7-27-2018

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Recommended Citation
Contreras, Jorge L., The Anticommons at Twenty: Concerns for Research Continue Science 361(6400): 335-337 (Jul. 27, 2018)

Science 27 Jul 2018:
Vol. 361, Issue 6400, pp. 335-337
DOI: 10.1126/science.aat4684

BIOMEDICAL RESEARCH

The anticommons at twenty: concerns for research continue

Emerging trends in exclusionary rights may affect research.

By **Jorge L. Contreras**

Fifty years ago, Hardin famously predicted that unrestrained use of a common resource could lead to its overuse and depletion – the so-called "tragedy of the commons". Thirty years later, Heller and Eisenberg introduced the term "anticommons" to the research policy lexicon (1), postulating that unfettered exercise of individual property rights could lead to an equally tragic underutilization of resources. Drawing on analogies from land use planning, they reasoned that if multiple holders of intellectual property (IP) rights, particularly patents, covering a biomedical technology can individually block others from conducting research on that technology, then overall research progress could be stifled. Though many observers now agree 20 years later that empirical evidence of an anticommons in biomedical research is inconclusive (*4*), if not wholly refuted (*5, 26*), there are emerging areas beyond patent law in which the proliferation of exclusionary rights may threaten research in much the way that Heller and Eisenberg predicted.

While a common resource such as a pasture or a river is held by multiple parties for the benefit and use of all, an anticommons is held not in common, but in separate but co-dependent fragments whereby any individual owner may block others' use of the whole. Heller and Eisenberg were particularly concerned with privatization of "upstream" research tools – basic scientific discoveries and techniques that can be used to develop a range of "downstream" diagnostics and therapeutics - arguing that "each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation" (*1*). For example, a proliferation of patents – sometimes called a patent thicket -- covering specific protein receptors or basic DNA sequencing techniques could impede research on a broad range of applications. Only by limiting the potential hold that multiple patent holders may have over basic research tools, they argued, can the inefficiencies that are likely to emerge from anticommons be averted (*1*). They thus called on governmental actors such as the U.S. National Institutes of Health (NIH) to "ensure coherent boundaries of upstream patents and to minimize restrictive licensing practices that interfere with downstream product development."

In their conceptualization of the anticommons, Heller and Eisenberg challenged earlier theoretical work (e.g., (17)) that argued that assets, including inventions and other intangibles, will be put to their highest and best use only if they are affected with private interests that incentivize their owners to manage and exploit them efficiently – a property-based solution to Hardin's tragedy of the commons. Heller's and Eisenberg's work signaled a new wave of interest in the application of commons-based solutions to intellectual assets, building on the foundation laid by Ostrom and others in the area of tangible common pool resources. In addition to privatization strategies, tragedies of the commons can also be solved by collective management of common assets. In the regime of the anticommons, it is excessive privatization of resources that hinders, rather than helps, the productive use of assets.

THE SEARCH FOR ANTICOMMONS

Soon after the Heller and Eisenberg article, researchers began to seek empirical evidence of a developing anticommons in biomedical research. The proliferation of patents on individual genes and key sequencing processes was of particular concern. One study reported that U.S. patents covered approximately 20% of known human genes (3), and another found that patents had a negative impact on the use and development of molecular diagnostic tests (21).

Others worried that patenting human DNA and other research tools could result in serious impediments to the development of multi-gene diagnostic panels and DNA chips that could simultaneously test for large numbers of genetic variants, as well as high-throughput genotyping and sequencing platforms and animal models (19). A different angle on the potential impact of propertization of genetic information on downstream biomedical research showed that genetic variants contractually protected by the private firm Celera Genomics, when compared to public data on comparable variants from the Human Genome Project, "generated economically and statistically significant reductions in subsequent scientific research and product development" (22).

Findings like these set off alarm bells throughout the research community and seemed to validate the anticommons hypothesis. However, outside of genetics, studies found that the behavior of biomedical researchers was not substantially affected by the existence of patents (*4*). In many cases, academic researchers simply appeared to ignore patents in their research (*4*).

POOLING, AGGREGATION, COMMONS

If we have not seen the emergence of a pronounced patent anticommons in biomedical research, it is worth asking why. One oft-raised possibility is that rational private actors, when faced with the fragmentation and congestion threatened by an anticommons, will develop collective and mutually-beneficial solutions to enable research to advance nevertheless. Such "pooling" approaches have arisen to address rights fragmentation in industries ranging from music to automobiles and aircraft to radio and telecommunications (*5*).

Heller and Eisenberg recognized that the gridlock threatened by anticommons could be remedied through bargaining and the formation of IP pools. Yet they expressed reservations about the general viability of IP pooling solutions. They identified several distinct features of the biotechnology and pharmaceutical industries that could make successful bargaining over patent rights less successful than in fields such as aviation and music, including: transaction costs associated with accumulating sufficient rights to practice biotechnology inventions; the heterogeneous interests of patent holders; and cognitive biases causing patent holders to over-estimate the value of their own technical contributions (*1*).

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But despite years of advocacy surrounding potential patent pools for HIV/AIDS and SARS research, and the emergence of significant pooling activity in other industries, relatively few patent pools – and none of commercial significance – have formed in the pharmaceutical or biotechnology sectors. Several factors could explain the absence of pooling in this arena: the need for at least some market exclusivity in an environment with extremely high costs of product development, clinical trials and regulatory approval; patent holders' desire to retain control over their assets; and concerns over compromising commercial secrecy by collaborating with others (26).

While the formal pooling of fragmented property interests in biomedical research may not have materialized in a meaningful way, this sector is also characterized by a remarkable, and arguably unique, outpouring of valuable discoveries to the public domain. The sum of these contributions may be moving us toward a comprehensive medical information commons (*10*) – the very antithesis of the anticommons predicted by Heller and Eisenberg. The beginning of this trend is often traced to the 1996 Bermuda accord reached by leaders of the Human Genome Project (HGP) which required all HGP research groups to deposit their sequence data into public databases twenty-four hours after being generated. The ethos of rapid, public release of genomic and related data has now become the norm in many fields of biomedical research and has even expanded to the commercial sector (*9*). Voluntary data sharing by research institutions and corporations has also emerged in areas such as testing for BRCA mutations, largely in response to the proprietary data approaches taken by firms such as Myriad Genetics (*5*).

Thus, just as collective action by affected stakeholders has been shown by Ostrom and others to avert tragedies of the commons involving scarce shared resources, the collective action of the biomedical research community – governments, institutions and individual researchers – developed a powerful response to the potential fragmentation and propertization of the research environment (*5*). It is likely that the success of these public research commons has contributed to the dearth of observed anticommons effects.

There may be other reasons that anticommons did not take hold in the biomedical sciences to the degree envisioned by Heller and Eisenberg. For example, in line with their recommendation that upstream research tools be licensed broadly and non-exclusively, NIH adopted a policy in 1999 urging its grant recipients to license patented research tools on a non-exclusive basis in order to promote their greatest utilization, commercialization and public availability (*1*). In 2007, a group of eleven major U.S. research universities followed suit and committed, in a set of core principles known as the "Nine Points", that research tools should be made as broadly available as possible. Today, more than one hundred research institutions around the world have voluntarily subscribed to the Nine Points.

Finally, over the past decade patent laws in a number of countries have become weaker, not stronger, with respect to the protection of upstream biomedical innovations. Beginning in 2010, a series of U.S. Supreme Court decisions clarified that "products of nature", "mental processes" and "abstract ideas" are not eligible for patent protection. As a result, it has become increasingly difficult to patent basic biomedical discoveries in the United States, so much so that some have begun to ask whether the lack of patents in certain areas (molecular diagnostics, personalized medicine) will itself impede future innovation and discovery (25).

ANTICOMMONS ON THE HORIZON?

Despite the absence of a serious patent anticommons in biomedical research today, Heller's and Eisenberg's warning should not be ignored. There are several areas beyond patent law in which the proliferation of exclusionary rights could impede biomedical research and product development in ways that are similar to those that Heller and Eisenberg first envisioned.

First, in the vacuum left by limitations on patenting human DNA, some firms have increasingly turned to trade secret law to protect data that they collect from patients and test subjects (*13*). In most countries, trade secret law gives an enforceable property-like right to the holder of commercially valuable information that is deemed to be confidential. And unlike patents, which expire after twenty years, trade secret protection continues in perpetuity, so long as the relevant information remains secret. Trade secrecy also challenges research in ways different than patents. For example, a patent is an official document that publicly discloses the patented invention, thus enabling others to study and improve upon its features and techniques. Trade secrets, by their nature, need never be disclosed to the world, thus limiting the opportunity for follow-on research and improvements.

If more data is treated as secret by researchers, there may be less overall growth in knowledge and the medical information commons may not grow as anticipated (10). In addition, the withholding of data by individual researchers may give rise to anticommons effects. In fields that are characterized by large bodies of interdependent observations, the withholding of individual research results may stymie the development of a full understanding of the field. This fragmentation effect is particularly salient in the area of molecular diagnostic testing, in which different testing labs may each collect genetic variant data from patients, but the true potential of this data will only be realized if it is combined and analyzed together. The inability of researchers to conduct cross-cutting analyses could result in less accurate diagnostics and fewer therapeutics. Thus, while holding data privately does not have the same exclusionary effects as obtaining a patent (i.e., others are not precluded from independently generating the same data), the difficulties that emerge in consolidating data from different sources, coupled with the reduction in overall welfare arising from a lack of the full spectrum of results, fall close to Heller and Eisenberg's anticommons.

Eisenberg anticipated this issue in 2008, observing that with "practically excludable" resources such as data and biological samples (i.e., where exclusion is based not on legal restrictions, but on the need for one researcher to provide the resource to others), it is up to users to persuade owners to permit access (*4*). As such, a data-driven anticommons could emerge if enough researchers keep their data proprietary and share it only on condition of payment or not at all. There are few effective regulatory solutions to this issue under current law, but the continued encouragement (or requirement) of data sharing by research funders, healthcare payors and leading journals could avert the worst effects of such an anticommons.

Second, despite the recent tightening of legal requirements for patent eligibility, patenting activity continues around the world with respect to emerging biomedical technologies such as CRISPR gene editing. The potential exists for significant fragmentation of the CRISPR patent landscape – not through disaggregated ownership of CRISPR patents themselves (though that is also possible), but through parcelization of the CRISPR patent estate via narrowly-drawn licensing agreements controlled by a handful of private "surrogate" companies empowered by the academic research institutions that made foundational CRISPR discoveries (*12*). These companies may have incentives to license technology to others on a limited gene-by-

gene, indication-by-indication basis that does not encourage the full breadth of potential research and product development. And while some CRISPR patent holders have granted favorable rights to academic researchers, this solution is neither universal nor binding nor permanent. As a result, policy makers should continue to remind academic research institutions of their public commitments to work toward wide dissemination of the fruits of their research and to discourage the exclusive licensing of broadly applicable research tools. If such reminders prove to be insufficient, research funding agencies could more definitively require the broad availability of funded research through licensing.

Finally, a new and potentially significant form of fragmentation has recently emerged with respect to individual health information. A spate of recent legal disputes in the U.S. have led to increasing calls for personal ownership of genetic and other health information (*15*). The rationales for this privatization movement are varied, ranging from concerns over individual autonomy, privacy and dignity, to offering a more palatable alternative than corporate ownership, to creating a basis for data-based market transactions, to dissatisfaction with existing regulatory and administrative data protection frameworks in the U.S. and EU. Yet despite the good intentions behind many of these proposals, granting individuals an enforceable property interest in information about themselves, including the right to receive compensation for its use, could pose significant impediments to data-driven research, particularly in the coming era of mega-cohort studies involving a million and more individuals.

Thus, while Heller and Eisenberg worried that fragmented interests held by a few dozen or hundred patent owners could severely impede biomedical research, the possibility that millions of individual data subjects could demand clearance, oversight or payment in order to use their data in successive studies, or could withdraw their data from existing databases and ongoing analyses, has far more dramatic ramifications for biomedical research (15). To avert this version of the anticommons, policy makers and courts should continue to resist calls for individual data ownership and look instead to meaningful regulatory and legal measures to protect individuals against invasions of privacy and abuse by researchers.

BROADER LESSONS

Though the patent-driven biomedical anticommons envisioned by Heller and Eisenberg does not appear to have emerged widely, researchers and policy makers must remain vigilant as new sources of potential anticommons emerge. Admittedly, the precise parameters of exclusivity generated by new forms of property fragmentation vary, and they do not all exhibit the same features, or lend themselves to the same solutions, as patent-based anticommons. Nevertheless, it remains the case that the combination of extensive propertization with fragmentation and parcelization of ownership can lead to transactional gridlock and underutilization of socially valuable assets.

Thus, it is worth looking beyond biotechnology patents to the more general distinction between fragmented and common ownership models. Most importantly, no matter how unobjectionable the legal and commercial rationales underlying propertization strategies may first appear, attention should be given to the downstream effects that potential anticommons could cause. If serious impediments to socially valuable activity, including biomedical research, are likely to result, then policies limiting the impact of such anticommons should be considered and weighed in the balance.

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10.1126/science aat4684