Keeping score, strengthening policy and fighting bad actors over access to research tools

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A mix of policy options that enhances access to research tools is available to courts, legislators and government bureaucracies, including research agencies and patent offices.

Translational research is increasingly multidisciplinary, collaborative and reliant on platforms that aggregate data, materials and methods. Should policy makers and courts be concerned about patent holders locking up such research reagents? Although the wholesale disaster predicted by the anticommons hypothesis seems to have been overstated[1], adverse impacts on research and innovation may occur, for example, when platform technologies or repositories require the aggregation of patent rights held by diverse actors[2]. Adverse impacts result not only from the granting of patent rights but also from their management, especially licensing practices. The real question is whether policy levers are sufficient to mitigate the excesses of the patent system, or whether more and better policies are needed. Should policy respond to a few bad apples and outlier cases, or do courts and policy makers already have the tools they need to respond to perturbations in an imperfect and noisy system?

We drew together evidence from high-profile cases that implicates the academic research enterprise and illustrates policy responses influenced by diverse stakeholders. Legislators, government bureaucracies, courts, universities, scientists, civic action organizations, patient advocates and other stakeholders all voice concerns, but rarely in a coordinated manner. History suggests that legislative reforms provide the most consistent responses, but given the diversity of interests, the reforms generally represent a compromise in which no one stakeholder group is fully satisfied. Courts interpret and apply legislative provisions in the context of interparty disputes. Government bureaucracies, from intellectual property (IP) offices to funding agencies, implement both legislation and court decisions. Institutional policies and guidelines also add to the mix of potential policy responses. Because of the complexity of legislative reform, we focus here on recent jurisprudence and the use of existing policy options that ensure access to research reagents in the United States. Lessons from the US experience are instructive for other jurisdictions with active biotech sectors.

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Lack of coherent legislative reform

Recent debates over the US *America Invents Act* (AIA) illustrate the complexities of legislative reforms to patent statutes[3]. *Madey v. Duke University* made clear the very limited research exemption under US case law, and early drafts of the *Act* included such an exemption, but that provision did not become law[4]. One problem was in the definition—it is difficult to draw clear distinctions between noncommercial research covered by a research exemption, research that is translational, and research with commercial intent. Australia recently amended its patent law in line with that of some European countries (e.g., France, Germany, United Kingdom). It implemented an experimental use exemption[5], which enables research on a patented reagent (for example, research to improve the reagent) rather than general research with the reagent (i.e., using the patented reagent for its intended purpose in research).

Another mechanism, compulsory licensing authority, was contemplated but rejected in the 1952 revisions to the *US Patent Act*[6] to the chagrin of some legal scholars, who presciently predicted its absence would cause future problems[7]. Compulsory licenses are grants by a government or a court for public interest use of an invention without the consent of the owner of the patent rights. Discussions most commonly arise in the context of access to medicines in emergency situations or for countries facing health crises where the compulsory license may be issued to a generic drug manufacturer. Because compulsory licenses are generally available after negotiations have broken down, the rights holder is entitled to fair compensation set by an arbitrator. In some jurisdictions, compulsory licenses are permitted when exploitation of the patent rights violates competition law or the patent holder abuses his/her rights, for example, with excessive prices. A narrower type of compulsory licensing exists in the United States, namely, government use provisions. These are available in two forms, first under the *Bayh-Dole Act*[8]—for inventions resulting in whole or in part from federal funding—and second under Judiciary and Judicial Procedure (**Box 1**)[9]. These provisions may enable government noncommercial use for the public interest, such as the protection of public health. Indeed, the US government threatened Bayer Pharmaceuticals (Leverkusen, Germany) with government use for the antibiotic drug Cipro (ciprofloxacin) during the 2001 anthrax attacks, forcing Bayer to reduce its prices[10]. Collectively, these statutory mechanisms provide potential escape valves when rights holders thwart research interests[11]. However, even when available, their use to protect broad research interests has been limited, with one example discussed below.

Box 1 Government use provisions for IP in the United States

The *Bayh-Dole Act* was enacted in 1980 to promote commercialization of government-funded research[8]. It enabled universities and other institutions that received federal government grants and contracts to own any resulting patents (under most conditions). To protect US government interests, however, the *Act* contained two provisions that reserved rights for the government in the fruits of federally funded research and development.

Government use rights. Retention of Rights under 35 US Code §202(c)(4): The Federal Government retains a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." This means that the university or research institution that receives federal funds must grant the US government the right to use the invention for its purposes. Accordingly, the government can use this "license" over government-funded patent rights to defend against any alleged infringement for government use.

March-in rights. Under 35 US Code §203: March-in rights allow a government agency to compel the controller/owner of those patent rights to grant a license or to itself grant a license to "a responsible applicant or applicants." The agency, such as the NIH, may so act in four specific circumstances if the patent owner is not reasonably using the patent rights in the public interest, including not adequately meeting the "health and safety" needs of the public. Since the enactment of the *Bayh-Dole Act*, the NIH has received four requests to exercise its march-in rights; those requests were denied.

Authorization and consent may be applied to patents and copyrights when the use is "for and on behalf of the US government"[9]. It applies to all R&D contracts; its application means that the US government does not need to seek or negotiate a license to practice a patented invention. Section 1498 limits the government's liability for patent infringement. Although the patent holder is entitled to reasonable compensation, it cannot seek an injunction, damages or lost profits against either the government or the government contractor authorized to use the patent. Thus, in the absence of key remedies such as injunctive relief and damages, it is not worth the expenditure of time and money to sue the contractor for patent infringement. A further disincentive is that the suit would be against the US Department of Justice. The wording for and procedures relevant for granting Authorization and Consent are outlined in the *Federal Acquisition Regulations* 52.227-1 and 27.2012-2, respectively. Authorization and Consent is most commonly used in defense R&D contracts; however, it has been employed for the use and development of research tools[2].

Jurisprudence: the courts step in

Without coherent statutory mechanisms in play, the United States Supreme Court has recently concerned itself with how exclusive rights might block, or "pre-empt" science and upstream innovation far from commercial application. Its policy lever of choice has been to constrain patentable subject matter in major cases for four years in a row (**Box 2**); the US Patent and Trademark Office (USPTO) has issued a recently revised and controversial guidance document to interpret this jurisprudence for the community[12].

In *Association for Molecular Pathology* (*AMP*) *v. Myriad Genetics*, a fight over Myriad Genetics' (Salt Lake City, UT, USA) patents on *BRCA* genes associated with risk of breast and ovarian cancer, the Court drew a distinction between discovery and invention, invalidating patent claims on DNA molecules that could be found in nature[13]. It has further invalidated method claims on a diagnostic patent in *Mayo Collaborative Services v. Prometheus*[14] and invalidated claims on business methods in *Bilski v. Kappos*[15] and *Alice Corp. v. CLS Bank International*[16]. In contrast, the Federal Court of Australia upheld Myriad's gene patent claims in *D'Arcy v. Myriad Genetics*[17]. The Australian court focused more on the interests of prospective inventors and the value of a patent incentive and less on the detrimental effects on research, in part because Australia had recently broadened its statutory research exemption.

On October 30, 2014, Chief Judge Leonard P. Stark of the US District Court of Delaware applied *Mayo v. Prometheus* and *AMP v. Myriad Genetics* to invalidate the so-called 'junk DNA' patents held by Genetic Technologies (GTG) in litigation against Bristol-Myers Squibb and Merial[18]. GTG claimed methods for detecting allelic variation and haplotypes by amplifying genomic regions that span a noncoding sequence in linkage disequilibrium with the allele to be detected. Its claims had been confirmed in four re-examinations before the USPTO. Although GTG provided genetic testing services, primarily in Australia, its other business was to demand substantial licensing fees for its patents from companies and, controversially, licensing fees from universities and research institutions, albeit at lower rates for nonprofits than its corporate fees. One estimate identified nearly 2,000 potential licensees[18]. Many, including the US National Institutes of Health (NIH) director Francis Collins, condemned GTG for its aggressive licensing practices[19]. GTG brought US suits from 2002 to the present against 33 defendants, including pharmaceutical, biotech, genetic testing and bioinformatics companies. Many settled, including Myriad Genetics and Applera (Norwalk, CT, USA), and now the patents have been invalidated, bringing to an end the remaining six open cases. Judge Stark concluded that GTG's claims were over laws of nature, and the additional analytical steps merely applied "well-understood, routine conventional activities already engaged in by the scientific community"[18]. The case suggests that past biotech patents run the risk of being found invalid if aggressively enforced.

Litigation: defending against the excesses of patent trolls

Although *AMP v. Myriad* has stolen much of the limelight and driven policy responses from the USPTO and other agencies, other cases illustrate how patents can affect research. Some cases involve suits against research institutions over patented inventions, defying the claim that patent holders always exercise rational forbearance in suing researchers for patent infringement. Leading this trend are nonpracticing or patent assertion entities (NPEs), commonly known as patent trolls, which aggressively assert patent rights through litigation. NPEs now file 62% of all IP infringement lawsuits in the United States, a tripling in the past two years[20]. Hallmarks of fields ripe for NPE activity are uncertainty in the scope of both claims and infringing activities[20]. Noting this, commentators have speculated about the potential impact of NPEs on biotech and biomedical research institutions[21,22].

NPEs operate from a position of strength—they cannot be countersued for infringement because they have no products in a market that would be threatened, and they have no repeat-player constraints. In uncertain environments, NPEs may "over-assert" claimed inventions to cover products and processes that were never meant to be included within the patent by its inventor or examiner[20]. Nevertheless, such assertions are costly to counter—patent litigation can range from $1–6 million or more, depending on complexity. NPEs therefore rely on it being more cost-effective to pay a royalty than to engage in litigation. Thus far, specific

legislative measures to control NPE activities have not passed the US Congress. The last remaining patent reform bill of the 14 introduced in 2013 narrowly targeted NPEs that sent opaque or misleading demand letters[23].

In a recent case, the innocent-sounding Alzheimer's Institute of America (AIA) secured substantial revenues from research institutions and companies using and distributing mouse models of a double mutation in *APP* (*APPswe*), a mutation responsible for one very rare form of inherited early-onset Alzheimer's disease. After more than a decade of litigation, involving five separate cases in which AIA asserted its patents against 18 defendants, including one university, one foundation and three not-for-profit research organizations, AIA lost decisively before a jury in a district court[24], and the Court of Appeals for the Federal Circuit upheld that decision in May 2014 (ref. 25). The litigation consumed 18.7 cumulative court years in six jurisdictions, engaged 98 lawyers on the record (39 engaged by not-for-profit research organizations, foundations and universities), and had 1,143 court filings (docket entries) for motions, pleadings, complaints, certifications, demands, notices, affidavits and stipulations. These indicate the significant cost of infringement litigation for research institutions.

AIA was the case of an NPE willing to shake down biomedical research institutions. However, the case also illustrates defensive actions and policy levers that research institutions can use to push back (**Box 3**). The first line of defense was to challenge the validity of AIA's patents. Problems certainly existed in the USPTO's grant of these broad early patents over research tools. Although the litigation centered on infringing uses of *APPswe* mice, the putative inventor, Michael Mullan, never produced a transgenic animal, and indeed no research group managed to generate an Alzheimer's mouse model until 1995. A different group produced an *APPswe* transgenic mouse model for Alzheimer's disease research in 1996, four years after Mullan filed his patent[26]. It is clear that in 1992, the creation of a transgenic mouse—by a sole inventor who was a clinician-geneticist with no background in transgenic or mouse research—was at best highly speculative, and granting the patent was probably an error in the USPTO's evaluation of the state of the art at the time. Four years of intensive work by large teams to produce an *APPswe* transgenic mouse are proof of "undue experimentation," which invalidates a patent based on the criterion that the disclosure of the invention in the patent must enable the invention. Nevertheless, the USPTO granted Mullan patents claiming the DNA sequences and a patent claiming transgenic animals incorporating the mutations. Recent amendments to US patent law in the *America Invents Act* provide faster and less expensive means to challenge patent validity, namely, new methods for post-grant review of issued patents[3]. However, the case is a clear demonstration that patent offices' need to improve examination and enhance patent quality, underscored by the very late invalidation of GTG's intron patent claims.

AIA lost its *APPswe* patent rights for other, more idiosyncratic reasons. Because of a number of questionable actions by researchers, first at Imperial College and then at the University of South Florida, Mullan declared himself as sole inventor on the patent, which he assigned to AIA, an NPE controlled by a venture capitalist, Ronald Sexton. The judge ruled that Mullan excluded at least one co-inventor, John Hardy[24]. Owing to improper inventorship, the patent was rendered invalid. The judge also ruled that even if he were inventor on a valid patent, Mullan had no rights to assign the patent to AIA, because under Florida law, the patent rights vested automatically in the University of South Florida[24].

Despite the facts unique to the *APPswe* litigation, the saga illuminated a number of policy tools to use against NPE tactics. The NIH might have employed its march-in rights under *Bayh-Dole*, but in this case, the research was not funded by any US government agency. The NIH therefore retroactively employed "Authorization and Consent" (**Box 1**) to enable the Jackson Laboratory (JAX; Bar Harbor, ME, USA) to distribute *APPswe* mouse models to the research community. AIA had asserted not only patent infringement against JAX, but also demanded the names of researchers to whom JAX had distributed mice. These demands left JAX with the impression that AIA intended to assert its patents against the institutions of Alzheimer's disease researchers who had either developed novel *APPswe* lines, or who had used lines distributed by JAX for research. JAX therefore requested Authorization and Consent[9], which was granted by NIH's National Center for Research Resources. This had the effect of relieving JAX of infringement liability, as a government contractor, and effectively shielded JAX from suits over Alzheimer's mouse models and substituted the federal government as defendant. Rather than take on the US Department of Justice, AIA dropped JAX as a defendant. However, to our knowledge, Authorization and Consent has never been applied to standard grants from the NIH. Whereas the NIH might consider on a case-by-case basis whether the research is essentially for and on behalf of the US government, research grants that benefit the research community and the public may or may not satisfy this criterion, and there is no case law on the point.

More generally, the financial cost of AIA's loss in its case is also an early instance of what could emerge as a powerful judicial precedent and a disincentive for NPEs asserting invalid patents. Under new legal rules that make it easier to assess costs to losers in patent suits, the district court awarded legal fees to the winner in the case, so AIA must pay not only its costs

Box 2 Recent US Supreme Court jurisprudence on patentable subject matter under §101 of the *Patent Act*[6]

The following cases clarify that abstract ideas are not patentable and illustrate the distinction between discovery and invention:

Bilski v. Kappos[15]. The "machine-or-transformation test" that requires a process be tied to a machine or apparatus to be patent eligible is only one indicator of patent eligibility. Business methods patents are therefore not categorically excluded from patentability. In this case, however, risk-hedging commodities in the energy market were deemed an abstract idea not eligible for patent protection.

Mayo Collaborative Services v. Prometheus Labs[14]. A claim is unpatentable if it merely informs a relevant audience about certain laws of nature, even newly discovered ones, and any additional steps collectively consist only of well-understood, routine, conventional activity already engaged in by the scientific community.

Association for Molecular Pathology v. Myriad Genetics[13]. Naturally occurring DNA sequences cannot be patented even if they are isolated from the body. Artificially created DNA, including complementary DNA, is patent eligible because it is not naturally occurring.

Alice Corp. v. CLS Bank International[16]. Implementing abstract ideas on a computer is not sufficient to transform those ideas into a patentable invention. The claims in question were over a computer-implemented electronic escrow service—a service that enabled a third-party broker to receive and disburse money or documents on behalf of transacting parties.

but also the fees of the defendants it sued[27]. This measure was already on the books, but the rules for "exceptional circumstances" in which it could be used were only recently loosened to address patent trolls. The former chief judge of the Court of Appeals of the Federal Circuit (CAFC), Randall Rader, urged exactly this remedy to discourage patent suits based on invalid patents[28]. Legal scholars have also touted "loser pays" rules as a potent tool both to dissuade enforcement of invalid patents as well as to discourage infringement of valid patents[29]. Proceedings to determine who pays the legal fees in *Alzheimer's Institute of America v. Avid Radiopharmaceuticals* are entering the endgame supervised by a magistrate in Florida. One problem with this procedure is that it is largely secret. We may never know the price AIA paid for losing this case, and yet the power of the "loser pays" precedent depends on those contemplating litigation knowing the risks and costs. Nevertheless, fee shifting has been considered in other similar cases. In *Anticancer Inc. v. Leica Microsystems Inc.*, a federal judge in the Southern District of California narrowly avoided awarding attorney's fees against Anticancer Inc.[30]. The company attempted to enforce patents for the use of green fluorescent protein in animal models; the judge characterized the effort as "misguided."

Other changes in judicial rules also discourage NPEs by targeting specific tactics. NPEs commonly assert multiple patents against multiple parties, all of whom bear the burden of producing evidence to defend against claims of infringement. NPEs also threaten injunctions, which may damage the operations of innovative firms. Recent US Supreme Court decisions on enhanced standards for injunctions in patent disputes[31] and *America Invents Act* reforms limiting the number of defendants that can be sued in a patent infringement suit[3] contribute to curbing the litigation excesses of NPEs. A further option is to increase the standards for pleadings, to increase the investigational costs for plaintiff NPEs.

Finally, private actors are recognizing an opportunity posed by NPEs and are offering IP insurance specifically directed toward the threat of suits brought by NPEs, labeled "Troll Defense Insurance." Insurance, however, could be a double-edged sword, because in some circumstances it may encourage NPE suits as insurance coverage offers deep pockets to target.

Nevertheless, it is important to note that not all NPEs and not all patent aggregation is fairly characterized as "patent trolling." Some areas of research require collection of multiple inventions, and some entities such as universities and small companies primarily engaged in discovery research may have legitimate claims to downstream uses of their inventions and discoveries even though they do not themselves produce the goods and services that find their way to market. The 2010 National Research Council report cautioned against exclusive licensing of patents to "private patent aggregators whose business model is limited to asserting patents against established firms rather than seeking to promote further development"[32]. This is not a blanket condemnation, and a recent analysis of Australian law and practice also points to important nuances in judging the benefits and harms of patent aggregation[33]. There is no substitute for careful assessment of specific circumstances. The fact that abuses crop up and draw attention suggests a need for vigilance and use of the tools at hand to address them.

Box 3 Policy options to rein in bad actors in patent infringement litigation

Fee-shifting in patent infringement litigation. In *Octane Fitness v. Icon Health & Fitness*[27] and *Highmark Inc. v. Allcare Health Management System Inc.*[38], the US Supreme Court ruled on section 285 of the US *Patent Act* and relaxed the standard for awarding attorney fees to the winning party in patent litigation. This will make it easier for lower courts to impose financial penalties on nonpracticing entities (NPEs), and more broadly when courts consider the actions of patent holders (or infringers) to be unreasonable.

Higher standards for injunctions. The Court's decision in *eBay v. MercExchange* tightened the rules over the granting of injunctions in patent suits[31]. The CAFC routinely granted an injunction for any successful infringement claim. *eBay* required courts to apply the same four-part test to patent cases that weighs the interests of the parties in determining whether to grant an injunction in other contexts.

Increase standards for pleadings. On September 22, 2014, the Judicial Conference of the United States approved the elimination of Federal Rule 84 to eliminate bare bones pleading forms that were developed in 1934. It recommended that the US Supreme Court approve the change to bring patent pleading in line with recent jurisprudence from that court[39,40]. However, the CAFC has resisted heightened pleading in patent lawsuits[41]. Heightened pleadings standards increase investigational costs for patent holders; the provisions would especially affect those filing lawsuits against multiple defendants simultaneously.

Reforms under the *America Invents Act*[3]

Limitations in the number of defendants. 35 USC § 299 as amended by the *America Invents Act* limits the number of defendants that can be sued in a patent infringement suit. Such "joining" of defendants is a tactic often employed by NPEs to reduce their own litigation costs, while imposing litigation costs on each defendant. Just before this rule change took effect, NPEs filed 50 patent infringement suits against more than 800 defendants in a single day.

Post-grant review of issued patents (35 USC § 311). New provisions for *inter partes* review provide a faster and less expensive administrative procedure to challenge the validity of patent claims outside of patent infringement litigation.

Mitigating aggressive licensing practices

The cases above document that aggressive licensing and enforcement practices of patent holders can be deployed against research uses. These were also exemplified by DuPont's initial licensing terms for Oncomouse and Cre-*lox* technologies in the 1990s that included reach-through terms and imposed onerous reporting obligations on researchers. Cetus's initial threats to enforce its PCR patents also included researchers and their institutions[34]. DuPont (Wilmington, DE, USA) and Roche (Basel), which acquired the rights to PCR in 1991, backed down from their most aggressive licensing terms in the former case after intervention by the NIH to negotiate access for researchers.

Other threats arise in the aggregation of IP to build community-level research resources[2]. For example, two international consortia—the International Knockout Mouse Consortium and the International Mouse Phenotyping Consortium—are constructing standardized mouse models with phenotyping data to study gene function. These consortia distribute models through established repositories in North America, Europe and other developed regions. Some repositories, however, have difficulties in distributing to industry because of fear of third-party claims arising from IP that might have been infringed in the high-throughput pipeline for transgenic mouse development[2].

Underlying patents that cover reagents and methods are difficult to identify in this complex environment. Once again, the NIH provided the US repositories with Authorization and Consent, but repositories in other jurisdictions are not so protected. Restrictions on distribution to industry threaten the long-term financial sustainability of resource repositories because they limit the ability of repositories to impose a split pricing model of cost recovery for academic uses and higher fees for industry.

The shadow hanging over transgenic mouse repositories serves as a warning for other repositories operating in uncertain IP environments, such as the distribution of CRISPR-Cas9–generated plasmids. At least there, the Broad Institute, with the first patent issued for the technology, is liberally licensing the technology for academic purposes[35], but it is clear that the patent landscape for CRISPR-Cas9 will involve many players with disparate interests. Concerns about freedom to do research using this powerful new technology will be haunted by the potential for patent disputes in coming years. As the key actors holding IP in this space are likely, in the first instance, to be academic institutions, their selection of licensees and the terms of their licenses will be crucial, particularly regarding onward licensing by those licensees to the research community. The Association of University Technology Managers recommends some caution in licensing university technologies to NPEs, for example, and recommends best practices for licensing to preserve rights for research uses[36]. However, such laudable collective guidance may be trumped by increasing pressures on individual university technology transfer offices to generate revenue through technology licensing.

Conclusions

Who should act in the face of assertion of IP rights that limit research, and when should they act? Legislative initiatives, such as a research exemption or specific anti-troll legislation, have the potential to offer the most coherent and durable solutions, but legislation confronts *realpolitik*. We are therefore left with a variety of tools not specifically designed for ensuring that patent rights do not impede research, but that are useful nonetheless. Judicial decisions to award damages to winners and penalize losers, recent process-oriented reforms in the *America Invents Act*, and legal interventions such as Authorization and Consent are all available to funding agencies in some jurisdictions. An understanding of the broad range of policy options available, with examples of their deployment, should assist in tackling conflicts between assertion of IP rights and research uses. However, to claim special treatment and freedom to operate in research, research institutions must come to the debate with clean hands. Universities, in particular, need to ensure that they themselves do not behave in the same way as the patent trolls they decry[37].

COMPETING FINANCIAL INTERESTS

The authors declare no competing financial interests.

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