. The mass-production character of sequencing 3 billion base pairs of DNA, and the "top-down" organization such a task seemed to entail, set it apart from the investigator-initiated proposals for creative, small-scale, academic investigations that had been typical of NIH-funded research. Yet talk of private initiatives to sequence the genome repeatedly provoked concerns about ensuring access to the data for use in future research, renewing enthusiasm for public funding.

Private investors have repeatedly funded targeted projects within the broad scope of the Human Genome Project that seemed likely to yield commercially significant results, sometimes taking advantage of the reluctance of the public project to focus on "cream-skimming" projects that could jeopardize later support for the more costly job of completing a definitive reference sequence of the human genome.[7] In the early 1990s private firms focused on sequencing the estimated 3 percent of the genome that cells use to make proteins, using an approach called "cDNA sequencing." One such firm, Human Genome Sciences, was founded to exploit a research strategy pioneered by Dr. J. Craig Venter, then at the NIH, of using automated DNA-sequencing machines to obtain partial sequences (called expressed sequence tags, or ESTs) for genes expressed in human tissue samples.

6 For a definitive account of the origins of the Human Genome Project, see Robert Cook-Deegan, *The Gene Wars: Science, Politics, and the Human Genome* (New York: W. W. Norton, 1994). For an early analysis of the project from leading scientists, see National Research Council, *Mapping and Sequencing the Human Genome* (Washington, D.C.: National Academy Press, 1988).

7 Two recent histories offer excellent overviews of these events. See Kevin Davies, *Cracking the Genome: Inside the Race to Unlock Human DNA* (New York: Free Press, 2001); and Gary Zweiger, *Transducing the Genome: Information, Anarchy, and Revolution in the Biomedical Sciences* (New York: McGraw-Hill, 2001).

While academic researchers debated the wisdom of pursuing this strategy given available technology, resources, and priorities, private investors seized the opportunity to bypass skeptical government sponsors and peer reviewers and created a nonprofit research institution to support Venter's work, reserving commercial rights for Human Genome Sciences. This and similar efforts created valuable private databases of information, but academic institutions soon complained about the restrictive terms of access offered by the database owners.

In the mid-1990s, when new technology made it feasible to detect and identify single base-pair differences in the DNA of different individuals (single nucleotide polymorphisms, or SNPs), private firms invested in SNP identification. Like gene fragments, SNPs promised to be a valuable information resource for both academic research and product development. Recent experience with proprietary databases of gene fragments led some scientists to worry that proprietary SNP collections might not be accessible to them on reasonable terms, prompting the public Human Genome Project to compete with the private sector by allocating some of its own funds to SNP identification.

In May of 1998, just as the public Human Genome Project had completed its initial mapping goals and was entering the phase of large-scale sequencing of the genome, a new private company came on the scene with the goal of completing the sequence several years ahead of the public project – under the scientific direction of Craig Venter, who by then had left the NIH. The new company, to be called "Celera" after the Latin word for speed, would use a new generation of DNA-sequencing machines and pursue a "whole-genome shotgun sequencing" strategy that Venter had used successfully to sequence microbial genomes.[8] Like cDNA sequencing, whole-genome shotgun sequencing was a strategy that the academic community had so far passed up for the human genome,[9] leaving an opportunity on the table that private investors seized. But this was a more surprising plan from a business perspective. By this time cDNA sequencing had revealed many of the commercially promising genes (and generated patent applications on them). Although more genes were expected to surface in the course of completing the genome, most of the remaining sequence was presumed to be "junk DNA" of greater interest to scientists than to investors. Nonetheless, investors were sufficiently optimistic to drive the market capitalization of Celera up to over two billion dollars by the end of 1999.

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The sponsors of the Human Genome Project responded by accelerating and increasing their financial commitments to complete the public version of the sequence more rapidly. At first, they criticized Celera's proposed sequencing strategy, charging that it would leave significant gaps in coverage that would be difficult and costly to finish. Soon, however, the public project changed its own course in order to provide an unfinished "rough draft" of the genome as quickly as possible. The two groups claimed substantial completion of their respective efforts in simultaneous publi-

8 J. Craig Venter et al., "Shotgun Sequencing of the Human Genome," *Science* 280 (1998): 1540–1542.

9 See James L. Weber and Eugene W. Myers, "Human Whole-Genome Shotgun Sequencing," *Genome Research* 7 (5) (1997): 401; Philip Green, "Against a Whole-Genome Shotgun," *Genome Research* 7 (5) (1997): 410.

cations in *Science* and *Nature* in February of 2001.[10]

The brief history of public and private involvement in sequencing the human genome shows conflicting views from the two estates regarding the importance of making knowledge freely available in the public domain. Free access to the genome has been a mantra within the public genome community, repeatedly invoked as a motivation for accelerated disclosure policies and justification for accelerated funding to complete the sequence before private competitors capture it as a proprietary resource. Although it is a common ploy to invoke public-spirited justifications in support of requests for public funding, it is harder to dismiss the many concurring views emanating from the private sector, sometimes backed by private funds to generate information in the public domain.

From the beginning, scientists worried that it would be difficult to enforce norms of public disclosure and access for sequences generated by different scientists in different institutions. The usual trigger for disclosure in academic research – publication of results – would not serve as a timely enforcer for release of accumulating data that might not be ripe for journal publication until long after it was generated. The presence of commercial interests and the looming prospect of intellectual property claims heightened these concerns.

Controversy over the public or private character of the genome erupted more urgently in 1991 when the NIH filed patent applications on the first few hundred gene fragments (or ESTs) sequenced by Craig Venter. This was a provocative act on many levels. The patent filings, although consistent with U.S. laws encouraging government agencies to patent discoveries and license them for commercial development,[11] were in tension with rhetorical justifications for public funding of the Human Genome Project to ensure public access to the sequence. Foreign governments viewed the patent filings by a U.S. government agency as inconsistent with efforts to promote the Human Genome Project as an international collaboration to reveal the universal heritage of humanity. Patent claims for the discovery of mere fragments of genes struck many scientists as a premature reservation of commercial rewards for incomplete research results that were not yet meaningful and required further research to identify useful applications. Industry trade groups feared that patents on gene fragments would inhibit research to understand the role of genes in disease and would add to the costs of drug development.

Databases of ESTs quickly proved to be a valuable information resource for both private and academic scientists. But the two groups faced different constraints on their ability to gain access to the proprietary databases. As pharmaceutical firms signed database access agreements with price tags ranging from under $10 million to over $100 million, academic institutions balked at signing agreements that would commit them in advance to share future intellectual

10 J. Craig Venter et al., "The Sequence of the Human Genome," *Science* 291 (16 February 2001): 1304–1351; International Human Genome Sequencing Consortium, "Initial sequencing and analysis of the human genome," *Nature* 409 (15 February 2001): 860–921.

11 See Bernadine Healy, "Special Report on Gene Patenting," *New England Journal of Medicine* 327 (1992): 664; and Reid G. Adler, "Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization," *Science* 257 (1992): 908–912.

property rights with the database owners. Finally, in a dramatic inversion of traditional public and private roles, the Merck pharmaceutical firm agreed to sponsor a competing cDNA sequencing effort at Washington University, with newly identified sequences to be promptly disclosed in a public database.[12] Paradoxically, a controversy that began with patent filings from a government agency ultimately gave way to an extraordinary private-sector endorsement of the value of the public domain.

Another variation on traditional public and private roles occurred a few years later when ten pharmaceutical firms joined the Wellcome Trust Foundation to form the SNP Consortium, a private venture to identify common points of variation in the human genome for disclosure in the public domain. SNP identification had begun as proprietary research in the private sector, provoking the public Human Genome Project to call for a consortium of federal agencies to fund SNP discovery and to place the results in unrestricted public databases.[13] The candid justification for public funding was to prevent private appropriation of SNPs as intellectual property. But this strategy was constrained by the Bayh-Dole Act, which allows grant recipients to retain title to inventions unless the funding agreement specifies otherwise based upon an appealable finding of "exceptional circumstances."[14] Loath to invoke this rarely used and cumbersome provision, the NIH took a different approach. In its request for grant applications, the NIH stressed the importance of making SNP information readily available to the research community, advised grant applicants that their plans for sharing results would be considered by NIH staff as one of the criteria for an award, and warned that the NIH would monitor grantee patenting activity.[15] This approach was arguably in tension with the spirit, if not the letter, of the Bayh-Dole Act. Ultimately, the private sector again came to the rescue of the public domain with the formation of the SNP Consortium, which unabashedly proclaims a strategy of identifying and disclosing SNPs in order to prevent other firms from patenting them. Once again, in the Bayh-Dole era it appeared to be simpler for private firms to endow the public domain than it was for the federal government to do the same.

The importance of public access to the human genome figured prominently in the case for continued funding of the public Human Genome Project following Celera's entry into the field. Celera's founders acknowledged the importance of free access by promising initially to release Celera's raw sequence data to the public on a quarterly basis,[16] although the timing and details of this commitment wavered thereafter. The public sponsors of the Human Genome Project stressed the importance of prompt and unrestricted access to the sequence,

12 Eliot Marshall, "A Showdown Over Gene Fragments," *Science* 266 (1994): 208–210.

13 Francis S. Collins, Mark S. Guyer, and Aravinda Chakravarti, "Variations on a Theme: Cataloging Human DNA Sequence Variation," *Science* 278 (1997): 1580–1581.

14 35 US Code § 202(a), (b)(1), (b)(4), 203(2).

15 National Institutes of Health RFA HG-98-001, "Methods for Discovering and Scoring Single Nucleotide Polymorphisms" (9 January 1998) <http://www.nhgri.nih.gov:80/Grant_info/Funding/RFA/rfa-hg-98-001.html> (visited 1 August 2001).

16 Venter et al., "The Sequence of the Human Genome."

which they ensured by requiring grantees to deposit new sequence data in the publicly accessible Genbank database within twenty-four hours.[17] Celera's business model, which involves selling access to proprietary data and bioinformatics capabilities that subscribers would not pay for if they could get them for free, constrains its disclosure policies. Although Celera's promised quarterly data releases never occurred, Celera agreed to provide limited access to its data free of charge on its own web site as a condition of publication in *Science*, subject to restrictions that preserved the market for its proprietary products.

Celera has had more success than prior owners of proprietary genomics databases in marketing database access agreements to academic and government subscribers. It has made agreements on undisclosed financial terms with a number of major research universities and academic hospitals, as well as with the National Cancer Institute. Evidently Celera has something to sell over and above the information and tools that are freely available from Genbank, and evidently Celera's terms of access are not prohibitive for publicly funded investigators. Celera's database should be at least as good as the public database, given that Celera itself has free access to Genbank. At the same time, the existence of a public database with much of the same information presumably limits what subscribers are willing to pay (and what Celera is able to demand) for access to the proprietary database. The existence of Genbank may thus constrain Celera's market power in ways that make the proprietary data more affordable for all researchers.

The story of the Human Genome Project in the public and private spheres is not yet over. Although most of the genome has now been sequenced, the hard work of figuring out what it all means has barely begun. So far, the most significant intellectual property constraint on use of the sequence in research has come from the terms of database access agreements rather than from patents. But many patent applications are pending on genes, gene fragments, SNPs, and even DNA sequences stored in computer-readable medium, and many of these patent applications were filed before the same sequences were deposited in Genbank. Although the patenting of DNA molecules that encode therapeutic proteins is a well-established practice, the patentability of DNA sequences with more speculative utility is much contested and has not yet been addressed by the courts. Depending on how these issues of patentability are resolved, scientists might soon discover that they need patent licenses to make use of sequences they thought were in the public domain.

Although it may never be known whether public or private research efforts ultimately contribute more to future biomedical research and product development, it is probably safe to say that neither of these efforts would have achieved as much as quickly without the other. Apart from providing additional and complementary capabilities and enabling technologies, the private sector has repeatedly provided funding for productive research strategies that public sponsors passed over.

In a Big Science project that allocates government research funds according to a coordinated plan, the existence of a

17 Testimony of Francis S. Collins, Director, National Human Genome Research Institute, at a Hearing on the Human Genome Project before the Energy and Environment Subcommittee of the House Science Committee, 17 June 1998 (Lexis).

vigorous private-sector research enterprise limits the risk that good ideas will go unfunded, at least when they offer a reasonable chance of yielding practical payoffs. The peer-review process for allocating government research funds does much to ensure the political independence and high quality of public science, but it may tend to favor conventional approaches and prevailing beliefs over bold new ideas. Competition among researchers pursuing different strategies with similar goals speeds science along and improves the likelihood of success.

At the same time, freely available data from the Human Genome Project has undoubtedly accelerated research in both the public and private sectors. In addition to providing a free resource for users of genomic information, it has improved the completeness of proprietary databases (by providing data that owners may incorporate in proprietary products and by setting a benchmark that they must exceed in order to have something to sell) and improved terms of access to proprietary databases (by providing a free alternative that limits how much owners may demand). Although proprietary databases might be more profitable if there were no Genbank, the free database plainly has neither destroyed the market for proprietary databases nor undermined incentives to create them.

Numerous public-policy choices determine the balance between public and private research in Pasteur's Quadrant. These choices include legal rules about what may be patented and how patents are used and managed, as well as decisions about what kinds of research the government will fund and what strings are attached to public funding.

If science and technology were entirely separate estates, one might preserve an open domain for science by limiting what may be patented to technology while relying on public funding to promote science. This is arguably the intuition behind traditional legal exclusions from patent protection for natural products and laws of nature and for inventions with no demonstrated practical utility.[18] But steady pressure to provide patent protection for discoveries in Pasteur's quadrant has eroded these restrictions. Perhaps the erosion has gone too far.

Public vs. proprietary science

Long before the advent of commercial genomics, the courts had narrowly construed the exclusion dealing with products of nature to uphold patents on purified preparations of products isolated from nature.[19] Although intuitively appealing, excluding the stuff of nature from patent protection has no clear basis in the patent statute, and judicial opinions recognizing the exclusion have failed to articulate a consistent rationale for it. It has thus been vulnerable to the same systematic erosion of judicial limits on patentability that has recently made way for patents on computer algorithms and business methods.[20]

The utility requirement has a clear statutory basis,[21] and academic scientists have urged the PTO to use this

18 On exclusions from patent protection for natural products, see *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 US 127 (1948). On patents on inventions with no demonstrated practical application, see *Brenner* v. *Manson*, 383 US 519 (1966).

19 E.g., *Merck & Co.* v. *Olin Mathieson Chemical Corp.*, 253 F2d 156 (4th Cir 1958) (upholding patentability of purified vitamin B12).

20 See *State St. Bank & Trust* v. *Signature Financial Group*, 149 F3d 1368 (Fed. Cir 1998), cert. denied, 515 US 1093 (1999); *AT&T Corp.* v. *Excel Communications, Inc.*, 172 F3d 1352 (1999).

21 35 US Code §§ 101, 112.

requirement to reject patent claims on DNA sequences until their biological function is understood. But an appellate court sharply rebuked the PTO just a few years ago for applying a strict utility standard to biotechnology products; the court reminded the PTO that "usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development."[22] At least as presently understood, the utility requirement does not seem to preclude patenting fundamental discoveries with practical implications that remain unproven.

These time-honored limitations on the reach of the patent system have arguably been degraded without explicit attention from Congress and may now need to be fortified to preserve the freedom of scientists to study the natural world. A necessary first step would be a careful analysis of the purposes these rules serve in mediating the public-private divide in science and technology. On one hand, withholding patent protection could prove costly if it undermines private R&D incentives. On the other hand, the benefits to future research and product development of preserving the scope and vigor of public science might outweigh these costs.

Another option would be to carve out an exemption from infringement liability for researchers. Ideally, this approach would retain effective protection against competition in the commercial marketplace while minimizing the impact of patents on the research community.

But it is difficult to define the proper scope of such an exemption when there is no clear line between the commercial and research spheres. Should researchers in academic and commercial laboratories be treated similarly? Should patents on research tools that have no significant market outside the research community be subject to a research exemption that effectively eviscerates their commercial value? The Human Genome Project offers numerous examples of patented research tools that were marketed to both academic and commercial researchers to the great benefit of the research community. Such tools might never have been developed without patents, making the ultimate impact on research of such a change in the law difficult to predict. On the other hand, many important research tools have come out of government-funded university research, and their invention arguably did not require patent protection.

Yet another option, which would not require changing the patent rights of private firms, would be to provide public funding to generate research results in the public domain, even if the private sector is already performing similar research on a proprietary basis.

This was ultimately the strategy pursued by the public sponsors of the Human Genome Project, although they had to maneuver around the Bayh-Dole Act to do it. The extraordinary commitment in the scientific community to making the human genome sequence freely available offered the sponsors protective cover for a policy that grantees might otherwise have challenged as contrary to the law. But if the Bayh-Dole Act impedes the ability of public research sponsors to enrich the public domain of science, perhaps it needs revision.

The flourishing of a robust private genomics industry alongside the public Human Genome Project calls into question the strong presumption under the Bayh-Dole Act that the results of government-sponsored research must be pat-

22 In re Brana, 51 F3d 1560 (Fed. Cir 1995).

ented in order to preserve incentives for follow-on research in the private sector. That the pharmaceutical industry has repeatedly conspired with public sponsors to get genomic information into the public domain at its own expense is compelling evidence that proprietary control of information can impose significant costs on subsequent research and thereby obstruct, rather than promote, product development.

But public science is more than a prelude to product development. At its best, it is a social commitment to disinterested investigation of the world by credible experts operating under the critical scrutiny of their peers. It is a shared archive of an expanding knowledge base, a training ground for future researchers, and the germ from which future advances in human understanding will grow. Its social value does not depend on the ultimate profitability of the advances it spawns. If we need profit-seeking firms to tell us that the public domain has value, something important is missing from our understanding of science.

Public vs. proprietary science