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INTERSTITIAL EXCLUSIVITIES AFTER ASSOCIATION FOR MOLECULAR PATHOLOGY

Mary Mitchell* & Dana A. Remus**†

INTRODUCTION

The high profile cases *Bilski v. Kappos*¹ and *Association for Molecular Pathology v. United States Patent and Trademark Office*² have renewed public debate about the proper scope of patentable subject matter. The subject matter inquiry has traditionally been treated as a threshold inquiry in patent law, serving a gate-keeping function by defining the types of inventions that are eligible for patent protection. The Patent Office and courts have approached the subject matter inquiry both by determining whether an invention falls into a statutory category—processes, machines, manufactures, or compositions of matter—as well as by determining whether an invention falls into a category excluded from subject matter eligibility—often described in recent decades as laws of nature, natural phenomena, and abstract ideas.

The exclusions from patentable subject matter developed in the courts and have never been codified in the Patent Act. Although some commentators have argued that the exclusions are Constitutionally mandated, the Supreme Court and lower courts have consistently regarded them as judicial interpretation of statutory subject matter requirements. Courts and commentators have rationalized the exclusions as protecting the “basic tools” of scientific and technological research necessary for innovation. Because of the role of the subject matter inquiry in conditioning patent eligibility—a role perceived as critical to encouraging innovation—landmark subject matter cases have often arisen during times of technological change and economic upheaval.

The patents at issue in *Association for Molecular Pathology* cover isolated and purified forms of the human BRCA1 and BRCA2 genes responsible for heightened risk of breast and ovarian cancer, as well as methods for determining whether the sequence is present in clinical samples submitted by patients for testing. Like many other important subject matter

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1. See *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).
2. No. 09 Civ. 4515, 2010 WL 1233416 (S.D.N.Y. Mar. 29, 2010).

cases, *Association for Molecular Pathology* raises the policy question of whether the patents at issue and other similar patents “cause more harm than good to society and technological development.”³ The plaintiffs prevailed in the district court. If the decision is affirmed by the Federal Circuit, although gene patents would not be broadly invalidated, a new avenue would be opened for challenging patent validity.

The litigation is noteworthy not only for the legal and policy questions it raises, but also because two public interest groups, the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT), are serving as plaintiffs’ counsel. *Association for Molecular Pathology* is a rare instance of impact litigation in patent law, which has remained relatively untouched by conventional cause lawyering until recent years. The public policies championed by ACLU and PUBPAT are undoubtedly compelling. They include the salutary goals of making genetic testing more widely and inexpensively available, and encouraging scientific research. We question, however, whether judicial interpretation alone of 35 U.S.C. § 101, the eligible subject matter provision of the Patent Act, can provide the legal framework necessary to properly effectuate these policies.

In this Essay, we suggest that by focusing solely on shaping judicial interpretation of the exclusions from patentable subject matter, proponents of an expanded public domain fail to consider the possibility that states will expand what we term “interstitial exclusivities”—state-based legal rules, such as trade secret law and unfair competition law, that grant certain market exclusivities in inventions and that are not subject to federal constitutional limits on their duration. We argue that the expansion of existing interstitial exclusivities and the creation of new ones would alter existing incentive structures of intellectual property law, potentially provoking serious negative unintended consequences such as increased uncertainty surrounding patent validity, increased business costs, and increased secrecy in scientific research. We suggest instead that the creation of a public domain envisioned by ACLU and PUBPAT may be best achieved through concurrent efforts to enact legislative change, which would explicitly dedicate such inventions to a public domain.

I. INTERSTITIAL EXCLUSIVITIES

The problematic but incomplete overlap of federal and state intellectual property law has allowed for the creation of state-law exclusivities in inventions. We refer to these laws as “interstitial exclusivities” because they arise in the gaps where courts have concluded that federal patent law does not preempt state law.

The relationship between state and federal intellectual property protections—particularly with respect to the role of patent protection—is

3. See Memorandum of Law in Further Support of Plaintiffs’ Motion for Summary Judgment at 3, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Off.*, No. 09 Civ. 4515, 2010 WL 1233416 (S.D.N.Y. Jan. 20, 2010).

complicated. The federal and state regimes overlap and are similar in some respects, but differ significantly in others. Congress's patent and copyright authority derives from the Progress Clause of the Constitution, which enumerates the power to legislate along with a concurrent restriction requiring the exclusive rights to be granted by the federal government only for "limited times."⁴ However, trademark, unfair competition, and trade secret law are free from these durational limitations.⁵ Therefore, tensions have arisen where trademark, unfair competition, and trade secret protections partially overlap with patent or copyright rights, effectively extending elements of patent-like or copyright-like coverage for unlimited times.⁶

Under existing application of preemption principles, states may craft intellectual property laws conveying exclusivities in inventions without running afoul of the Patent Act. When state-based intellectual property laws are challenged because of perceived conflict with the Patent Act, courts review these statutes using implied conflict preemption principles—the Patent Act contains no express preemption provisions, and courts have not applied field preemption principles to intellectual property law. Conflict preemption is a notoriously muddled area of law,⁷ and courts have struggled to apply these principles consistently to state intellectual property laws.⁸ Beginning in 1973, the Supreme Court affirmed states' rights to legislate in the intellectual property field absent direct conflict, despite dicta in earlier cases suggesting broad federal preemption of state intellectual property laws.⁹ Similarly, it is unlikely that courts will find that state intellectual property protections impermissibly burden interstate commerce in all but the most extreme circumstances.¹⁰ Accordingly, when a litigant raises a preemption

4. U.S. CONST. art. I, § 8, cl. 8.

5. Federal trademark and unfair competition law is promulgated under the Commerce Clause. Trade secret law is state-based excepting two federal statutes, promulgated under the Commerce Clause—the Economic Espionage Act of 1996, which criminalizes trade secret misappropriation, 18 U.S.C. §§ 1831–1839, and the Computer Fraud and Abuse Act, 18 U.S.C. § 1030, which criminalizes the misappropriation of certain information contained on computers. We leave aside debates over whether trademark, trade secret, and unfair competition law are properly considered under the rubric of intellectual property.

6. IP overlap has been treated extensively in scholarly literature as well as case-law. *See, e.g.,* *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989); *Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205 (2000); *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003); Viva R. Moffat, *Mutant Copyrights and Backdoor Patents: The Problem of Overlapping Intellectual Property Protection*, 19 BERKELEY TECH. L.J. 1473 (2004). We leave for another day issues of problematic overlap among federal intellectual property rights.

7. Compare *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) with *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); see *Wyeth*, 129 S. Ct. at 1227 (Alito, J., dissenting) (explaining that the majority's conclusion "requires turning yesterday's dissent into today's majority opinion").

8. See Arthur Miller, *Common Law Protection for Products of the Mind: An "Idea" Whose Time Has Come*, 119 HARV. L. REV. 705, 745–46 (2006).

9. Compare *Goldstein v. California*, 412 U.S. 470 (1973) (upholding a California criminal piracy law concerning sound recordings), and *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974) (upholding state-based trade secret laws), and *Bonito Boats*, 489 U.S. 165, with *Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964) (invalidating a state unfair competition law that prohibited copying), and *Compco Corp. v. Day Bright Lighting, Inc.*, 376 U.S. 234 (1964) (same).

10. See *Goldstein*, 412 U.S. at 558–59; see also Miller, *supra* note 8, at 750.

argument, courts will generally engage in a very limited conflict analysis by looking to the stated purpose and legal elements of the state-based protection.¹¹ State lawmakers are left with room to create exclusivities in inventions.

Naturally, business firms game the legal overlap and interplay to gain valuable market exclusivities in their products. The correspondence between state trade secret and unfair competition laws and federal patent law is not one-to-one, nor could it be under existing law. For example, the exclusivity conveyed by trade secret law does not generally protect against independent development or reverse engineering, and secrecy requirements in some jurisdictions can be relatively difficult and onerous to maintain. Likewise, unfair competition laws in some jurisdictions require elements such as proof of intent to establish violations. Neither trade secret nor unfair competition laws are perfect substitutes for patent protection, but they still convey valuable elements of market exclusivity, often through liability rather than property rules. Recognizing this, businesses have adopted sophisticated exclusivity strategies that consciously engage federal, state, and private law to maximize market exclusivity.

Against this backdrop, we suggest that ACLU, PUBPAT, and their supporters consider the possibility that state lawmakers could extend additional or strengthened state-law protections over inventions excluded from federal protection because of narrowed subject matter eligibility. States have continued to make and develop intellectual property law. For example, some jurisdictions have recently revived the once disfavored “inevitable disclosure” doctrine in trade secret law, a legal fiction that assumes an employee who has certain knowledge will disclose it to a new employer.¹² Similarly, a recent Seventh Circuit case upheld an exclusive license of trade secrets between companies, explaining that trade secrets may be bought, sold, and licensed regardless of the fact that to do so requires their disclosure.¹³ And in an emerging area of intellectual property law, Utah recently passed the Utah Bioprospecting Act, which allows for regulation of bioprospecting activities, including the removal from state lands of naturally occurring microorganisms, plants, or fungi or information about the same for a commercial or research purpose.¹⁴ The legislation also mandates a royalty to the state resulting from commercialization of the results of bioprospecting and criminal penalties for noncompliance.

Although increased state activity in this area is not a certainty, it is a distinct possibility in light of the potential value of the inventions at issue.

11. See, e.g., *Bonito Boats*, 489 U.S. at 165–67 (examining the intent behind and legal structure of state trade secret and trademark protections and explaining they do not conflict with federal intellectual property law); *Kohler Co. v. Moen Inc.*, 12 F.3d 632, 642–43 (7th Cir. 1993) (using this analytical structure and declining to find conflict between federal trademark and design patent protection).

12. *Int'l Bus. Machines Corp. v. Papermaster*, No. 08-CV-09078, 2008 WL 4974508 (S.D.N.Y. Nov. 21, 2008).

13. *Am. Family Mut. Ins. Co. v. Roth*, 485 F.3d 930 (7th Cir. 2007).

14. UTAH CODE ANN. § 2:65A-14-102.

Simply put, there is nothing to stop state lawmakers from drawing even closer to patent law while still avoiding federal preemption, and very little reason to believe that state lawmakers would hesitate to do so.

II. THE LAW OF UNINTENDED CONSEQUENCES

If the district court decision is upheld on appeal, it will be a Pyrrhic victory for proponents of an expanded public domain. Inventions that have already been disclosed to the public as part of the patent bargain—which requires disclosure in exchange for the strong exclusivity protections conferred by patent law—would begin to create an expanded public domain.¹⁵ For example, the inventions at issue in *Association for Molecular Pathology* would become a part of the public domain because they were disclosed in the patents. But inventors and their assignees could keep future inventions out of that public domain by strategically gaming the protections of federal, state, and private law. A judicial narrowing of patentable subject matter through a broadened interpretation of the exclusions would radically alter the incentives provided by the web of state and federal intellectual property protections. Businesses may increasingly opt for secrecy-based protections for certain gene and biotech inventions if patent protection, along with its strict disclosure requirements, is no longer available. This could have far-reaching unintended consequences on commercial and inventive activity, including increased secrecy, increased litigation,¹⁶ and increased uncertainty throughout the system, which is already complicated by non-uniformity of state trade secret and unfair competition laws.¹⁷

Perhaps more importantly, narrowing the scope of patentable subject matter through interpretation of the exclusions could dramatically affect the way research and development are practiced. In addition to harming those who have developed and invested in gene patents in reliance on settled law, a narrowing of patentable subject matter may also chill the openness that patent protection fosters regardless of additional state action in the area if businesses tend toward secrecy-based intellectual property protections over the disclo-

15. See *Bonito Boats*, 489 U.S. at 156–57. In *Bonito Boats*, as in *Association for Molecular Pathology*, the invention at issue had already been disclosed to the public. The Court explained:

A state law that substantially interferes with the enjoyment of an unpatented utilitarian or design conception which has been freely disclosed by its author to the public at large impermissibly contravenes the ultimate goal of public disclosure and use which is the centerpiece of federal patent policy.

Id.

16. ACLU has actually stated that it seeks to encourage more litigation over patent validity. See Stephen Albaini-Jenei, *Bulletproof: Interview with ACLU Attorney Chris Hansen Over Gene Patents*, Patent Baristas Blog, Nov. 12, 2009, available at, <http://www.patentbaristas.com/archives/2009/11/12/>.

17. See David S. Almeling, *Four Reasons to Enact a Federal Trade Secrets Act*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 769, 776–77, 781 (2009) (noting investigation and litigation costs associated with nonuniformity of state law and noting choice of law and jurisdictional complications). Although forty-six states adopted the Uniform Trade Secret Act, interpretation varies widely, and states have often amended its provisions.

sure-based federal patent system. It could easily limit industry-university relations such as industry sponsored research, important biological material transfers between industry and universities, clinical trials, and other collaborations. Such collaborations are necessary for university researchers to have access to compounds, animals, and other research resources in cutting edge areas of science where industrial research and development is ongoing. Moreover, it may deter scientists from publishing and cause businesses to further limit publication by their scientists. It almost certainly would limit out-licensing opportunities for universities because of the strong culture of publication within universities. It would likely cause businesses to seek restrictive covenants with their employees more frequently, and to enforce such covenants more aggressively. Finally, it may greatly inhibit the movement of scientists and specialists between academia and industry and between competing companies.

As one of us has argued elsewhere, alteration of the patentable subject matter inquiry is best left to Congress because of the importance of subject matter eligibility to public policy goals, and because of Congress' institutional competency in addressing complex public policy concerns.¹⁸ With *Association for Molecular Pathology*, the process has already started in the courts, but it should not end there. Litigation alone has been widely recognized as, at best, an incomplete tool in achieving public policy goals. Impact litigation can be an effective means of placing pressure on the other branches of government and of publicizing policy issues, but courts are not as effective as the other branches of government at crafting and implementing long-term solutions that adequately account for costs and second order consequences.¹⁹ Those who seek to secure public rights in gene patents and other technologies should learn from past examples of litigation aimed at enacting social change, which benefited greatly from concurrent political efforts to enact legislative solutions.

Given the gaps that already exist in intellectual property law and the state-based exclusivities that can and do fill them, proponents of a narrow subject matter inquiry should concurrently seek legislative change. The legislative process is riddled with inefficiencies and interest group influence, but we think legislative reform is achievable. ACLU and PUBPAT have successfully leveraged impact litigation in the areas where it is most effective—bringing the debate to the public sphere and placing pressure on the other branches of government. Even a cursory review of the media coverage of the case demonstrates ACLU and PUBPAT's success at bringing the issues to the public's attention. Other related efforts are also receiving media attention, such as the recent empirical study by Duke University researchers

18. See Dana Remus Irwin, *Paradise Lost in the Patent Law? Changing Visions of Technology in the Subject Matter Inquiry*, 60 FLA. L. REV. 775 (2008).

19. See DONALD L. HOROWITZ, *THE COURTS AND SOCIAL POLICY* 262 (1977).

suggesting that gene patents stifle innovation,²⁰ as well as executive branch review of the issue.²¹ Additionally, the likely appeal of this case to the Federal Circuit may pressure the executive and legislative branches to act prior to a precedential appellate decision. ACLU and PUBPAT's challenge now is to channel the successes of impact litigation into effective legislative reform to lower costs and increase access to gene patents and other important technologies.

Unfortunately, the legislative solutions proposed thus far would not solve the problems created by existing and potentially expanded interstitial exclusivities. The NIH committee charged with evaluating gene patents recently proposed to create two exemptions from infringement liability—for gene patents used in patient care and for gene patents used in academic research.²² Even without the added complication of the pending litigation, the exemptions advocated by NIH would alter the incentive structure of intellectual property law, creating incentives for businesses to take advantage of existing interstitial exclusivities such as state trade secret law rather than seeking patent protection, and for states to expand or create new ones.

We believe the legislative solution that would come closest to creating the public domain ACLU and PUBPAT envision would preempt states from acting in these areas by including express language both defining the exclusions from patentable subject matter and committing them to the public domain. In order for a public domain to be created to cover the exclusions, it must keep them within the purview of the federal patent system while simultaneously shielding them from state-based exclusivities that lack durational limitations and allow or require the secrecy of inventions.

We recognize that such legislation would need to be carefully crafted. Notably, partial preemption of state-based intellectual property protections could cause jurisdictional uncertainty concerning whether and under what circumstances federal courts would have subject matter jurisdiction over state-based claims implicating the exclusions.²³ However, Congress is the governmental body best suited to weigh options intended to reduce cost and

20. See Robert Cook-Deegan & Christopher Heaney, *Patently Complicated: Case Studies on the Impact of Patenting and Licensing on Clinical Access to Genetic Testing in the United States*, GENETICS IN MED., Apr. 2010 Supp. at 4.

21. For example, the Office of Biotech Activities within the Office of Science Policy of the National Institutes of Health recently issued a white paper on gene patents advocating legislative reform. See Secretary's Advisory Committee on Genetics, Health, and Society, Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, available at http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011 [hereinafter *SACGHS Whitepaper*]. Similarly, the Office of Science and Technology Policy and the National Economic Council recently issued a call for information on how to improve university commercialization of technology. See Commercialization of University Research: Request for Information, 75 Fed. Reg. 57 (Mar. 25, 2010).

22. See *SACGHS Whitepaper*, *supra* note 21, at 90–91.

23. See *Christianson v. Colt Indus.*, 486 U.S. 800 (1988) (holding that when patent law is not a required element of a properly pleaded complaint, federal subject matter jurisdiction is limited to cases where the relief sought requires adjudication of a patent issue); cf. *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002) (holding Federal Circuit jurisdiction does not extend over cases where a patent-based cause of action is asserted in a counterclaim).

improve access to technologies—whether it be through amendment of the Patent Act or through other legislative reforms such as the creation of health care subsidies.

Proponents of a narrowed patentable subject matter portray themselves as champions of a public domain. Yet the public domain they seek to create through impact litigation is at best elusive and at worst unreachable through litigation alone. The patentable subject matter inquiry is a complex issue requiring careful consideration by Congress to craft nuanced legal solutions that properly mind the gaps of federal intellectual property protection.